NEW & EARLY STAGE INVESTIGATORS

Career Guide

All the Tips & Strategies You Need to Launch a Successful Research Career.
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Best Regards,

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Introduction

Whether you’ve begun a faculty tenure-track appointment, an adjunct or postdoctoral fellow position, or a position leading a lab, a large part of your new job is to carry on an independent research program. As a new/early principal investigator (PI), you have a multitude of challenges -- and a significant learning curve -- to tackle.

Transitioning into your new role as boss and leader of your lab, to competing for precious grant dollars, you have a lot to learn. Hopefully, you’ve already gotten a handle on what your institution’s department chair or dean expects from you in terms of your research career.

Some institutions place more emphasis on teaching classes than on scholarly activity, and vice versa, says grant consultant Thomas R. Blackburn, PhD, president of Science Funding and principal of Grants Consultancy in Washington, D.C.

You’re transitioning from being part of a research team to leading your own team. You’re the boss now. And if that’s not enough, you have some significant funding hurdles to overcome -- mainly, a more limited selection of appropriate grant programs available to you as an early-stage PI.

**Important:** Be patient. You have several decades’ worth of research career ahead of you, so don’t become discouraged by proposal rejections and other bumps in the first few years. Many new PIs don’t get significant funding of any kind until several years or even a decade has passed.

Rejections are simply part of the learning process, and in fact they’re instrumental to improving your grant-proposal techniques. Expecting to get the massive, multi-million dollar grants right out of the gate is not realistic. Start slow and small, increasing the sizes of your grants gradually, until you work your way up to the big money.
CHAPTER I: New/Early PI Research Funding & Career Strategies

As a new/early PI, you may feel like your options in securing grant funding are seriously limited and that you’ll never get funded until you build more of a reputation and establish your credibility. This is not entirely accurate. You actually have several options for research funding, but first you need to do a bit of preparation.

Dr. Thomas R. Blackburn advises that you must begin by establishing the following attitudes:

• A grant is a collaboration between you and the funder.

• Approach grant-seeking with a positive and realistic attitude.

• Write proposals that match the funder’s priorities, fit your own characteristics, and describe significant, appealing research.

• Understand the proposal review process.

• Accept that not all of your proposals will be successful on the first submission, but understand that you can use a denial of funding as a step toward success.

In this section, you will learn:

✓ How to define your project’s scope;
✓ The top 10 grant proposal mistakes;
✓ Ways to contact POs prior to submitting a proposal;
✓ Best practices for preparing and writing grant proposals;
✓ How to get your work published and deal with authorship issues; and
✓ What you need to know about IP and patent laws.
SECTION 1: Launching Your Research Career: Define Your Project’s Scope

You have a groundbreaking research idea that will forever change the face of your field. You are confident that your research project will launch your career in the right direction. But before you start scrambling for grant money, you must hone your project’s scope, aims and resources.

5 Steps to Perfect Your Scope

A poorly-defined scope can lead to blown budgets, missed project deadlines, discouraged research team members and funding debacles. That’s why your first step in launching your initial research project as a PI -- or really any project down the line -- is to whittle down and define your scope.

1. Narrow down your scope. You can start off with a big goal, but then you need to narrow down your scope to what will be reasonable with the resources at-hand, says Stanly Portny, an independent project-management consultant and author of “Project Management for Dummies.” Many PIs soon realize that their project’s scope is far bigger than they initially thought, he notes.

   Consider your constraints and barriers, and keep narrowing the scope down until it’s manageable. Also, with this narrowed scope, you need to determine what will define the project’s success. This factor has a huge impact on how you determine your scope.

2. Detail what you will need to do. Now that you have a clearly-defined, reasonably-sized scope, your next step is to detail exactly what experiments you will need to do, as well as whether you have all the equipment and expertise you need, to accomplish the goal. Consider how long it might take to realistically reach your goal.

3. Decide how you will quantify your results. If your project idea is to find out whether a medication will reduce symptoms in lab rats, you’ll need to define how you’ll measure this. Quantify how much you want to reduce the symptoms and how you can measure that. Measurable data is key.

4. Identify the key people. Who will work on your project? Who will be on your research team? Identify all the individuals who will be involved with your project, including your lab team -- post-docs, co-
PIs, grad students and lab techs -- as well as supporting staff like animal-care personnel, administration and compliance officers, says Adam Schayowitz, PhD, director of business development for Biomarker Strategies.

5. Calculate your budget. Proactively working on the budget for your project may further narrow your scope, Portny says. Your budget should include all possible expenditures for the research work, including salaries, hiring expenses if necessary, and equipment and materials costs. Consider what you have in terms of start-up funds, and calculate your supplies based on the number of people on your research team.

As you work through these steps, avoid the most common scope pitfalls:

- Don’t allow your scope to fall out-of-whack with your proposed project’s costs and your technical abilities -- make sure these match up.
- Don’t make your scope so rigid that it doesn’t allow for unexpected outcomes -- ensure that your scope provides enough depth, redundancy and leeway to accommodate some curve balls.
- Don’t attempt to narrow down or fix your scope until you’ve carefully defined your central research question.
- Don’t propose every experiment you can think of on the system -- select the most useful and impactful experiments to achieve your goals.

Prevent the Top 10 Grant-Proposal Mistakes

The biggest mistakes in grant proposals tend to involve fundamental issues in the planning and idea stages -- specifically relating back to the project’s scope. Here are the top 10 pitfalls to avoid at all costs:

1. Lack of innovation. The research idea has little or no significance, or it poses an unimportant problem. Sometimes, lack of innovation involves references to irrelevant or inconsistent published work, while
other times you’ve simply presented a weak case showing little potential impact.

**Define:** What’s your project’s innovation?

2. **Derivative research.** If you’re proposing an idea that’s too similar to your previous research projects, reviewers will classify the proposed project as “derivative,” Blackburn says.

**Refine:** How can you make your research idea new and different from what’s already done?

3. **Weak or inexperienced research.** You don’t need eons of experience under your belt, but you do need at least the experience necessary to deliver results, explains Lisa Kurek, managing partner of Biotechnology Business Consultants.

**Strategies:** If the grantor allows for multiple-PI projects, as a new PI you may need to team up with a more experienced investigator. If you can’t partner up, you can publish on the topic in peer-reviewed journals to increase your funding chances.

4. **Poor experimental design.** When a reviewer says that your proposed project has “questionable experimental design,” he’s basically saying that your proposal doesn’t take into account the potential pitfalls and offer backup plans for dealing with those unexpected outcomes. “Poor experimental design” means that the reviewer doesn’t believe you’ve thought through the experiments enough and the experiments won’t answer the questions you posed.

**Revise:** Go back to your experimental design, identify the possible pitfalls that could occur, and then write down scenarios for how you would handle those situations.

5. **Unrealistic amount of work.** If the scope of your project encompasses several years of research, reviewers might see this as an unrealistic amount of work.

**Solution:** Provide clear milestones, and break the overall project down into smaller, more manageable (and more fundable) sections.
6. **Poor environment.** A poor or weak environment usually stems from lacking documentation of institutional support.

   **Elaborate:** Provide more in-depth and descriptive information on your institution’s resources, supporting policies and mentoring staff. Also, include those letters of support from the appropriate institutional officials.

7. **Human/animal subject or biohazard concerns.** Although issues involving biohazards, human subjects or animal studies won’t prevent you from getting funded, the lack of appropriate forms will.

   **Submit:** If you’re using these types of elements in your proposed study, you must submit the forms to prove that you’re following the federally-approved guidelines, stresses Mary Purcell-Miramontes, national program leader at the USDA’s National Institute of Food and Agriculture. If you fail to include these forms with your proposal, the grantor will reject your application without reviewing it.

8. **Lack of measurable objectives.** Your project won’t go anywhere if you don’t have tangible deliverables and measurable objectives that go straight to the heart of the programmatic goals and impact.

   **Identify:** Study your project description and experimental design, and create specific, measurable goals. What tangible deliverables -- data -- will your project yield? How will you measure your results?

9. **No explanation of impact.** If reviewers don’t understand how your project will affect the program’s goals, your proposal won’t go far at all.

   **Dig deeper:** You must include in your proposal a clear explanation of how your proposed research will help the grant program and/or how it will catalyze or otherwise impact the work of other researchers in the program.

10. **Poor writing.** If you’re not offering clear, layman’s language in your proposal, the PO or program manager may not understand your key points.

   **Clarify:** Write your proposal so that the programmatic relevance can be understood by scientists, laypersons, and to scientists that may not understand your particular field of study.
SECTION 2:  
Contact POs Before You Submit a Grant Proposal

For many PIs -- especially new ones -- contacting program officers (POs) can seem intimidating. But POs have a wealth of valuable knowledge to offer, and having a conversation with a PO can make or break your grant proposal. Some experts even suggest that communicating with POs is equally important as your grant-writing skills.

PIs should never write a grant proposal before first communicating with the PO, stresses Robert Porter, PhD, director of research development at the University of Tennessee. Porter has 30 years’ experience as a tenured professor, private consultant and research administrator, presenting grant-writing workshops at leading universities and medical schools nationwide.

There are many reasons why you should communicate with a PO before submitting your grant proposal, including ensuring that your proposal lands on “the right desk.” Also, what you read in the request for proposal (RFP) is usually just the “official line,” Porter says. Although program priorities change year to year, the RFPs and solicitations often don’t reflect these changes.

Additionally, review panels and POs tend to develop preferences over time that are “unspoken” and not reflected in the printed or posted materials, Porter notes. RFPs also don’t always reflect the research already performed and published.

If you’re nervous about talking with POs, keep in mind that many POs welcome your questions and are eager to offer assistance (although there are some who may not be so eager to offer assistance). Many federal granting agencies, including the NIH and NSF, have a “customer service” culture as well. POs can offer insights on:

- Whether your research idea is weak or strong;
- Which granting office is most appropriate for your specific project;
- Developing your research ideas to encourage proposal success; and
• The inside scoop on program track, including how your proposed research fits into their funded projects – keep in mind that some POs will tell you this, but some won’t.

Perhaps the most important benefit of talking with POs is you can make sure that your proposed research project has a shot at getting funded. “You are looking for signals that you might be heading down the wrong path. You don’t want to put hours or weeks of effort into a proposal when a five-minute conversation would let you know you’re barking up the wrong tree,” says Dr. Charlie Senn, director of proposal management in the Office of Research at the University of Tennessee.

**How to Navigate NIH/NSF Websites to Find POs**

When you’re ready to make the leap and contact a PO, the easiest way to find the PO’s contact information is right on the solicitation for NIH and NSF grants. But if you’re not looking at a solicitation or you’re trying to contact a PO at the NIH, you’ll find the massive websites of the NSF and NIH not quite so user-friendly in finding contact information for these individuals. The best way to navigate these sites is to think about your research project’s specific topic and how it fits into the agency’s different offices.

The NSF has directorates that are broken down into divisions, while the NIH has different offices, centers and institutes. If you’re looking for a PO’s contact information on the NSF’s website, you can begin at the home page and select a link that best describes the subject-matter category of your proposed research project. You’ll see these links on the left side of the web page. The links take you to the NSF’s different directorates.

*Example:* “If you choose engineering from the list, it will take you to a menu that has engineering organizations, www.nsf.gov/dir/index.jsp?org=ENG. They are each of the divisions within engineering,” says Maria Zacharias, acting head of Media and Public Information in the NSF’s Office of Legislative and Public Affairs. Then, you would choose from the six different divisions within the NSF Engineering Directorate.

So if you chose the Civil, Mechanical and Manufacturing Innovation (CMMI) link, you would end up at this division’s homepage, which displays the programs and funding opportunities in that division. You could then click on a specific program, and the first thing you’ll see on that page is the PO’s contact name, phone number
If you’re trying to find a PO at the NIH, begin with the institute or center that best fits your proposed research topic. For example, say your project focuses on developing a new treatment for hay fever. You would first go to the National Institutes of Allergy and Infectious Diseases (NIAID) web site, and then navigate to the Grant Cycle page.

From there, you would scroll down to the “Contact Staff for Help” section and select from the box on the right side of the page one of the divisions that best fits with your research topic. In this example, a fitting division would be the Division of Allergy, Immunology, and Transplantation (DAIT). So you would select the DAIT link and connect to the Finding People page. From there, you can search the Employee Directory to find a PO.

Another strategy for finding the right PO is to ask your colleagues doing similar work who their POs are, suggests Dr. Harold Perl, senior lead PO in behavioral research, dissemination and training, Clinical Trials Network, at NIH’s National Institute on Drug Abuse.

**Carefully:**

- Study the program objectives detailed on the website;
- Review the program mission statement; and
- Search the recent program awards and read the abstracts.

You can even select two or three grant programs that you feel fit with your project idea, Porter suggests. And if you end up on the phone with the wrong PO for your research topic, don’t worry. The PO will likely redirect you to the right person.
Choose from 3 Different Strategies for Timing Your Contact

Although you certainly want to contact a PO before you submit your grant proposal, you can employ a variety of strategies for how you utilize POs as a resource. In the very early stages, when you are just beginning to formulate your idea, you can initiate a dialogue with a PO, or you might contact them after you’re starting to write your grant proposal in response to a solicitation.

1. Early contact could give you a distinct advantage. The most experienced PIs tend to contact POs when they’re just thinking of an idea -- and that’s the best time to call, Perl says. “We can give you direction, advice -- even suggestions for potential collaborators.” But if you wait to contact POs until the application deadline is two weeks away, “it’s usually too late for us to help,” he notes.

2. Write a concept paper or “pre-abstract” to discuss with the PO. Another strategy is to write up a brief concept paper or pre-abstract and send it along via email to the PO prior to having a phone conversation. Your concept paper should “state the problem” and include a brief rationale, along with how you plan to answer the research question, Perl says.

A pre-abstract is similar to a concept paper and you can think of it as a kind of “elevator speech,” Porter notes. Your pre-abstract should include your proposal’s goals, methods and anticipated outcomes, as well as why the project is unique and how it will contribute to the field. Keep your pre-abstract limited to no more than three paragraphs and conclude it with a basic question: “Is this concept a suitable match for what your program wants to fund?”

3. Contact POs when you’re ready to write the proposal. Say you’re writing a proposal that fits nicely with a specific program solicitation, and you know that you have a good chance of your proposal at least making it to an intermediate review stage. In this case, you can contact the PO at about the time you’re preparing to start your application, after you’ve emailed the PO your single-page pre-abstract first. Note: The PO’s contact information is listed on the program solicitation.
Prepare for the Call

When you’re anticipating a phone conversation with a PO, you can do several things to prepare (which will help to calm your anxiety). First, keep a written description of your proposed project or research idea accessible during your call. If you wrote a concept paper or pre-abstract, you can print it out and place it on your desk. Second, write down a list of questions you want to ask, such as:

- Does my project fit your current objectives and priorities?
- What would you recommend to improve my funding chances?
- What are some of the most common reasons proposals are rejected in your program?
- What is the anticipated success ratio? (Note: Some POs will not tell you the success rate.)

Keeping these items in writing and in front of you during the phone call will help you to get the most out of the conversation. Note: You may need to jog the PO’s memory by reminding him of the emails you exchanged or giving a brief run-through of your concept paper or pre-abstract.

**Crucial:** Ensure that you can convey your enthusiasm for your research idea, and be prepared to detail how your proposal has significant impact, says Matthew Fenton, PhD, chief at the Asthma, Allergy and Inflammation branch of the NIH’s NIAID. When you can explain to the PO over the phone how your proposed project will “move the field forward, change or make new paradigms, or lead to findings that will have broad utility in other research areas,” this tells the PO that you’ll be able to communicate the same in your application, he notes.

**Listen Carefully to Pick Up on ‘Signals’**

As you ask the PO your questions and discuss how your research idea fits with the particular program, listen for “buying signals,” Porter advises. If the PO gives you suggestions, take them as instructions.

**Example:** During your phone conversation, the PO asks, “Have you considered adding a statistician to
your research group?” This is a buying signal, meaning that the PO is interested in your idea and is offering a suggested change to give the proposal a better chance of success. Take this suggestion as a firm instruction.

On the other hand, you might get signals that the PO is concerned about the fundamental viability of your idea, Senn says. For instance, if the PO is worried that your proposed project would be more “incremental” than “transformative,” he might ask a question like, “How would this transform the field -- as opposed to adding to what’s already being done?”

**How to Make the PO Remember You -- In a Good Way**

After the phone call, you should follow up with a thank you note. In the note, write four or five brief bullet points that summarize what you heard the PO say during the phone conversation, Porter recommends. This not only shows the PO that you were paying careful attention, but it also allows him the opportunity to correct or expand upon any talking points from the phone conversation.

You might also request a face-to-face meeting with the PO, if the traveling distance is feasible. But even if you can’t have an in-person meeting, the exchange of emails and phone calls will keep your name fresh in the PO’s mind until your proposal hits his desk.
SECTION 3:
How to Prepare & Write Grant Proposals

Grant reviewers look at hundreds -- if not thousands -- of proposals on a regular basis. With the fierce competition in the research-funding world, coupled with the ever-increasing number of submitted proposals, your application must really stand out to have a chance of getting funded.

You can take certain preparative measures to ensure that your grant proposal is up-to-snuff. Here are the eight essential steps to writing winning grant proposals.

1. **Double-check your eligibility:** This may seem obvious, but some people submit grant proposals to organizations that don’t even fund that type of research work. Find out your eligibility before you write the grant proposal. The solicitation should tell you who the appropriate applicants are, says Gail Vertz, GPC, CEO of the American Association of Grant Professionals.

2. **Understand the organization’s priorities:** Stay abreast of grant organizations’ ever-changing priorities and interests, as well as what’s going on in your field. Talk with POs, submit drafts of proposals or concept papers, ask questions -- do whatever is necessary to determine the grantor’s current priorities and whether your ideas fit with what the agency is looking for, says Deborah W. Garnick, ScD, professor at the Institute for Behavioral Health, Schneider Institutes for Health Policy at Brandeis University in Waltham, MA.

3. **Start small:** As a new PI, you can’t expect to win a multi-million dollar grant right away. So be prepared to start out small and increase the size of the grants you win over the years.

4. **Show your passion:** There are exciting parts of the grant process -- usually the beginning -- but there are also a lot of hurdles, says P. Alan Lennon, PhD, MAEd, assistant professor in the Molecular Genetic Technology Program at the University of Texas - MD Anderson Cancer Center in Houston. After all those hurdles, and as you get toward the end of the process, there’s not so much excitement, he notes. Keep your passion level high, so you can show that enthusiasm to grantors in your proposal and during communications with POs.

5. **Assemble a team:** Get competent, goal-oriented and trustworthy people on your team to achieve
proposal success, Garnick advises. While you’re at it, nab yourself a mentor to help with proposal preparations and career advice.

6. **Meet project officers:** Reviewers and POs are usually eager to meet the up-and-coming scientists in the field, so don’t be afraid to approach them, Garnick says. Get your mentor or another senior investigator to introduce you to her key grantor contacts.

7. **Tell a story:** When you’re composing your grant application, write your narrative as just that -- a story. If you tell a story instead of just regurgitating the facts and figures, you’re writing persuasively and communicating effectively.

8. **Fill in the gaps:** Before you submit that proposal, go back through it to make any corrections needed and edit it for clarity. Minimize the problem areas that reviewers tend to focus on while reading proposals. Also, double-check that your jargon is appropriate, the goals clear and all sections completed accurately.

### How to Get Your Proposal to the Top of the Stack

Whether you’re applying for a grant from a federal agency like the NSF or NIH, or from another funder, proposal reviewers typically look for the same or similar key points of interest in your application narrative, such as scientific merit, potential impact and proof of your expertise for the project. But clear writing can trump all, because if you aren’t writing well, you aren’t effectively communicating any of these points in your proposal.

When you’re composing a grant proposal, the intense pressure to succeed and intimidation of the grant’s importance to your project can cause you to lapse into a lofty, formal tone of writing. Resist this urge -- and remember that first and foremost the proposal is supposed to communicate and persuade.

Clear writing not only helps your proposal’s readability, but also saves precious word count. Most grant proposals have limited page counts, so you need to use every word wisely. Study the following examples:

**Wrong way:** “It is important to realize that, due to the highly ruminant nature of giraffes, there exists...
an opportunity for deleterious or unpredicted results. Some results may include: a) generation of unreasonable and/or potentially unviable offspring, b) depletion of the natural environment of foliage and c) desecration/obliteration of migrational pathways.”

**Right way:** “Highly ruminant giraffes may produce harmful or unexpected results, such as generating unreasonable or otherwise unviable offspring, depleting foliage, and desecrating or obliterating migrational pathways.”

What are the key differences between these two examples, and why is the second one better? Here are your clues:

- **Concise vs. Wordy** - The first passage is 49 words long, while the second says the same thing in just 28 words. Concise is always better, because being concise gives you more space to talk about your research, enables the reader to better understand your proposal and prevents a busy reviewer from missing your proposal’s important points.

- **Nouns & Verbs vs. Adverbs & Adjectives** - Use nouns and verbs more often in your writing, and fewer adverbs, adjectives and conjunctions. Nouns and verbs communicate more information and convey meaning best.

- **Active vs. Passive** - Whenever possible, use active voice instead of passive voice. For example, instead of writing, “X will be added to Y,” say “I will add X to Y.”

- **Minimize using “of:”** If you see the word “of” more than once in a single sentence, tighten and simplify the sentence to make it less wordy.

- **Leave your personal opinions out.** Don’t clutter your proposal with personal opinions or attitudes, such as comments about unresponsive past funders and other researchers who don’t have your priorities. Stick to the facts and the main objective - getting your project funded.
SECTION 4: Building Your Reputation: Get Your Work Published

As a new investigator, you know that getting your work published is a huge part of earning credibility in your field and the foundation of a successful academic career. But when you’re thinking about publishing, the question of when isn’t as important as why. You should base your decision to publish on the science, and not simply your desire to see your name in journals.

Although the NIH Office of Extramural Research will tell you that, in terms of the frequency and timing, publishing your work is entirely up to you and your team. But the NIH does want you to wait until it’s received and reviewed your final report on the project, according to Martha S. Mihaly, PhD, an independent consultant in Washington, D.C.

Nevertheless, PIs tend to struggle between quantity and quality when it comes to publishing -- and really, both count. Consider the following factors of when to publish:

• **Do you have reasonable confidence in the findings?** If you have doubts about your findings, keep in mind that if you publish and others don’t replicate the findings, this could negatively impact your career, warns Linda M. Isbell, PhD, associate professor of psychology and graduate program director at the University of Massachusetts.

• **Do you have great data that belongs in a top-tier journal?** Are you willing to wait to get published in a top-tier journal, rather than publishing sooner in a lower-level journal? If your work is ground breaking but just needs some additional data, you may want to hold out for the higher-level journals. Publications in top-tier journals will have a much greater impact on your field, career and future funding opportunities, Isbell says.

• **Do you feel that your research will hold up in front of peer reviewers?** Ensure that you publish only when you feel that your research is ready. You might not want to sit on your data too long, but you may hold off on publishing until you’ve repeated the experiment two or three times, notes Gregory Lanza, PhD, professor of medicine at Washington University Medical School in St. Louis.

• **Do you have the support of your team members to publish?** Finally, remember that your work isn’t
solely your own -- you had a team involved with the research. Therefore, the decision to publish shouldn’t be just your own either. You should get the consent of all the team members to publish, recommends Elisabet Nalvarte, PhD, research associate professor at the University of Missouri.

Get a Leg Up on the Competition

Despite the increasing number of scientific journals, getting published has become increasingly competitive. In fact, the rejection rate is higher than ever before, says Dr. Marissa Carter of Strategic Solutions, Inc., a professional medical-research editing service based in Cody, Wyo.

Journal editors are constantly flooded with submissions from new and established PIs, post-docs, and grad students. Many are non-native English speakers from outside the United States who want to publish their work in American journals. Primarily, journal editors will weed out the poorly-written articles first. Second, they will evaluate the work to determine whether the studies are flawed, Carter notes.

There are several ways you can greatly improve your chances of getting published:

• Hire a professional editor. Editing services can vary, depending on what the firm offers. Typically, you’ll get copy editing or line editing to correct style, improve grammar, clarify expression and enhance structure. Some firms also offer full content review, where the editor will dig into the science and concept of your article.

• Hire a ghostwriter. This seems straightforward enough, but beware of ethical issues, such as articles ghostwritten by private industry. In general, ghostwriting is not ethical for journal submissions.

• Work with a mentor. If you feel confident about writing the article yourself and without an editor, enlist the help of a more senior PI or mentor to shape your article. Seek out a PI at your institution who has had success in getting published throughout their career.

Hiring an editor or ghostwriter is likely a good decision if you’re pressed for time, if you’re not a good writer, if English isn’t your first language, or if multiple researchers are involved. But you should write the
article yourself if you:

- Are doing systematic reviews;
- Can do it yourself and have time to do it;
- Have the ability to write the article, but have a fear of writing; and/or
- Don’t want to pay for the editing or ghostwriting services.

**Careful:** If you use an editor, many journals will require that you include a co-author credit. The New England Journal of Medicine, for instance, requires a credit for anyone who substantially contributed to an article. Likewise, if you use a ghostwriter, the International Committee of Medical Journal Editors requires a co-author credit.

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**Strike the Right Balance with the Number of Papers You Publish**

New PIs often wonder how many papers they should publish each year. There’s no real magic number -- and publishing huge quantities shouldn’t be your goal either. The frequency of publication is a little tricky.

On one hand, publishing too many papers signals that you’re more interested in getting your name in print rather than making discoveries. On the other hand, publishing too few papers tells granting organizations and other funders that you’re not spending their money wisely. The key is to strike a balance.

You shouldn’t use the raw number of papers you publish in one year as a metric of your productivity, warns Toranj Marphetia, spokesperson for the Medical College of Wisconsin. Instead, you should base the number of publications per year on the following factors:

- **The type of published work.** Is the publication an original article, a review, an editorial or a case report? Reviews and editorials don’t make much of an impact, even if they’re featured in higher-level journals, according to David D. Gutterman, MD, senior associate dean for research at the Medical College of
Wisconsin. Original discoveries rank far higher.

- **The journal’s quality or “impact factor.”** The quality of the journal featuring your work is a huge factor. The career impact of publishing two papers per year in a top-tier journal is equal to or greater than publishing 10 papers per year in lower-level journals, Gutterman notes.

- **The number of published papers for your lab.** A better way to look at your published-paper productivity is in the broader scope of your lab, rather than just your own publications, says Everett E. Carpenter, PhD, associate professor of inorganic and materials chemistry and PI at Richmond’s Virginia Commonwealth University. The number of papers published each year from all of your team members as a whole really gives funding agencies a realistic idea of your lab’s focus and productivity.

Also, the number of papers you publish each year will depend on how big your lab is, meaning if you have just two people working for you, you are not going to get 10 papers published in a year. Realistically, you will probably publish just one or two, if you’re lucky.

**How to Deal with Common Authorship Issues**

If you’re like most PIs, you’ll deal with some authorship issues from time to time. Issues can range from copyright laws to failure to list a contributing author. The International Committee of Medical Journal Editors (ICMJE) has a set of guidelines with the following criteria for authorship:

1. Substantial contributions to the conception and design, or acquisition of data, or analysis or interpretation of data;

2. Drafting the article or revising it critically for important intellectual content; and

3. Final approval of the version to be published.

The ICMJE requires that you meet all three authorship criteria. Another consideration for authorship is if you’re the PI who acquired the funding for the project or you’re the PI in charge of heading up the research
Unfortunately, many PIs don’t pay attention to these guidelines, says Dena Plemmons, PhD, research ethics program director at the University of California - San Diego. And scientists who are aware of these guidelines have a tough time interpreting them. Here are a few key tips to avoid authorship disputes:

- **Decide who the co-authors will be upon project conception -- not project completion.** If you determine the co-authors early on, you’ll avoid many problems figuring out who provided “substantial contributions.” You can always add people later if necessary, but decide on the standards ahead of time for including co-authors.

- **Determine what your institution deems as “substantial contribution,” not just what the ICMJE says.** For example, some institutions may view data acquisition as a substantial contribution, warranting a co-author listing, while other institutions do not (although many institutions don’t want to get involved with authorship unless there’s a complaint). The ICMJE views data acquisition as an insufficient contribution. Decide among the PIs what you’ll deem as substantial enough to get on the co-author list.

- **Don’t drop a co-author just because he changed institutions.** Beware of taking a co-author off the list after he switches institutions. As one lawsuit (Giordano v. Claudio, et al., No. 09-1456, E.D. Pa, 5/24/10) demonstrates, you could face some serious legal troubles if you do so.

**Fair Use Vs. Plagiarism: Know the Difference & Stay Out of Hot Water**

Another hot authorship issue is plagiarism -- and its differences from “fair use.” Even seasoned PIs often struggle with the division between the two. Because you need to build on previous work, using lots of paraphrasing and direct quotes of prior literature, you must understand the boundaries of fair use, cautions Suzanne K. Ketler, JD, PhD, an intellectual property attorney with Roetzel & Andress in Akron, OH.

The fair use doctrine spells out the various uses of published works that do not infringe on copyrights. Allowed purposes include “criticism, comment, news reporting, teaching (including multiple copies for classroom use), scholarship, or research.” Although the nature of your publication is factual and scholarly, and
therefore generally protected under the fair use doctrine, you shouldn’t assume that your published works will always pass the fair use test, Ketler warns.

As laid out in the doctrine, fair use depends on four main factors:

1. **The purpose and character of the use (including whether the use is commercial in nature or for nonprofit educational purposes).** Don’t simply copy the material verbatim. Instead, be sure that you use the material in a “transformative” way. This means that you added to the copyrighted material some new material, expression, information or meaning, Ketler explains.

2. **The nature of the copyrighted work.** This factor typically deals with factual information versus fictional materials, Ketler notes. Disseminating factual material benefits the public, so you have more wiggle-room with factual than you do with fictional material.

3. **The amount and substantiality of the portion used in relation to the copyrighted work as a whole.** The less of the copyrighted work you use, the more likely the use will be fair.

4. **The use’s effect on the potential market for or value of the copyrighted work.** If your use of copyrighted material impedes the new or potential markets for the material, you’re outside the fair-use haven. But this is usually not a significant factor for PIs.

**Bottom line:** Whenever you’re uncertain about whether your use of another’s work constitutes fair use or crosses the line into plagiarism, seek guidance at your own institution. Many universities, libraries and other institutions provide guidelines with examples and assistance for fair use, Ketler says.

Roughly 80 percent of Office of Research Integrity cases involve plagiarism.

*Source: Debbie Parrish, JD, private-law practitioner representing PIs in research misconduct investigations.*
5 Crucial Ways to Prevent Unintentional Plagiarism

Your paper will go through a computer program to detect any plagiarism. Perhaps the biggest pitfall is not intentionally plagiarizing others’ works, but instead plagiarizing while not realizing that you’re doing it. Although most cases of plagiarism that fall under the scrutiny of the Office of Research Integrity are intentional ones, some are unintentional. Here are the five best ways to avoid plagiarism, based on the most common mistakes that can land you in hot water.

1. Don’t plagiarize yourself. If you use the same wording and even images in a publication that you used in a previous paper published in another journal, you’re essentially plagiarizing yourself. Remember that even your own work published in a journal is subject to copyright laws. You must get approval from the journal to use your same content again, with proper citation, advises Daniel Salsbury, managing editor for the Proceedings of the National Academy of Science.

2. Remember citations and quotation marks. Cutting and pasting text, and then forgetting to place quotation marks around the text and add the citation is a common mistake, says Janet D. Stemwedel, PhD, associate professor of philosophy at San Jose State University and author of the blog Adventures and Ethics in Science. Right when you cut and paste the text, place the quotation marks around it and add the citation. Or, you can highlight it or change the text color if you want to rewrite it later on.

3. Beware of submitting papers concurrently. Dual submission of the same manuscript to different publishers is a big no-no. In fact, many publishers will banish you from their journal if you violate their policy of dual submissions. Submitting the same paper to multiple publishers can also result in copyright infringement, so try to avoid doing this altogether.

4. Don’t forget an author. Authorship disputes and plagiarism claims often overlap, says Debbie Parrish, JD, a private-law practitioner. Contributors that you leave out of the paper can claim plagiarism when you use any of their work in the publication.

5. Understand the difference between private versus public information. Unless the material you want to use in your paper is labeled “public domain,” you are committing a copyright violation if you use it without proper permission -- even if the material is posted in a public place.
SECTION 5: What You Should Know About IP & Patent Laws

Intellectual property (IP) and patent laws can be tricky. You might assume that a discovery in your lab is your IP, but it might not be. The first thing you must do is go to your institution’s office of technology, to fill out disclosure forms. Usually, your institution will handle all the IP and patent issues – but if your university doesn’t want to patent your discovery, it’s up to you to protect the IP.

When you’re thinking about turning your discoveries into IP, keep in mind these key facts:

- **A patent gives you exclusive rights to develop your idea, but not necessarily to bring it to market.** A patent doesn’t give you the automatic right to make something. To bring your idea to market, you’ll need to follow all the other applicable regulations.

- **Once you get a patent, that patent does not guarantee that it doesn’t infringe on another’s IP.** Winning a patent doesn’t mean you might not infringe on someone else’s patent, nor does it guarantee that continued development of the invention may not eventually infringe on someone else’s patent.

  “Literal infringement” occurs when each element of your product is found in at least one patent claim. The “Doctrine of Equivalents” refers to when your product functions in the same way to produce the same result as the claimed invention, even though there are differences between your product and the claimed invention.

  **Crucial:** Always perform a freedom-to-use search of any patents that you could possibly infringe upon, including looking forward to see what might be infringed with future development.

- **Patent right is not a right to manufacture.** A patent does not give you a monopoly, because most everything is an improvement of something else, says Howard Rockman, a Chicago patent-law attorney for scientists. A patent grants the holder the right to exclude others from using the patent for a limited time -- typically 20 years.

- **You have just one year after public disclosure to file your patent application.** If you don’t file the application, you lose your rights to the idea. Before you publicize your findings, check with your tech-transfer
office to ensure that you don’t accidentally reveal too much. If someone can make your invention based on your disclosure, the one-year rule is in effect.


- **Protect your international patent rights before any disclosure whatsoever.** International patent laws are different. In most countries, you lose your patent rights at the time of public disclosure. “Overseas, you must have a patent app on file in your home country at time of disclosure,” Rockman says.

The Patent Cooperating Treaty extends the time to file foreign counterpart patent applications for about two and a half years from the original U.S. application filing date, but there is no “international patent.” Europe has a single patent examination process covering all European Union countries.

- **Ease your worries with a provisional patent application.** You can file a provisional patent application to legally establish a date for your invention and eliminate the one-year public disclosure rule, so you get priority over anyone who comes up with the same idea later on. Your institution will file the provisional patent, unless it relinquishes ownership and you have to file yourself.

- **Who owns the IP rights?** Although inventors initially own all patent rights, most universities and corporations own the IP rights due to agreements the scientist signed. “Many universities will give the inventor a percentage of income generated by the patent or royalties from it,” Rockman notes. The university can also assign or license the patent rights to you.

- **Budget for patent applications.** Although the fees can vary widely, you should expect to pay out legal fees of $4,500 to $20,000 to prepare and guide a patent application through the process.

- **What you need to get a patent: “obvious” versus “not obvious.”** To get a patent, you need to show the following four things.

  1. *Patentable subject matter* --
Includes:
- articles of manufacture,
- machines,
- compositions of matter,
- methods and improvements thereof,
- computer related subjects, living organisms, and
- methods of doing business

Excludes:
- mathematical formulas,
- items found in nature,
- abstract ideas, and
- non-useful and non-working inventions

2. Utility -- Show how the invention is useful for some purpose; excludes perpetual motion machines.

3. Novelty -- Show how the invention is new and is not found in even one piece of prior art. Other requirements include:
   - Invention must be invented before another,
   - You must file the patent application within one year of public disclosure,
   - Experimental use does not equate to public use,
   - You should execute a non-disclosure agreement before invention disclosure prior to filing a patent application.

4. Non-obviousness -- Prove whether the invention is an obvious solution to someone schooled in the art. If differences between inventions and prior art would be obvious to a person of ordinary skill in the art, no patent will issue. Also, keep in mind that prior art includes one in a different field attempting to solve a similar problem.

Aside from patents, you have several other IP vehicles at your disposal, including copyrights, trademarks, trade secrets and semiconductor mask works. There are also several different types of patents: apparatus, article, composition of matter, method, and plant. In a patent, you would include the following data:
• Drawings of inventions;
• Complete written description of invention;
• Claims;
• Abstract; and
• Cited prior art.

**Remember:** You have just 1 year after the time of disclosure to file your patent application; after this time, you lose your rights.

### 9 Ways Your Lab Notebook Isn’t Up-to-Par

Your lab notebook serves many important purposes, particularly when you need to show your due diligence while applying for a patent. Under U.S. law, you must be the first person to “conceive the idea” for the invention to get the patent. This is where your lab notebook comes in -- providing crucial evidence of the date you conceived the idea.

Careful notes about the date your conceived the idea or when the invention is “reduced to practice” (i.e., when the invention begins doing what it’s intended to do) isn’t enough, however. To follow the legal rules of evidence, your lab notebook must conform to certain standards.

**Most important:** Electronic notebooks with data-management systems are not always acceptable as legal evidence. You must always keep a hard copy form of your notebook with all data included in it, according to J. Peter Fasse and Ingrid A. Beattie, intellectual property attorneys with Fish & Richardson, P.C. Of course, keeping an electronic notebook is essential for always having a back-up copy of your information.

Here are the top other ways your laboratory notebook needs to improve so you can use it as proper evidence if a patent issue or any other problem arises:

1. Use a **permanently bound, hardcover** notebook with either pre-printed page numbers or page numbers written in permanent ink on the front and back of every page in the top outer corner. This shows that
you’ve entered information into the lab notebook in chronological order and have not added or deleted any pages.

2. Always record information in your lab notebook using **permanent ink**.

3. Enter all **observations and data** on the **right-hand pages**. On the left-hand pages, include all calculations, figures and sketches, along with clearly-identified steps in each calculation and the units of all the quantities you used.

4. Write your project entries in a **narrative style**, and describe the project’s:
   - objective;
   - expected outcomes or theories;
   - methods, materials and equipment; and
   - sets of measurements or calculations, including the reasoning behind them.

5. Record your observations and the formulas for any calculations you use, even if you actually perform the calculations with a spreadsheet or other electronic tool. Also, **cite the sources** for any information you use from a datasheet, textbook, etc.

6. **Date and initial any changes** you make to entries in your lab notebook. If you make a mistake, don’t white-out or erase any entry -- instead, **cross out mistakes** using a **single strike-through line**, so the writing is still readable. The same goes for tables or figures that you need to re-do.

7. Identify the **original experimental data** clearly, using tables and units of measured quantities (not just the values). If you record data readings electronically, print out the readings and tape or glue the paper into your lab notebook.

8. Always **summarize your results** when you finish a project, noting the data or observations you’ve collected, where you left off with your work, your plans for continuing the project (if applicable), and any samples you’ve saved, including how and where you saved them.
9. Summarize the concept clearly in a **separate entry** if your work leads to an idea that you want to patent, and then sign and date the entry. Then, have a corroborator (not a co-investigator) and a third person who is able to understand your idea but isn’t an inventor **sign and date the entry** as well.

Here are some other reminders about maintaining your lab notebook in a professional manner:

- ✓ Record **your name** and the **starting date** for entries in the notebook on the inside or outside of the front cover.
- ✓ Use the notebook’s first three pages for a **table of contents**, and add new projects to the table of contents as you begin notating them throughout the notebook.
- ✓ **Never remove a page** from the lab notebook.
- ✓ Start every new project on a **new right-hand page** in the notebook. Title this first page and list the names of everyone who is working with you on that project.
- ✓ Write the **date on every page**, and write it in the same place -- whether in the top right corner, top center, etc.
- ✓ Leave a **few blank pages** at the end of each experiment to add further analysis and conclusions. If you don’t end up using these pages, simply draw an X on the blank page (corner-to-corner) and initial the pages.

### Make Your Electronic Data Pass the Credibility Test

Most PIs are using electronic storage for data, along with their paper lab notebooks. But can you use digital data as sufficient proof of invention? The short answer is “maybe” -- if your data passes the test. According to patent attorney **Lisa Dolak** at Syracuse University, your electronic data must be:

- **Admissible** -- Evidence for proof of invention must consist of the inventor’s testimony and reference exhibits of three key elements of invention: conception, diligence, and actual reduction to practice, according to
the courts and the U.S. Patent and Trademark Office.

- **Corroborated** -- Independent of your personal testimony, a witness must vouch for the inventor through direct observation of the experimental work and sign the lab notebook. Courts have recently relaxed the corroboration requirement slightly, but still an inventor’s testimony and records alone are not sufficient. Whether you keep a paper notebook (which you should) or keep electronic invention evidence, you should make sure that a third party witnesses your work and records regularly.

- **Credible** -- Put simply, your story must add up, based on the admissible, corroborated evidence. You must show that you created and organized all your notebook entries in a credible way (see previous section 9 Ways Your Lab Notebook Isn’t Up-to-Snuff).

<table>
<thead>
<tr>
<th>1. Conception</th>
<th>- You thought of a novel invention;</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Diligence</td>
<td>- You document how you attempted to make your invention work; and</td>
</tr>
<tr>
<td>3. Reduction to practice</td>
<td>- It works.</td>
</tr>
</tbody>
</table>

But for electronic data, demonstrating credibility is more complex. You must ensure that:

- **All entries are electronically signed.** Although signatures aren’t legally necessary, they will connect entries with the author, who should be the inventor.

- **All entries are witnessed.** Witnesses strengthen your case as a whole, and a witnesses’s electronic signature corroborates your case.

- **All entries are securely and promptly dated.** The dates in your electronic data entries are crucial, because you need to prove that you invented first. You can use automatic time-stamping by your internal document management system, as well as third-party “digital notary” and “digital surety” services to give your dates credibility.
• **All data are secure, while active and while stored.** The patent office wants to know that all entries and data were entered by the person who said he entered it. You should combine at least two of the three security keys: biometrics (something you are); a physical key (something you have); and a password (something you know).

• **All data are safeguarded against alteration.** In paper lab notebooks, alterations are pretty easy to spot. But in electronic data, alterations are much more difficult to detect. You must protect all your electronic data using digital signature, digital notary and audit-trail technologies.

Your electronic data entries must be:

• Electronically signed;
• Witnessed;
• Securely and promptly dated;
• Secured by biometrics, a physical key, and/or a password; and
• Safeguarded against alteration.

### How to Secure Early-Stage Patents

A recent court ruling (*Ariad Pharmaceuticals Inc. v. Eli Lilly and Co., No. 2008-1248 (Fed. Cir. 2010)*) has changed how you can get early-stage patents. If you’re aiming to commercialize an innovation, you must secure a patent pretty early-on in the discovery process. And doing so used to be fairly easy -- you could simply submit manuscripts as patent applications and the office would grant patents on little more than theories.

Now, you will either have to wait until you have an adequate written description before filing a patent application or you’ll need to reasonably “predict” what other compounds, peptides or genes could be representative of the genus you want to lay your claim to, says **Sara D. Vinarov, PhD, JD**, a patent attorney with Quarles & Brady LLP in Chicago.

Simply put, your patent application must contain a written description of the invention, meaning that you
must actually have invented what you’re claiming to have invented. The problem for most PIs is that they want to publish results as soon as possible, when most of the time the invention hasn’t been fully realized, notes attorney Lindsay S. Adams with New York firm Day Pitney LLP.

For a determination of possession, you must include:

- A reduction to practice;
- Disclosure of drawings or structural chemical formulas;
- Sufficient relevant identifying characteristics;
- Method of making the claimed invention;
- Level of skill and knowledge in the art; and
- Predictability in the art.

**Strategy:** If you’re not able to meet these requirements but want to publish and protect your ideas, consider filing a provisional patent application on your initial findings, Vinarov recommends. Then, follow up with additional provisional applications with broader claims supported by additional disclosures, so you form an overlapping application “portfolio” that serves as the basis for non-provisional applications.

When you’re obtaining a patent, the patent application includes:

- Full disclosure of the invention;
- Claims to specify the differences between your invention and the prior art;
- Allows for one skilled in the art to replicate the invention upon expiration of the patent; and
- Description of the best mode of carrying out the invention at the time the patent application is filed.

In the examination process, the patent examiner will compare your claims to prior art. If the “office action” you receive is a rejection, you would assist your patent attorney in defining the differences between the claimed invention and the prior art that the examiner applied. You can amend claims to limit the scope of the patent coverage, and thus avoid the prior art.
Whose Name Goes on the Patent Application? Deciding Factors

A sticky subject for many PIs is deciding whose name will go on the patent or determining inventorship. Although you may look at this question in a similar way as whose name is listed as author on a publication, determining inventorship is really a whole different ball game.

“Inventorship is a legal question -- not one of collegial or managerial convention,” says Jim Baker, PhD, director of technology and economic development at Houghton’s Michigan Technological University. Because the Patent and Trademark Office decides the rules on inventorship, institutional rules don’t apply.

Warning: If you fall back on the more comfortable procedures used in deciding what author names go on a manuscript for deciding inventorship, you could end up with an invalid patent, Baker cautions.

So what’s the right way to determine inventorship? The patent guidelines point to the “threshold question”: Who conceived the invention? Unless a person contributes to the conception of the invention, he is not an inventor, Baker explains. A legal inventor must have had an inventive contribution to a single claim, which could be one of many.

Misconception: Your status as PI has nothing to do with inventorship. Although you likely fit within the legal definition of an inventor, you still must make an inventive contribution for the Office to legally consider you an inventor.

Still, as the PI you play a crucial role in determining the inventors, despite whether you’re one of them. “Essentially, the PI’s function is to ensure that the legal counsel preparing and prosecuting the application has all relevant information regarding who contributed what intellectually and practically to conceive and demonstrate ... the invention,” Baker says.

You should assist legal counsel in retrieving lab notebooks and coordinating communication among project participants and either the institution’s technology transfer office or legal counsel. You also play an important role in helping to settle disputes.
Loose Lips: Prevent Accidental Disclosures that Could Sink Your Patent

Because patents rely on no “prior art” existing for your discovery, a leak of your findings -- even accidental in nature -- could destroy your chances of getting a patent. Accidental disclosure can happen, whether via e-mail or social media sites like Facebook, Twitter, MySpace and LinkedIn. But you need to make sure that these harmless messages don’t cause a denial of your patent application.

**Problem:** When IP goes public, you can’t get it back. Leaked IP that becomes public information could turn into “prior art.” Also, “publication” can mean information disseminated and accessible, not just printed. So this can include e-mails, social media posts, research papers on FTP servers and conference presentations. Any one of these can ruin your patent application.

Here are five ways to protect IP:

1. **Remind staff to keep work-related social media posts general in nature.** Also, tell your employees not to use the “notes” function in Facebook to describe their work -- too many details can result in accidental disclosure. Also, they should avoid posting detailed information about their research, especially anything related to the point of “novelty,” on any website or blogs.

2. **Make sure staffers know what should stay confidential.** Warn your staff about e-mailing proprietary information to people outside your research group or organization. Keep the smallest circle possible, and ensure that everyone in your circle understands what’s IP, trade secrets or other confidential information. If staffers are communicating with colleagues outside the research group, they need to keep details as general as possible.

3. **Remind your employees of your organization’s monitoring policies.** If your institution has policies reserving the right to monitor e-mails, IMs and other Internet activities -- including even private e-mail accounts accessed at work -- ensure that your staffers know this. Also, remind them regularly to keep certain matters confidential and the organizational monitoring of e-mail.

4. **Have a system in place to respond to accidental leaks.** If your staffer thinks he has disclosed confidential information, make sure he knows to tell you right away. Then, you need to notify your technology transfer office to determine whether the leak qualifies as disclosure.
5. **Caution staffers about the dangers of forwarding and hacking.** Ensure that your employees know that they have no control over an e-mail after they send it -- it can go anywhere. Communication and e-mail forwarding outside the research group should contain little to no details about your proprietary work.
CHAPTER II: NIH & NSF Grants, Foundation & Corporate Funding

Despite the serious competition for research funding, you have a multitude of options for seeking grants. You can apply for funding from federal granting agencies -- mainly the NSF and NIH -- or from private foundations. Yet another option is corporate funding.

Selecting the right funder depends on the nature of your proposed research project and what kind of funding model you and your institution are comfortable with. Always visit your Sponsored Research Office before applying for any funding. This office is your go-to resource for funding your research projects.

In this section, you will learn about:

- NIH and NSF grants for new/early PIs and how to win them;
- NIH’s New Investigator and Early-Stage Investigator policies;
- NIH’s grant-review process and five review criteria;
- NSF’s Merit Review criteria and how to decode them;
- How to get foundation and corporate funding;
- How to diversify your funding sources and develop a “strategic funding plan;” and
- The do’s and don’ts of research collaboration.
SECTION 1:
NIH: Choose the Right Grant Program to Win Funding

At the NIH, you have several excellent grant programs to choose from that are tailored to new and early investigators. Perhaps the most popular are the “K awards,” but there are others you may want to look at as well.

Best NIH Grants for New/Early PIs:

- K01
- K08
- K22
- K23
- K99-R00
- R03
- R15

NIH Vs. NSF -- What Are the Differences?

Is your proposed research better suited for funding through the NIH or NSF? If your research project relates in any way to human health, you’ll have a far better chance applying for an NIH grant. Even if your research is “basic science” that has some kind of potential to influence a disease’s diagnosis or treatment, NIH is still a better fit than NSF.

But if you’re focusing on pure physics, math, computer science, astronomy, polar research or oceanography, NSF is your best fit -- not NIH. Still, there’s some overlap with funding areas between the NIH and NSF. Specifically, research that involves traditionally NSF-focused subject matters but that have some indirect biomedical relevance would potentially fly at either agency.

Example: Although NIH has no interest in funding research to explore the impacts of the Gulf oil spill on the Florida Everglades, the agency might fund research involving writing computer algorithms for computed
tomography scanners. Even though the research involves mathematics, there’s a potential medical benefit that would appeal to NIH’s mission.

The most notable overlaps between the NIH and NSF are in biology and chemistry, but nanotechnology and materials science also have some overlapping focus areas. For instance, in biology both agencies have funded projects involving bacterial and viral invasions of cells, DNA repair, cell division, the use of model organisms to understand human biology, the control of development by genes and the development of antibiotics for medical devices.

Also, both agencies have advanced initiatives focused on investigating the structure of proteins and nucleic acids. Both are investing in new materials and nanotechnology to produce artificial skin, drug-delivery systems and biosensors, as well as in studies to develop more environmentally friendly industrial-scale processes.

NSF (not NIH) has dedicated programs and divisions for research areas like astronomy, polar research and geosciences. On the other hand, NIH has an institute that supports research on environmental health topics like the role of environmental toxins in disease. Also, NSF has a broader range of research topics in the “hard sciences,” while NIH focuses on health and medicine.

NIH has institutes dedicated to social, behavioral and economic sciences, while NSF has the same interest areas but also includes topics that are not health-related. Both agencies fund projects involving bioinformatics, bioengineering and biomedical imaging.

**Dual submission:** Can you apply to both NIH and NSF? If you’re a new investigator, yes. Only new investigators without previous federal funding as a PI or co-PI can submit proposals to both agencies.

But don’t expect the same type of review criteria at both agencies. NSF bases its grant proposal reviews on two criteria: Intellectual Merit and Broader Impacts. NIH uses five core review criteria: Significance, Approach, Innovation, Investigator(s) and Environment.

Additionally, keep in mind that NSF funds far fewer research projects than NIH -- NSF’s annual budget is usually $6 to $7 billion, while NIH’s budget is much larger at around $31 billion. NIH tends to sponsor about five times as many research proposals each year as NSF.
Good News: Important 2012 Updates

The NIH has been supporting new investigators in various ways throughout the past few decades, but recently has adopted policies to reverse the decline in the number of new investigators receiving significant grants. Specifically, NIH is attempting to award grants for new investigators at success rates comparable to those for established PIs submitting new applications.

NIH is clustering new investigator applications together during review to further level the playing field. These policies, however, apply to only traditional R01 grants. You won’t get this type of special treatment when applying for any other type of NIH grant.

NIH will not consider you a “new investigator” if you’ve been awarded any major independent research award in the past. But you can still be a new investigator if you’ve received any of the following small or early stage research grants, or any training or career awards:

- **F Awards** - All Fellowships;
- **G07** - Resources Improvement Grant;
- **G08** - Resources Project Grant;
- **G11** - Extramural Associate Research Development Award (EARDA);
- **G13** - Health Sciences Publication Support Awards;
- **G20** - Grants for Repair, Renovation and Modernization of Existing Research Facilities;
- **K Awards** - All Individual and Institutional Career Awards;
- **L30, L32, L40, L50, L60** - Loan Repayment Contracts;
- **R00** - Pathway to Independence Award-Research Phase;
- **R03** - Small Grant;
- **R13** - Research Conference Grant Program
- **R15** - Academic Research Enhancement Award;
- **R21** - Exploratory/Developmental Grant;
- **R25, R90, RL9, RL5** - Research Education Grants;
- **R34** - Clinical Trial Planning Grant;
- **R36** - Dissertation Award;
- **R41** - Small Business Technology Transfer Grant-Phase I;
• **R43** - Small Business Innovation Research Grant-Phase I;
• **R55** - Shannon Award;
• **R56** - NIH High Priority, Short-Term Project Award;
• **S10, S15** - Biomedical Research Support Shared Instrumentation Grants
• **S21, S22** - Research and Institutional Resources Health Disparities Endowment Grants
• **SC2, SC3** - Competitive Research Pilot Projects;
• **T32, T34, T35, T90, D43** - All Training Grants; and
• **X01** - Resource Access Award.

**New for 2012:** NIH also decided that new investigators who are within 10 years of completing their terminal research degree or completing their medical residency will be termed “Early Stage Investigators” (ESIs). Like new investigators, ESIs will get careful treatment at review time for R01 proposals.

**Consider These Smaller, Targeted Grants First**

**K Awards:** The biggest advantage to K awards is that NIH designed them to give you “protected time,” meaning that the grant funding covers your salary, research and training so you can focus on developing your early research career. You must dedicate at least 75 percent of your time to the K award activities, but the grant gives you some serious breathing room while you’re preparing your preliminary data for a bigger grant, like the R01.

NIH has four K grants that it typically awards to new and early-stage investigators:

• **K01** -- Mentored Research Scientist Career Development Award (for basic laboratory research)

• **K08** -- Mentored Clinical Scientist Research Career Development Award (for basic laboratory research with a clinical component)

• **K22** -- Career Transition Award (for postdoctoral fellow transitioning to a faculty position)

• **K23** -- Mentored Patient-Oriented Research Career Development Award (for research involving patients)
You have to take a unique approach to win a K award. Employ these expert-recommended strategies to make your proposal catch reviewers’ attention:

- Stick to **relevant research** that breaks new ground, advises **Roxana Bendixen, PhD**, a research assistant professor at the University of Florida’s Department of Physical Therapy. Talk with a program officer before you apply to ensure that your proposal harmonizes with a particular institute/center’s (IC’s) mission.

- Keep your research plan **realistic** so that it appears “doable” to reviewers. Ensure that your project is inline with: the context of your prior research; your knowledge and expertise; your current position; and your institution’s ability and willingness to support you.

- Spell out your **specific aims** in clear, exact terms. You have only 12 pages for the entire K grant application, so using precise language is crucial. Don’t write in generalities, but instead briefly and specifically describe the type of experiments, how you’ll perform them and what you’ll be observing.

- Outline solid steps in your **career-development plan**. You need to explain two things: your long-term career goals, and what you’ll do to achieve them.

- Line up your **mentors**, preferably before you even begin your K grant application. Select strong mentors who will support you and meet with you regularly while you’re working under the K award.

- Show a detailed, year-by-year **training plan** with specific activities and designated time to prepare your R01 application. Reviewers like to see that the K award is essentially a stepping stone toward nabbing an R01 grant.

**R15 Grant:** The Academic Research Enhancement Award (AREA), also known as the R15, is a highly-competitive grant for supporting hands-on student involvement in research. The award is up to $300,000 in direct cost per project period of up to three years, plus your negotiated F&A (indirect cost) rate. This grant allows for a modular budget if your direct cost is $250,000 or less.

The AREA program is particularly well-suited for early investigators, because for this grant the NIH is looking to fund promising new PIs who have limited resources and whose institutions have limited research
funding. The R15 grant program has three main goals:

1) **To support meritorious research.** NIH views meritorious research as a renewable form of investigation that has an impact on peer-reviewed contributions, says Dr. Sridhar Mani, professor of medicine and genetics at the Albert Einstein College of Medicine in New York.

2) **To strengthen the research environment of the institution.** The NIH wants sees the R15 grant as providing “seed money” to foster more long-term, sustainable investigation, thus enriching the institutional research environment, Dr. Mani explains.

3) **To expose students to research.** You’ll need to provide evidence that the students are performing research and that your lab is a learning environment. And because the R15 is renewable, the NIH wants to see your students co-authoring publications and presentations.

*Caveat:* The eligibility criteria for the R15 are pretty restrictive. In fact, the NIH even keeps an updated list of institutions that are not eligible for R15 AREA awards (http://grants.nih.gov/funding/area_ineligible.xls). First, only baccalaureate or advance degree granting institutions are eligible. Second, your institution must have received $6 million or less in research grants in four out of the last seven fiscal years -- not including “C,” “S” and “G” grants. Basically, R15s usually go to institutions with not much grant money.

Third, your institution must fall within the NIH’s specified types of health professional schools and colleges. Lastly, you need to ensure that the right NIH Institute or Center (IC) for your research topic accepts R15s -- not all of them do.

**R03 Grant:** The NIH Small Grant Program, better known as the R03 grant, is a funding mechanism for small research projects with short time durations and limited needed resources. The R03 is not renewable, can last up to two years and allows for direct costs of up to $50,000 per year.

To apply for the R03, you do not need to submit any preliminary data. R03 grants are appropriate for funding pilot or feasibility studies, secondary analysis of existing data and small, self-contained research projects, according to the NIH. New/early PIs can benefit from seeking R03 awards because they:
• Require a somewhat less onerous proposal process;
• Don’t require extensive prior publication, research or funding;
• Are smaller amounts of money and time; and
• Are generally more accessible to new/early PIs than other types of research grants like the R01.

Why the K99-R00 is Made Especially for You

The Pathway to Independence Award, known as the K99-R00, is a two-phase grant program to support new investigators and ESIs in their transition from a mentored postdoctoral research position to that of an independent researcher. This grant program essentially aims to give you a jump-start to your independent research career, with access to NIH funding that most new investigators don’t see until later on in their career.

You must hold a clinical or research doctorate and have no more than five years of postdoctoral research training at the time of your application or resubmission. NIH also wants you to commit at least 75-percent of full-time professional effort.

The K99-R00 award covers a maximum of five years, with two distinct phases:

1. Mentored Phase (K99) - Your total yearly cost for this phase is capped at $90,000, with research support costs of up to $20,000. NIH allows for up to two years time for the mentored phase to get additional training, complete research, publish results and transition to an independent research position.

   In your proposal, you must have a research project that you’ll undertake during the K99 phase and transition to the R00 phase. You’ll also need to choose a reputable mentor for this initial phase of the grant program. Note: At the time you apply for the K99 phase, you must not already have a full-time tenure track assistant professor position.

2. Independent Phase (R00) - The second phase allows for a total cost of no more than $249,000 per year. This figure encompasses salary, fringe benefits, research support and indirect costs. At this point in the program, you must have accepted a tenure-track full-time assistant professor position.
The second phase can last up to three years to support your research activities as an independent scientist. NIH expects you to use this time to also prepare an R01 application.

NIH determines your eligibility for this grant program based on evidence of your “non-independence,” such as:

- Your research is funded entirely by other PI’s grants;
- You conduct your research entirely in another investigator’s lab;
- You have a full-time appointment at the academic institution that’s the applicant institution;
- You haven’t hired postdoctoral fellows or been the responsible supervisor for grad students; and
- You lack other faculty rights and privileges like attendance at faculty meetings.

NIH determines your “independence” -- and therefore ineligibility for the grant program -- based on the following factors:

- You currently or previously held an independent research faculty or tenure-track, position or its equivalent, in academia, industry or elsewhere;
- You have more than five years of related postdoctoral research training at the time of application or resubmission;
- You’ve been the independent PD/PI on a project funded by a major NIH research grant, career development award or other peer-reviewed NIH or non-NIH research grants of more than $100,000 in annual direct costs;
- You’ve been a project leader on sub-projects of P01 (program project) or P50 (center grants) awards;
You received a start-up package for support of your independent research;

- You have research space dedicated to your own research; and/or

- You are eligible to apply for independent research funding as the PI of an R01 or other equivalent research grant.

**How to Compose a K99-R00 Proposal**

Reviewers will score your K99-R00 application based on several criteria, most of which are standard criteria for NIH proposals. But keep in mind that reviewers will focus on certain categories that are especially important to the Pathway to Independence Award.

In composing your application, pay special attention to the information you set forth on your mentor(s), career development plan and career goals, and your environment and institutional commitment. Outlined below are the review criteria for K99-R00 grant proposals.

**Candidate:** To assess the candidate, reviewers look at your bio and letters of reference. Specifically, you’ll need to demonstrate your:

- Track record of research productivity and quality of peer-reviewed publications;

- Pre- and postdoctoral research training experience;

- Potential to become an outstanding, successful independent investigator who will contribute significantly to your chosen field of biomedical-related research;

- Research creativity and potential to develop a creative, independent research program; and
• Ability to achieve an independent, tenure-track or equivalent position within the time period you request for the K99 phase.

**Career Development Plan / Career Goals & Objectives:** The career plan and goals that you outline in your proposal need to really “wow” the reviewers. You’ll need to prove that:

• Your career development plan’s proposed didactic and research components appropriate for your current stage of scientific and professional development, as well as for your proposed research career goals;

• Your proposed career development plan will contribute substantially to your scientific and professional development, including your successful transition to independence;

• Your proposed timeline for transitioning to the independent phase is appropriate, given your current stage of scientific and professional development along with the career development you proposed for the initial mentored phase; and

• If you’re currently in a research training program, the proposed career development plan would enhance or augment the program and the additional training is necessary.

**Research Plan:** Although the K99-R00 is primarily a career-focused grant program, you still need significant proposed research with scientific merit. You need to prove that your proposed research plan is:

• Appropriate for your level of training and appropriate as a vehicle for developing the research skills that you described in your career development plan;

• Appropriate for developing a highly successful R00 research program, based on the scientific and technical merits, experimental design, and methodology;

• Scientifically sound and, for the R00 research plan, a logical extension of the K99 phase research;
• Likely to contribute significantly to our understanding of biomedical problems (R00);

• Viable in the long-term, addressing an innovative hypothesis or challenging existing paradigms (R00); and

• Likely to foster your career as an independent investigator in biomedical research (R00).

**Mentors, Co-Mentors, Consultants, Collaborators:** Reviewers will spend extra time looking at your mentor or co-mentors, because mentorship is a crucial part of this award program -- particularly in the initial K99 grant phase. You must show that:

• Your mentor has a strong track record in training future independent researchers;

• Your mentor’s research qualifications and experience, scientific stature, and mentoring track record appropriate for your career development needs;

• Your mentor’s proposed supervision during the initial mentored phase is adequate, and your mentor is committed to your continued career development;

• Your mentor has a comprehensive plan to support the proposed K99 phase career development and research plans, as well as your transition to independence; and

• Your consultants/collaborators have appropriate research and/or mentoring qualifications for their roles in the K99 phase.

**Environment & Institutional Commitment:** Reviewers want to know that your institution will provide the right environment and resources to support your transition to independence. Show that your institution:

• Provides a high-quality environment for your development;
• Has adequate and appropriate research facilities and educational opportunities, including collaborating faculty, to support your research and career development goals;

• Is committed to fostering your development and transition from the K99 mentored phase to the R00 independent phase; and

• Allows for the required 75-percent full-time minimum professional effort for the K99-R00 award’s training, career development and research activities.

If applicable to your proposed work, reviewers will also score your proposal based on these additional sections:

• Protections for Human Subjects;
• Inclusion of Women, Minorities, and Children;
• Vertebrate Animals;
• Biohazards;
• Training in the Responsible Conduct of Research;
• Select Agents; and
• Resource Sharing Plans.

**Important:** After you complete the K99 phase, the R00 independent phase won’t begin automatically. Your institution must submit on your behalf a separate application to get the R00 grant. The NIH must receive the R00 application at least two months prior to the award activation date.

**Secrets to a Winning NIH Proposal -- Section by Section**

NIH reviewers are generally tasked with rating your proposal based on five criteria items: significance, approach, innovation, investigator(s), and environment. But these five items aren’t the only things reviewers will look at -- other sections of your proposal are just as important. For instance, your Specific Aims section is where the real meat of your proposal is, explaining the importance of your work.
**Significance:** How is your research cutting-edge? What kind of impact will your research project have on your field? How will achieving your project’s aims further drive scientific knowledge, technical capability and/or clinical practice? How will achieving your aims alter existing knowledge impacting your specific field?

**Approach:** Is your approach well-reasoned, feasible and logical? Can you in fact complete the project goals given your resources? What are your expected results? What are the potential problems and solutions?

Among the five criteria, reviewers tend to focus on the Approach section the most, says Christopher Francklyn, PhD, professor at the University of Vermont and veteran reviewer for the NSF and NIH. And a good Approach begins with a strong hypothesis -- one that is testable, and will either drive out prior incorrect theories or open the door to new thinking about the problem.

You can have a single hypothesis governing your entire proposal, or you might have a specific hypothesis for each aim, Francklyn notes. The decision is entirely up to you.

Either way, as a less-experienced PI, you’ll need to keep your project ideas close to the “testable-hypothesis” end of the research scale, Blackburn says. When you’re a new investigator, reviewers don’t believe you have the ability and experience to identify and isolate the really significant observations from a sea of data.

**Specific Aims:** Do the aims test the hypothesis (Approach)? Can the aims provide a basis to refute the hypothesis if it is wrong?

You can have any number of Specific Aims in your proposal -- there is no hard-and-fast rule, Francklyn says. But most NIH proposals have three or four aims in the research plan. Depending on the nature of your specific research and discipline, having fewer than four aims can lead reviewers to believe that your project won’t likely have a significant impact. But having more than four aims may be too many for the amount of experiments in the set amount of time.

**Best bet:** Each Specific Aim should represent a somewhat independent project and should not depend upon the success of another. For each Specific Aim, Francklyn recommends using a standard format with separate sections of: Rationale (why?); Experimental Approach (how?); Outcomes (potential results); and Alternatives
(what you’ll do if an experiment fails).

**Innovation:** How will your research project change the current standards or paradigms in your field? How is your research idea groundbreaking (not just “new”)? How will your work change the direction of research, or substantially refine or improve the existing methods in your field?

**Environment:** Do you have the appropriate scientific environment for the project? Do you have institutional support and commitment for your proposed research? Do you have the right equipment and departmental support?

**Biosketch (Investigators):** The biosketch is a short but important part of your NIH proposal where you detail your professional and technical credentials and expertise, according to Francklyn. This is the part that reviewers look at for the “Investigator(s)” review criterion.

In addition to your name and credentials, the biosketch contains four sections: personal statement; appointments and honors; selected peer-reviewed publications; and other support.

- **Personal Statement** - Utilize your personal statement to remind reviewers of your training and expertise, as well as your accomplishments and other background elements that make you qualified to lead the research project. The NIH’s fairly recent addition of the personal statement section has proved to be a sort of equalizer among senior PIs and early-stage investigators.

- **Appointments and Honors** - Use this section to note distinctions that you’ve earned, including awards from private foundations, past fellowships and junior faculty distinctions. You can also include in this section any professional society memberships, as well as professional courses or workshops you’ve attended that support your technical expertise.

- **Selected Peer-Reviewed Publications** - Your publication list is a place to really showcase your past work. Limit the total number of publications to 15, with the first five listed those most relevant to your current work. The next 10 publications you list should still relate to the proposed work in some way. As you select the publications to list, consider the impact (most prestigious journals, highest-cited papers), technical relevance (demonstrates your expertise in your proposal’s major technical approaches), and timeliness (most recent
publications, publishing dates that show momentum over time).

- **Other Support** - As a new/early PI, you don’t have to worry much about this section. In fact, reviewers don’t place hardly any importance on Other Support.

  **Strategy:** As a new PI, your biosketch section will really shine if you’re collaborating with a more senior PI. A multiple-PI project tends to ensure that you have any expertise gaps covered by one investigator or another.
SECTION 2:
NSF: What You Need to Know to Get These Grants

The NSF has several different types of grant programs available that are especially useful for new/early PIs. Like NIH’s K-awards, the NSF has the following awards that are appropriate for newer investigators.

Best NSF Grants for New/Early PIs:

- CAREER
- EAGER
- RAPID
- RUI

**CAREER:** The Faculty Early Career Development (CAREER) program aims to support junior faculty who excel as teacher-scholars via outstanding research, education, and integration of education and research. New and continuing CAREER awards are typically up to $220,000 per year, with a minimum total award amount of $400,000 for the five-year duration.

Although the CAREER program essentially provides grant money so you can develop your academic career, your proposal must have an integrated research and education plan at its core. You cannot submit more than three proposals for this grant.

The eligibility criteria for this award are fairly specific, but usually not difficult to meet for most new/early PIs. You must:

- Hold a doctoral degree in an NSF-supported field;
- Be untenured until Oct. 1 following the proposal deadline;
- Have not previously received a CAREER award; AND
• By Oct. 1 following the proposal deadline, be employed in a tenure-track (or tenure-track equivalent position) as an assistant professor or equivalent title at either:
  o an accredited U.S. institution that awards degrees in a field that NSF supports, or
  o a U.S. organization that is non-profit and non-degree-granting, such as a museum, observatory or research lab.

Your Project Summary should focus on your plans to integrate education and research activities, and your Project Description should explain how the proposed activities, over the five-year period, will “build a firm foundation for a lifetime of contributions to research and education in the context of the PI’s organization,” the NSF states.

**EAGER:** The EArly-concept Grants for Exploratory Research (EAGER) award is for “high risk/high reward” projects that are not likely to survive the normal peer-review process. Projects suitable for funding under EAGER are those that have a high chance of failure, but still have the potential for a high payoff, explains Sam Scheiner, PhD, program director in the NSF’s Division of Environmental Biology.

EAGER awards are not necessarily tailored for new/early PIs, but they are for the kind of radically different and transformative ideas that newer PIs tend to have. These awards are usually capped at $300,000 and up to two years in duration. EAGER renewals are subject to a full external merit review.

In the proposal, you must provide a five- to eight-page Project Description that describes why the project is appropriate for EAGER funding and why it doesn’t fit into any other NSF programs.

**RAPID:** Grants for Rapid Response Research (RAPID) are targeted for proposals involving a serious urgency to accessing data, facilities or specialized equipment, or responding to crises or natural disasters. Like EAGER, these grants do not have to pass an external review but instead undergo only an internal merit review.

RAPID awards are typically up to $200,000 for one year, and renewals are subject to a full external merit review. RAPID proposals must include a two- to five-page Project Description that focuses on why the research is urgent and why a RAPID award is the most appropriate funding mechanism for the proposed work.
**RUI:** The Research in Undergraduate Institutions (RUI) program is a good choice for early investigators who work in undergrad institutions. The RUI program supports research by faculty via funding of research projects and shared-use research instrumentation. RUI award amounts can vary widely, to more than $100,000, and the project duration can be from one to three years.

**Important:** Keep in mind that NSF’s individual directorates offer a multitude of field-specific funding opportunities that you may find appropriate for your early career and research activities.

**Focus on Merit Review Criteria: Keys to Winning NSF Funding**

No matter what kind of grant program you choose to apply for, NSF reviewers will rate your grant proposal based on two merit review criteria: Intellectual Merit and Broader Impacts. These criteria are so important to the NSF that if you don’t include them front-and-center in your Project Summary Page, as well as throughout your proposal, the agency will return your proposal without even reviewing it.

**Michael Lesiecki, PhD,** executive director of the Maricopa Advanced Technology Education Center, says that to write a winning NSF proposal you must:

- **Study the grant criteria** carefully before you begin working on your proposal. Understand the general grant proposal guidelines, as well as the specific instructions under the applicable agency program and particular funding opportunity.

- **Highlight the merit review criteria** in your Project Summary, placing Intellectual Merit and Broader Impacts in separate, bold headings.

- **Think like a reviewer** as you write your proposal, and try to make the reviewer’s job easier by clearly identifying the key elements (like the merit review criteria) that he’s looking for in your application.

- **Use summary paragraphs** in each section to reinforce your proposed project’s Intellectual Merit and Broader Impacts throughout the application.
Keep Intellectual Merit at the Core of Your Idea

So, what are Intellectual Merit and Broader Impacts, and what do they mean to your research project proposal? Intellectual Merit is similar in concept to the traditional idea of scientific merit. Specifically, NSF defines Intellectual Merit as what your proposed project will do “to advance knowledge and understanding of undergraduate science, mathematics, engineering and technology education.”

NSF reviewers will rate the Intellectual Merit of your proposed project based on five criteria:

1. How important is the project?

Provide clear statements in the proposal that define your project’s magnitude. You can even write, “This research is important because ...” Write from a scientific point of view to boost your credibility in the reviewer’s mind. Make a scientist-to-scientist connection. Also, capture the reviewer’s attention with clearly-stated urgent or timely issues related to your project.

2. How well-qualified is the PI and other involved individuals?

Sure, the reviewer can read through the attached curriculum vitae for you and your team, but you need to reinforce your qualifications within the proposal. Remind the reviewer of your team members’ exact qualifications, and then tie that expertise back to the proposed research project.

Call out the qualifications using the NSF’s own language. Use the term “well-qualified,” and in your summary statement at the end of this section, write: “The investigators are particularly well-qualified based on their background and experience ...”

3. How creative, original or potentially transformative is the proposed research?

The NSF is looking for research projects that could potentially move the field into a new direction or change the field in a new and innovative way. Again, use the NSF’s key words like “transformative,” communicating clearly how your project is important. For instance, “These activities are potentially transformative because ...”
4. How well-conceived and organized is the proposal?

Utilize proper formatting and logical organization in your proposal to demonstrate this point. You may find that fitting all the important things you have to say about your proposed work into the set page limit is difficult, but resist the temptation to use formatting tricks like reducing the font size to cram more information in.

The NSF actually has specific formatting guidelines for proposals, so you should follow these exactly:

- Keep all margins to at least 1 inch;
- A vertical space of 1 inch should contain no more than six lines of text;
- The font size should remain no smaller than 10 points for Arial, Courier New or Palatino Linotype fonts;
- The font size should remain no smaller than 11 points for Times New Roman and Computer Modern family fonts;
- You can use font sizes of less than 10 points only for mathematical formulas and equations, Symbol-family fonts, and captions for diagrams, tables or figures; and
- Use single-column page formatting (never two-column formatting) for proper electronic viewing of your proposal.

5. How well-resourced is the proposed project?

The reviewer wants to know that you have the laboratory facilities to perform the proposed activities, or that you have access to the necessary facilities and equipment. You can even write: “This project is particularly well-resourced for the following reasons ...”
Expand Your Thinking to Identify Broader Impacts

Broader Impacts involves your proposed research’s potential to make a greater impact beyond the project’s scope. NSF reviewers want you to convince them that your work will potentially impact your field, related technology or infrastructure and society as a whole. NSF defines Broader Impacts as how your proposed project “will advance discovery and understanding while promoting teaching and learning.”

Like Intellectual Merit, Broader Impacts also have five main criteria. The only difference is that, unlike Intellectual Merit, you don’t need to meet all five Broader Impacts items but instead only the ones most relevant to your research topic.

1. Does the proposed project advance discovery and understanding while promoting teaching, training and learning? Examples:

   - Develop and contribute educational materials based on your research that you can include in a teaching database, such as a K-16 digital library;

   - Involve K-12, undergrad or grad students as participants in your research;

   - Integrate your project activities into K-12, undergrad and grad teaching of science, math and engineering;

   - Collaborate with educators and researchers to incorporate your research into learning and education;

   - Involve your grad and post-doc student researchers in undergrad teaching activities;

   - Invite student teams involved in your research to make presentations to professional societies;

   - Establish mentoring programs for high school, undergrad and grad students, as well as research technicians; or
Involve your team and your project activities in the recruitment, training or professional development of K-12 math and science teachers.

*Key:* Provide specific action items and collaborative agreements.

2. *Does the proposed project address under-represented groups?* Examples:

- Involve students from under-represented groups as participants in your proposed activities;
- Seek out educational and research collaborations with minority students or faculty;
- Collaborate with students and faculty from non-PhD-granting institutions and other institutions serving these groups;
- Mentor scientists and engineers from under-represented groups who are new to submitting NSF proposals;
- Participate in workshops and conferences in which diversity is a priority;
- Develop new approaches like information technology and connectivity to reach out to under-represented groups, communities and individuals;
- Collaborate with faculty and students at Experimental Program to Simulate Competitive Research (EPSCoR) institutions, colleges for women and community colleges; or
- Visit campuses and establish education collaborations at institutions that serve under-represented groups.

*Key:* Don’t simply state your institution’s minority demographics -- instead, plan how you will involve women, ethnic groups, disabled individuals and/or geographically-limited groups in your work more broadly.
3. **Will the project enhance the infrastructure for research and education?** Examples:

- Collaborate with researchers and institutions in other disciplines, particularly in other U.S. academic organizations, as well as government and industry with international partners;

- Develop and operate shared research and education infrastructures, such as science and technology centers, engineering-research centers and other facilities;

- Involve your team in developing and disseminating next-generation instrumentation, multi-user facilities and other types of shared platforms;

- Improve or upgrade computing infrastructures, such as large databases, digital libraries, or networks and associated systems; or

- Develop methods to expand multi-user facilities so that they’re sites of research and mentoring for larger numbers of engineering and science students.

**Key:** This Broader Impacts item is a good fit for your project if you’re aiming to produce new technologies or improve on existing ones. Also, you might develop collaborations with interested parties to disseminate your information.

4. **Are you disseminating broadly?** Examples:

- Integrate your research with educational activities to communicate your information in a larger context;

- Participate in multidisciplinary research activities, conferences and workshops;

- Collaborate with nature centers, museums, science centers and other similar organizations to create exhibits related to your work;
- Involve the public or the related industry in your research and education activities;

- Give presentations to the broader community at libraries, museums and other public venues;

- Offer data derived from your work for inclusion in databases and digital libraries;

- Publish your data in a wide variety of formats, such as CD-ROMs, press kits, Websites and non-technical literature; or

- Offer research results and educational materials in useable formats for Congress members, industry leaders, policymakers and other audiences.

**Key:** Explain how you will effectively inform others of your project’s results to enhance scientific and technological understanding. Most professional societies and associations have educational-outreach arms that offer great dissemination opportunities for your research results.

5. **Does the research offer societal benefits? Examples:**

- Analyze, interpret and share your research results in a variety of different formats that non-scientists can easily understand;

- Collaborate with scientists at federal government labs and agencies;

- Partner with private-sector scientists to integrate your research into broader activities of national interest;

- Explain how your research and discovery will benefit society by supplying specific examples of the results’ possible application; or

- Supply information derived from your research to federal, state or local agencies for their use in
policy development.

**Key:** Although societal benefit is perhaps the most difficult Broader Impact item, it’s also one of the highest-ranking for reviewers.

First and foremost, you can’t address the Broader Impacts criterion as an afterthought, says Thomas R. Blackburn, PhD. You need to start thinking about and listing Broader Impacts right at the beginning of your work on your proposal. Start with a list of possible Broader Impacts themes that you can weave into your proposal.

**Example:** Say you’re a field biologist studying giraffe maternal behavior in the wild and in zoos, and you’re applying for an NSF grant. You could get the ball rolling by jotting down a few quick Broader Impacts ideas, such as:

- Internships for non-major undergrads?
- Exhibit at zoo?
- Recruit high school students as assistants for zoo observations?
- Present seminars to local university psychology/anthropology classes?

As you move forward with your Project Description, you can refine your ideas and even come up with new, better ideas for Broader Impacts activities. This quick list, however, at least gets you thinking about Broader Impacts and how the activities could relate to your research project.

**Buzzwords:** Blackburn also suggests that you use certain “keywords” from the NSF in your Project Description and Summary to call-out your Broader Impacts. For instance:

- **Role models** -- If one of your Broader Impacts activities is to recruit female students through collaborators in your seminar series, use the term “role models” instead of “collaborators.”

- **Accessibility** -- If you plan to install wheelchair ramps to allow students with disabilities to participate in a lab experiment, use the words “accessibility” and “inclusiveness,” instead of “wheelchair ramps.”
Research infrastructure -- If your newly-developed software improves signal-to-noise in counting duck eggs, as well as potentially in all animal husbandry research, label this improvement as “research infrastructure” instead of just “improvement.”

**Top 6 Tips on Decoding & Communicating Broader Impacts**

Even the NSF admits that the concept of Broader Impacts is tough to understand for most PIs -- and even reviewers, mainly because the concept has different meanings for different PIs and disciplines. And then, you have to write these fantastic ideas for Broader Impact activities into your proposal. This is no easy task.

The concept of Broader Impacts was really a result of shift from federal granting agencies viewing research as an end unto itself to seeing it as an R&D investment, according to Martin Butler of The Butlers & Associates, a research grant consulting firm. Butler offers the following tips for composing Broader Impacts that will win the admiration of NSF reviewers.

1. **Categorize your impacts.** One way to realize the full breadth and depth of your research’s potential impact is to pinpoint how your Broader Impacts fall into these four categories -

   - **Social Impact:** Improving quality of life, such as enhancing safety and security, reducing poverty, improving integration, boosting education and literacy rates, reducing marginalization, etc.

   - **Environmental Impact:** Improving the quality of air, land, water, soil, species and ecosystems, as well as advancing environmental management, stewardship and sustainability.

   - **Economic Impact:** Growing the gross domestic product (GDP), increasing employment rates, jobs and exports, improving production efficiency, reducing costs, as well as producing new technologies, products, patents, licenses, companies or jobs.

   - **Health Impact:** Reducing disease incidence, mortality rates and healthcare costs, as well as improving patient satisfaction, quality of life, safety or recovery.
Your project may overlap into more than one category, Butler notes. Think about your research in terms of what it will produce in the future and how it could impact these areas in the long term and on a bigger scale.

2. **Know what to share.** Within your discipline, you can achieve your Broader Impacts by sharing a variety of things that your research yields. You can share:

- Knowledge, citations and references;
- New methodologies and approaches;
- New models for teaching, mentoring, training, outreach and research;
- New methods to integrate research, education, disciplines and/or sectors; and/or
- New or improved research infrastructure and collaborative models.

3. **Utilize “impact vehicles.”** Impact vehicles are the tools and methods you use to share the new information, knowledge, data and technologies that your research project produces. Share your “wealth” through impact vehicles like:

- Publications
- Reports
- Presentations
- Workshops
- Conferences
- Partnerships
- Collaborations

4. **Use collaborators and partners.** Your partners and collaborators are essential links on your “impact chain.” Using your partners, your research’s impact can include translating the new knowledge into new:
o Approaches or methods;
o Standards, guidelines or codes of practice;
o Decision-making or partnership models;
o Models for overcoming challenges or problems; and/or
o Products, services, processes, technologies, tools, devices, materials, pharmaceuticals, treatments or techniques.

5. Identify your “blast radius.” Your “blast radius” is essentially the various levels to which your research’s impact extends. The extent can reach from the individual, institutional, disciplinary, community, state, regional, national, international and global levels.

Return to Sender: Why NSF Would Refuse to Review Your Proposal

Aside from neglecting to include the two merit-review criteria in your Project Summary and throughout the rest of your proposal, there are several other situations in which NSF would send back your application without reviewing it.

Your proposal will get rejected without review if:

➢ The project is inappropriate for NSF funding;

➢ You submitted the proposal with insufficient lead-time prior to the project’s scheduled start date;

➢ You submitted a previously-declined proposal without making substantial revisions;

➢ You received a “not invited” response, meaning that NSF turned down your preliminary proposal and didn’t invite you to submit the full grant proposal;

➢ Your proposal doesn’t conform to the GPG and program solicitation guidelines for page limits,
formatting or electronic submission;

- You didn’t meet the announced proposal deadline; or

- Your proposal duplicates another that the NSF already awarded.
SECTION 3:
Secrets to Nabbing Foundation & Corporate Funding

Foundation grants and corporate sponsors are great resources for investigators of all experience levels to get necessary funding for research projects. Foundation or corporate funding isn’t the easiest avenue for new PIs, but they offer alternate funding sources to diversify your options and increase your chances of getting the money you need to launch your research career.

Understand What Private Funders Want

Foundations can be national, regional or local. If you want to nab funding from foundations and corporations, you need to first understand what they want from you. Although their specific missions and preferences can vary widely, private funders tend to want two main things: research that makes an impact on the real world (translational research), and a well-qualified research team.

**Translational Research:** Many foundations and corporations prefer to fund research that can translate to the clinic, producing a real-world, tangible impact. This “bench-to-beside” ideology is common among private funders, and you’ll need to link that real-world impact to the funder’s mission and objectives.

**Competent Team:** Private funders also want to know that you are equipped to actually accomplish the research you’re proposing. You need to show that you have the right personnel with the right qualifications and expertise to do the work. Additionally, show the funder that you have the equipment and facilities needed to carry out the research.

If you really want to delve into the private funder’s proverbial mind, you can:

- **Attend the funder’s events.** Foundations often have different kinds of events, such as dinners, conferences and informal meet-and-greets, many of which are open to the research community. These events are excellent opportunities to network with the foundation’s key decision-makers, and to learn more about what types of projects the organization tend to fund.
Become a peer reviewer. What better way to get detailed insight into a funder’s granting processes than to become a peer reviewer? Reviewing grants for a private funder will give you an opportunity to get information on how the foundation allocates its funds and what kinds of research initiatives are high on the priority scale. Unfortunately, you can’t become a peer reviewer by simply asking – you need enough stature for the funder to ask you.

Getting Started: Perfect Your Research Idea Before Looking at Potential Funders

You should have a well-thought-out research idea before you even think about searching for a possible foundation to fund your project. Why? If you don’t have a good understanding of your own idea, you won’t do very well in convincing a funder to give you any money.

Start with the research idea first, and then save your search for funding until the end of that process, advises Andrea Buford, research development specialist at Northern Illinois University’s College of Health and Human Sciences, Office of Sponsored Projects. Also, a well-formed idea will convey your excitement. If you aren’t enthused about your idea, that tone will come through in your writing -- and POs judging your application will pick up on that and throw out your proposal.

After you’ve honed your idea, start your search for foundations that fit with your research topic. Don’t try to fit your research exactly to a foundation’s mission, just so you can get funding. Instead, look for another foundation whose mission is a better match for your idea, Buford says.

Start local: If you’re looking at only the national and international foundations, you’re probably missing some great private-funding sources in your own area. Community and local foundations are usually easy to find and typically want to invest in your area’s welfare. But they often take interest in a variety of research topics.

Check online for listings of local foundations. Some excellent foundation databases include:

✓ The Foundation Directory (www.fconline.foundatiioncenter.org)
The Sponsored Research Association International Foundation List and Private Fund Information (www.srainternational.org)

GrantSearch - the AASCU Grants Resource Center (www.aascu.org/grcinfo/GRCtools.htm)

When you search these types of foundation databases, search in your city and state in addition to a national search, recommends Richard Dunfee, Executive Director of the Grants Resource Center for the American Association of State Colleges and Universities (AASCU).

Employ 4 Strategies to Find the Right Funder

Aside from sifting through countless websites and reading mission statements, you can try four other unique strategies to find a foundation that’s a great fit for your research idea:

1. **Go to your sponsored research office.** Take your research idea to your institution’s Office of Sponsored Projects or Research Administrator (RA). Not only can your RA help you to hone your idea, but she can also assist you in your search for the right funder. Your RA can tap into massive private-foundation databases and may have relationships with foundations.

   RAs sometimes even receive regular requests for applications from foundations. Ask your RA to send you any potentially fitting requests via email or alert you of new funding opportunities.

2. **Network your way to the right foundation.** Networking is an excellent way to make contacts, talk about your research and get tips on the right foundation for your specific work. Start within your institution, networking with senior colleagues who already have relationships with foundations, as well as staff in your institution’s offices of sponsored research, development, alumni and president. Tell colleagues about your research and ask if they have a relationship with any foundation POs or board members who would be interested in your ideas.

   Another way you can get your foot in the door is to find a contact who knows a PO or board member at
a foundation from which you want to try to get funding, says Luz Rodriguez, training coordinator at the Foundation Center. Here are the steps you can take to find this contact:

- Search the Foundation Center’s database, the Foundation Directory, for studies in your field;
- Try to find someone you know who received funding, and then contact him;
- Ask how his organization got funded (if he made a contact at a particular conference, you could attend that conference next year); and then
- Ask if he would be willing to introduce you to the foundation’s PO.

3. **Present your research idea at a symposium.** Try to get on the agenda to present your research at a symposium. (Hint: You’ll need an intriguing publication or abstract to get on the program.) While you’re at the symposium, network with the other presenters and attendees -- who often include foundation POs. If a foundation PO hears your presentation, he may invite you to apply for funding.

4. **Get your institution’s “gatekeeper” to work as a “matchmaker.”** Your institution’s “gatekeeper” is an administration official who typically works in the university’s development or advancement office -- usually the office in charge of fundraising functions. Not only do gatekeepers help you to find and apply for grants, but they also are the main contacts for communications with foundation and corporate representatives.

   Institutions who have a staff member with this “gatekeeper” role usually task the position with acting as a matchmaker of sorts, wedding the best projects and researchers at the institution with the right private funders. “We try to be the liaison between the university and foundation, facilitating the process, so we can keep tabs on everything,” says Eric Reinhard, assistant director of Pennsylvania State University’s Office of Corporate and Foundation Relations.

   **Important:** Keep in mind, however, that not all institutions have a designated staff member who acts as gatekeeper. And at those who do have this position, the staffer doesn’t always want you to call them a “gatekeeper.” Also keep in mind that your institution may have a foundation associated with it.
How to Submit an Unsolicited Proposal

About 60 percent of foundations in the United States don’t accept unsolicited proposals, according to the Foundation Center. But this doesn’t necessarily mean that you can in no way request funding for an unsolicited project proposal. In fact, at these foundations you can often make an online request to submit a proposal.

Before you make the online request, however, you’ll need to do some due diligence. First and foremost, you must ensure that the foundation is the right fit for your proposed research project, stresses Tonya Graham, executive director of Geos Institute. Carefully read the foundation’s guidelines, mission statement, recently-awarded projects and FAQs on its website -- before you send that request.

When you’re sure that the foundation is a good fit for your research, prepare your online submission using these tips:

➢ Make your submission look as professional as possible. Remember, this is your one opportunity to make a good impression.

➢ Demonstrate that your institution is reputable and would utilize the foundation’s grant money properly.

➢ Tailor your submission to the specific foundation -- don’t cut and paste wording from a boilerplate proposal.

➢ Pay attention to any instructions on the foundation’s website that says it will accept proposals by invitation or nomination only.

Write a Winning Letter of Inquiry

Many foundations request that you write a letter of inquiry to kick off the funding-proposal process. This single letter -- usually an email these days, but sometimes a snail-mail letter -- can make or break your chances for getting that precious funding.
Your letter of inquiry must be strong, and typically one page or a half-page in length, says Cynthia Duncan, PhD, a former program director at the Ford Foundation. In your email, conclude your letter by saying that you’ll follow up with a phone call in about one week, allowing the PO time to ponder your proposal.

Include a brief background, highlight the relevant previous findings, and then explain how those findings fit with your proposed project, advises Erik Dent, PhD, assistant professor at the University of Wisconsin School of Medicine and Public Health. You don’t need to provide too much information. In fact, you should keep your letter of inquiry brief -- similar to a Project Summary/Abstract for an NIH grant proposal, he says.

**Crucial:** Write your letter of inquiry using layman’s terms. Many foundation POs and grants managers who are reading your letter are not scientists.

Your letter of inquiry should contain six key points:

1. **Introduction** - Include a brief run-down of your institution’s name, a project description, the amount of funding you’re requesting, your methodology, a timeline for project completion and you staff’s qualifications.

2. **Organization description** - Give a short history of your institution or organization and account of current programs. Also, explain why your institution is the right environment for your proposed project.

3. **Statement of need** - Here’s your opportunity to convince the foundation that your project is important and can meet a crucial demand. Explain how your research will make a difference in your field, advises Doris Parent, Associate Director of Corporate and Foundation Relations at Gallaudet University.

4. **Methodology** - Describe your project’s major activities, your objectives, and the names and titles of key staff.

5. **Other funding sources** - List any other funding sources you approached, including other foundations, corporate funders or granting agencies.

6. **Closing summary** - Wrap up your letter of inquiry with a final summary, restating your project’s
intentions and major aims.

**Pay Attention to Internal Deadlines for Foundation Grant Proposals**

When you’re writing a proposal for foundation funding, your most important deadline is the one that the foundation has for applications. But you have other deadlines that you can’t miss, including internal deadlines at your institution. You can’t miss these deadlines either, or else you’ll blow the foundation’s deadline entirely.

Your first step in planning the foundation proposal writing process is to learn your institution’s internal deadlines, says Kay Verble, executive director of The Sontag Foundation. Many universities want to review every outgoing grant application, and many foundations want grant proposals approved by institutional reviewers prior to submission, she notes.

Find out how long the internal review process is at your institution, and allow for extra time. For example, if the review process takes three weeks, plan instead for at least four to five weeks.

**Beware:** If your institution is a larger one, your internal review process could be quite lengthy -- and very stringent. For instance, the University of Pittsburgh has an internal review process that begins at least eight weeks prior to the funder’s deadline and involves several layers of reviews, revisions and approvals.

A good rule of thumb is to set a writing schedule to meet internal review deadlines -- and, of course, the foundation’s application deadline. Typically, you should allow at least two months for planning and writing your application, at least one month for receiving feedback, and then another two weeks for the final review and proofreading. Note: Proposals for complex research can take even longer.

**Best bet:** Try to send in your application as early as possible. If you send your proposal to the foundation well before the deadline, you allow for extra time to submit any missing or additional necessary information, Verble says.
SECTION 4: How to Diversify Your Funding Sources: Strategic Funding Plan

Research grants are becoming increasingly competitive, particularly those from agencies like the NIH and NSF. But employing a “strategic funding plan” can help you to diversify your project funding and get the money you need to carry out your research.

A strategic funding plan involves a project budget designed in a “piecemeal” fashion, as well as a plan for identifying and getting funding from a variety of stakeholders. The plan also includes a database of grant opportunities. A strategic funding plan has several important benefits, including:

• Helping to offset the increased need for grants and the decreased monetary resources available;

• Easing the tight turnaround time and rushed proposal preparation for federal grants;

• Increasing discretion regarding how you spend the funding subsidies;

• Providing an opportunity to leverage the money you already have to get more;

• Getting grants from funders who tend to support only those projects that already have monetary support from other sources; and

• Developing a well-rounded budget that covers all your project components.

How it works: A strategic funding plan involves using “budget buckets,” matching pieces of your project’s financial needs to the appropriate type of funder. You should include several different types of funders in your plan. These include:

• Federal agencies that support research centers and universities -- NIH, NSF, Department of Health
and Human Services (HHS), Department of Treasury, Department of Energy (DOE), Department of Housing and Urban Development (HUD), Department of Transportation (DOT), etc.;

- **State agencies** that use departmental programs funded through the state or via pass-through funding from federal agencies;

- **Private or non-profit foundations** on the national or local level -- WK Kellogg Foundation, Robert Wood Johnson Foundation, Gerber Foundation, WT Grant Foundation, etc.;

- **Corporations** through corporate foundations or corporate giving programs -- Qwest Foundation, Meijer Foundation, Bayer giving program, etc.; and

- **Individual donors** who might support your project.

**Match the Right Funder to Each ‘Budget Bucket’**

The next step is to find the appropriate type of funder for each piece of your project budget, or “budget bucket.” Most research-project budgets have research expenses, F&A, capital/facility costs, and so on. You need to identify what resources you need to do the research work. What are the sources of funds needed?

And some federal granting agencies, for example, won’t usually cover general operating expenses as F&A. Therefore, you need to find the right type of funder for this budget bucket. You can match up the kind of funder to each budget category:

**Research Expenses**
- Federal agencies
- Private foundations
- Corporate giving programs

**Capital/Facility Costs**
- Federal agencies
• State agencies

**Program Support**
• State agencies
• Private foundations

**General Operating Support / F&A**
• Corporate foundations
• Corporate giving programs
• Private foundations
• Sponsorships

**Discretionary Funds**
• Corporate foundations
• Corporate giving programs
• Sponsorships

**Revenue-Generating Opportunities**
• Small business loans
• Program revenues

*Example:* Say your total project budget is $200,000. You can break down your budget in this way:

• **Research expenses:** 50 percent or more ($100,000+) from federal granting agencies -- federal grants typically cover the research team’s salaries and fringe benefits.

• **Capital/Facilities Costs:** 20 to 25 percent ($40,000 to $50,000) from federal and state agencies – your institution will calculate these costs.

• **F&A:** 10 percent ($20,000) from private or corporate entities – your institution will calculate these costs. Although federal agencies will usually fund F&A, they often don’t fund at the rate you would like and
sometimes won’t reimburse other costs associated with your general operating expenses that don’t fall into the F&A category.

- **Supplies:** 10 to 20 percent – varies depending on your specific project. Your supply budget might be $15,000 to $20,000 per person working on the project, and then anything extra.

### Strategies to Get the Funding You Need

As a new or early PI, you probably have several problems in getting those big grants. If you’re like most of your colleagues, you might not have the track record that funders would prefer to see. Maybe you’re working for a private research center and are ineligible for many federal or state grants. Whatever the case, you can try other options for funding your research.

**Private Funding:** First, look at any existing relationships that your institution has with private foundations. You can usually get a list of these foundations from your institution’s coordinating office for sponsorships, grants and funding. Search this list for private foundations that supported projects similar to yours, had a good relationship with your institution and will likely be receptive to funding a project again.

**Corporate Support:** Corporate funding has several distinct advantages -- first, corporations require little grant administration, and second, they have few restrictions on how you spend the money. But you will likely need to provide corporate funders with proof of how you’re using their money and recognition of the corporation’s role in your project.

When you’re targeting corporations for funding to support your research project, keep in mind that they’re looking for strategic philanthropy, marketing and promotional benefits, and increased brand awareness and recognition. Corporations usually limit funding to just 5 percent of their assets, but projects that may create marketing opportunities leading to revenue generation will entice corporations to spend more money based on an expanded marketing budget.

**Sponsorships:** Private organizations tend to look for true “sponsorship” opportunities, in which the funder receives recognition benefits and an opportunity to promote their brand in exchange for their funding support.
Private funders want to know their ROI for supporting your project, often calculated using the number of “impressions,” meaning the number of people who see the corporation’s name. So, if possible, offer:

- An estimate of the population reached by marketing;
- The number of constituents or colleagues who will see the company’s name; and/or
- The number of readers who might see research materials printed with the corporation’s name.

**Educational Opportunities:** In addition to sponsorships and grants, you might explore education as another avenue to find funding sources. An educational grant might provide additional funds for your research if you’re incorporating instructional materials or sessions with participants.

**Other Stakeholders:** Other stakeholders can be any group that could potentially benefit from your project.

**Find Funders & Get Their Interest in Your Project**

After you’ve checked with your own institution to find funders that support similar projects, you can expand your search by thinking about the funders’ motives and interests. Ask:

- What does the organization want?
- Can the stakeholder benefit in some way from funding my project?
- What can I offer to spark interest in supporting my project?
- Does my research include marketing opportunities?

You need to design a “win-win” situation for the stakeholder and your research. This means that the funders will get the benefit of reaching their potential client base in some way, thus boosting their brand recognition and marketing reach. Look for stakeholders who:

- **Have a client base that’s similar to the demographic of your research participants.** *Example:* The stakeholder pays for your printing costs if you print the organization’s name on the consent forms, research protocols or educational materials.

- **Want to reach your constituents or colleagues.** *Example:* Place the funder’s name on a plaque mounted at your lab or institution, particularly if the sponsorship funds support building a facility.
Another critical step is to start planning very early. Early planning can help you develop well-targeted, successful proposals. At the same time, proper planning and preparation enable you to identify and jump on opportunities for leveraging funding.

Even if your research project is only in its infancy, you can still begin to identify potential stakeholders and other funders, and even work out a rough budget. You’ll need to get your action plan in place early, especially if you want to leverage funding to get more support because timing your proposals is critical. When you’re using a long-term strategic funding plan, you can start out even several years in advance of your future project.

**Leverage Existing Funding to Attract ‘Bandwagon’ Funders**

“Bandwagon” funders are typically private foundations that are reluctant to support research that doesn’t already have significant support from other sources. These funders often don’t have the resources to investigate applicants or their organizations, and instead base their funding decisions on whether other funders are supporting the project or have supported it in the past.

Bandwagon funders have similar desires as agencies that offer awards from matching or challenge grants, which may, for example, want to see that you’ve met the capital campaign goals the foundation establishes before awarding funds. To attract these bandwagon funders, you need to follow specific steps:

1. **Plan your timing** -- Know what opportunities are coming up before the bandwagon funders are accepting proposals. You’ll need to win those other grants before you can point out the awards in the proposals for bandwagon funders.

2. **Highlight your wins** -- Advertise the grants you’ve won for your project in your proposal for the bandwagon funder.

3. **Tell about in-kind support and donations** -- Donations of materials or services needed for your research is important to highlight as well, because many bandwagon funders will see these as further evidence that your project is a viable investment.
Keep your funders engaged and involved in your research to encourage their continuing and future support. Share your project’s progress, results and developments as often as possible:

- **Invite them to events** - Even if you think that representatives from the funding organization won’t come to your events, send the invitation anyway to give them the opportunity to actually see what impact their support has made.

- **Send updates** - Send your funders detailed updates on your research project’s development and accomplishments, explaining the findings and any implementation efforts.

- **Add them to your mailing list** - Add your funders to your institution’s newsletter mailing list, providing them with the opportunity to learn about not only your project, but also the other activities at your organization.

- **Say “thank you”** - A simple “thank you” can go a long way, so don’t forget to thank your funders for their support to let them know you appreciate their role in making your project possible.

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**Develop a ‘Funding Database’ to Increase Your Success**

Although a “funding database” seems like a monstrous undertaking, it really isn’t. You can simply maintain a list of grant opportunities in a single file -- such as an Excel spreadsheet, not necessarily complicated software. Your basic goal is to capture and arrange all the information that you gather on funding opportunities in one easily accessible place.

As you’re researching funding opportunities, gather the following information into a single file or database:
• Grant name
• Grant agency, foundation or organization;
• Award amount;
• Proposal deadline;
• Grant purpose (from your budget buckets and the grantor’s guidelines);
• Eligibility criteria (including eligibility restrictions or exclusions);
• Web site link(s) to more information; and
• Links to “living” shared documents, such as requests for proposals (RFPs) and proposal pieces.

Create a separate row or column for each prospective grant, matching up the cells so you can easily compare the data for different grants. Use a consistent format and file location so your other team members can access and understand it.

Your funding database will allow you to keep track of upcoming grant proposal deadlines, compare and prioritize various grant programs and funding opportunities, and anticipate late-breaking RFPs from federal agencies. The funding database will also make developing a support-leverage plan much easier, because you can organize the deadlines for various private foundation grant proposals.

The database will give you extra lead time for RFPs and make putting together grant proposals quicker and easier. For instance, many federal agencies release their RFPs just three or four weeks before the proposal deadline. But if you know a particular grant has a proposal deadline around late November each year, you can include this information in your database and get started on your proposal much earlier than your fellow grant competitors.

**Don’t Submit a ‘Standard Proposal’**

No matter how much preparation and planning you’ve invested in your strategic funding plan, you’ll blow the entire thing if you think you can submit a “standard proposal” to all the potential funders. There’s really no such thing as a one-size-fits-all funding proposal, and submitting a standard proposal to a wide variety of funders can be a “rookie” mistake.
If you’re diversifying your funding sources, each will have different interests, requirements and proposal formats. So you should tailor your appeal to meet the prospect’s interests. Although you can work from a standardized source document, you must revise your proposal to fit the funding organization. To minimize the effort and time this will take:

- **Look at your budget buckets to tailor your proposal.** Select groups of expenses that are related and fit into a specific funder’s interests.

- **Identify the stakeholders that are right for each part of your project’s budget.** Then, target your proposal to focus on the win-win situation, in which you’re giving the funder what it wants and you’re getting what you need.

- **Cast a smaller but better-targeted net.** Many novice grant writers and PIs think if they cast a wide enough net, they are guaranteed funding. Unfortunately, this strategy typically results in wasted time and frustration. Instead, apply only for funding that fits your project exactly.

**Use These Resources for Funding Success**

If your go-to resource for research funding is grants.gov, you need to diversify your web searches to find all the other valuable funding opportunities. With the resources listed below, you can find everything from private and corporate foundations to local, state and federal government agencies.

- **Foundation Center:** [http://foundationcenter.org](http://foundationcenter.org)

  Foundation Center is an excellent search engine to find private foundation grants. The site publishes information about the foundations, including how much they fund each year, what types of projects they support and examples of past awardees.

- **Foundation Search:** [http://www.foundationsearch.com](http://www.foundationsearch.com)

  A Canadian company that covers funding opportunities throughout North America, Foundation Search
offers information on private funding programs, as well as information on foundation grants. A membership fee applies.


  Grant Spy is a search engine focusing on grant programs, rather than foundations. You can get a basic subscription for federal and foundation grants information for $19.50 per month, and state grant information for an additional $6.99.

- **NCURA:** [http://www.ncura.edu/content](http://www.ncura.edu/content)

  You can get a click-through list of many different funders at the National Council of University Research Administrators’ (NCURA’s) website. NCURA’s links range from federal agencies to small business innovation research (SBIR) websites to nonprofit research administration organizations.

- **SPIN -- InfoEd International:** [http://www1.infoed.org](http://www1.infoed.org)

  InfoEd International’s Sponsored Programs Information Network (SPIN) is a funding database search engine that aggregates data from thousands of government, private and nonprofit funding sources worldwide. SPIN even has a proposal development module that generates a template for a specific funding opportunity, with all the pertinent sponsor and program details. A fee applies.

- **SRA International:** [http://www.srainternational.org](http://www.srainternational.org)

  The Society of Research Administrators (SRA) International offers a list of click-through links on its Grants Web directory for all funding available through local, state, federal and international government agencies.
SECTION 5: The Do’s & Don’ts of Research Collaboration

As a new PI, you may find yourself collaborating on your first few research projects. Sometimes, obtaining grant funding is difficult when you’re relying on just your own credentials. Whether you team up with a more senior colleague or even a foreign investigator, the way you handle the collaborative relationship can make or break your project.

Collaborating with a colleague on a research project has many distinct benefits, as well as some pitfalls. If you’re considering collaborating on a project, you should weigh these advantages against the potential drawbacks.

Pros:

• **You’ll have access to another scientific mind.** A strong, effective collaborator will bring unique, insightful perspectives on shaping experiments, interpreting data and validating or challenging your more provocative ideas. Each PI can bring unique skill sets based on their experience or area of expertise, sparking creativity and adding new aspects to your research, says Caroline J. Harrison, program manager of CareerWISE at Arizona State University.

• **Your project can better attack multiple scientific approaches.** A collaborator broadens your technical arsenal, enabling you to try multiple approaches simultaneously and quicken the pace of discovery. And when you’re finished, that multi-pronged approach will result in discoveries with a higher impact than those with a single approach.

• **Reviewers will be more excited about your proposed project.** As an early-stage investigator, reviewers will be more apt to fund your project if you’re collaborating with a more senior PI or a more established lab.

• **You can expand your knowledge base and grow as a scholar.** Working with a more senior PI gives you the unique advantage of having a type of mentoring relationship while you collaborate on the research
Cons:

- **You’ll have to surrender at least some control.** When you’re collaborating with a co-investigator, you’ll naturally have to relinquish some control over the project’s scientific direction. In a full collaboration, each co-PI will have a say in the direction, purpose and methods of the work. You’ll also need to agree on the allocation of resources, among other important decisions.

- **You need to trust your collaborator completely.** For a true partnership, you need to not only have confidence in your own personal goals, but also have confidence in your collaborator. You must get to know your partner’s strengths and weaknesses, and understand what’s inside or outside his comfort zone.

- **You’ll have to work out the balance of power.** If you’re a junior investigator working with a more senior PI, the natural tendency is to develop a rather unequal power relationship, with the more experienced collaborator taking the helm. But if you allow this unequal power distribution, you may end up in a subservient or supportive role, which can hurt your future funding, promotion and tenure.

**Create a Memorandum of Understanding to Settle Issues**

To minimize these potential issues and reduce the chances for conflict or hiccups throughout the project, you can address these issues up-front with your partner. You might create a memorandum of understanding (MOU), in which you and your collaborator would address these concerns together.

An MOU can help greatly when you’re planning to submit a multiple-PI proposal, because you’ll likely need to offer up a Leadership Plan as part of your application. An MOU should address the different PIs’ roles and responsibilities and how you’ll resolve any disputes. The MOU should also set out a consensus on your research project’s:

- **Scope.** You must have a general agreement about the nature of the scientific problem that you’re trying to solve, as well as the types of approaches best-suited for your project. You should agree on how you’ll
handle disputes about direction and which labs are responsible for which areas.

- **PI responsibilities and authority.** Who has final authority? Decide whether your project will have one PI with other collaborators or two co-PIs. Address authorship issues like sequence as well to avoid misunderstandings later on.

- **Resources and personnel.** Decide how you will utilize resources, handle supervision of staff, and any indirect cost return considerations if you and your collaborator are in different departments. If you’re seeking multiple grants to support your project, decide how you’ll allocate funds for supplies and equipment, as well as salaries and other expenses.

- **IP rights.** Plan how you’ll allocate potential downstream income and revenue, if your work is truly novel and has beneficial IP aspects for your institution.

- **Communication methods.** Are you planning to work with a collaborator in your same institution or elsewhere? Collaborators who are close by are easier to work with, having frequent face-to-face communication. But when you’re working with scientists far away, you need to establish and schedule regular communication methods.

## How to Craft a Leadership Plan for a Multi-PI Proposal

If you’re planning a multiple-PI project, you’ll need to follow the rules for submitting this type of proposal. Proposals involving multiple PIs must include a Leadership Plan, which will impact your priority score. The mandatory components of your Leadership Plan are:

- **Rationale and justification** for having more than one PI;
- Administrative and scientific **responsibilities for each PI**, including which investigator is responsible for each Specific Aim and who will be the primary contact;
- The team’s governance and **organizational structure**;
- **Conflict-resolution** procedures;
- **Policies** for data sharing, communication, IP and publication;
You can simplify the way you address each of these points by taking the following four steps to develop a successful Leadership Plan:

1. **Determine your project’s major goals.** After you decide on the project’s major objectives, divide up the PI responsibilities based on backgrounds, experience and skills, advises Robert Frey, principal of Successful Proposal Strategies, LLC.

2. **Decide on your management approach.** You must have a comprehensive management approach that includes the project’s organizational framework. This framework must include the topic and scope, the length and extent of subjects that you’ll study, techniques and procedures, and tools and processes to monitor and control costs.

3. **Define each PI’s roles and responsibilities.** Clearly identify each PI’s roles and responsibilities, and use the information in each PI’s Biosketch or resume to support his assigned role. You’ll also need to include each PI’s:
   - Applicable leadership and programmatic experience;
   - Number of employees/students managed;
   - Number, size, scope and complexity of grants managed; and
   - Grant-making organizations worked with.

4. **Decide on the communications plan.** A well-defined communications plan is crucial to your Leadership Plan, Harrison says. You will need to show that the PIs will continuously monitor, refine and modify every phase of the proposed project. Your communications plan must cover personnel, costs, individual tasks, work plans, and communications interfaces with the grant-making organization (e.g., group meetings, in-person contact, telecommunications or web conferences, etc.).
Build Respect, Trust to Work with Foreign Colleagues

If you’re thinking about pitching your research idea to foreign colleagues, your initial approach could either get them on-board immediately or scare them away. You can’t be too direct and ambush foreign colleagues with your “big plans.” Your foreign colleagues may interpret your “big plans”, what you may see as confidence and enthusiasm, as arrogance.

In many foreign countries, your enthusiasm may not always be well-received, says Kevin Leyden, PhD, director of West Virginia University’s Institute for Public Affairs. You may come across as too bold or overbearing, which could scare away potential foreign co-investigators.

Also, foreign collaborators will sometimes think, “The U.S. research is using us and what do we get in return?” Often you need to win over the government more so than the collaborator.

**Best bet:** Build trust and rapport with foreign co-investigators, especially those in developing countries, and take a gentler approach, advises James Kazura, MD, director of the Center for Global Health and Diseases, and professor of international health, medicine and pathology, at Cleveland’s Case Western Reserve University.

Show deference to your foreign colleagues, and really listen to their ideas. Also, show respect for their customs and environment, Kazura stresses. When you take a more subtle approach, foreign colleagues are more likely to trust you and become interested in collaborating with you.

After you have colleagues on-board to work with you on an international research project, how you proceed and handle the collaborative work can also make a big impact on your project’s success. Here are some tips on working with collaborators in foreign countries:

- **Iron out IP issues.** Your institution will ask:
  - Will the subawardee receive unpublished proprietary information from you? Confidentiality agreement / possible export-control issues
  - Will the subawardee receive materials from you like samples or biological materials? Material transfer agreement / potential export-control issues
Does the project involve a technology that you invented? Affect IP clause in subaward agreement -- must address potential improvements to existing invention

- **Perform a Financial Risk Assessment.** Ask:
  - Does the foreign institution have prior experience and success in managing sponsored projects? Identify the institution’s strengths, weaknesses and potential problem areas.
  - Does the institution have adequate administrative and fiscal structures, including policies, procedures and staffing? Address risk issues through subaward terms and conditions, training, and/or closely monitoring work.
  - Can the institution meet federal requirements for grant management?

- **Plan and budget for face-to-face meetings.** Although videoconferencing and the many other technological communication wonders are helpful, don’t dispel the importance of face-to-face meetings. Set aside some grant money to have at least one in-person visit with your foreign colleagues. Not only are face-to-face meetings respectful, they’re also crucial to your success, Kazura says.

  Additionally, if you’re going to visit your foreign colleague, be respectful of your host’s schedule. Don’t expect him to drop everything for your visit. Instead, try to arrange your arrival at a time that’s most convenient for your host.

- **Beware of paperwork overload.** American legal documents are simply lost in translation in many countries, so try to minimize the paperwork. Have any extensive legal forms carefully translated, and initiate discussions with your foreign colleagues to answer their questions on what they didn’t understand due to the translation.

  Also, you may be able to eliminate some documents altogether. For example, you might obtain a waiver for the Health Insurance Portability and Accountability Act (HIPAA) forms if your potential subjects in the foreign country are illiterate.

- **Respect your foreign colleague’s customs regarding time, scheduling and deadlines.** Punctuality
and deadlines aren’t as important in some cultures as they are in the United States. For example, in Europe quality and accuracy are typically considered far more important than meeting a deadline, Leyden says. And in some cultures, showing up an hour or more late for a meeting isn’t a big deal.

**Solutions:** Set aside several hours for every meeting with foreign colleagues, particularly during the project’s planning stage, Leyden advises. Also, be very flexible when scheduling phone conferences with your foreign colleagues, and try to conform to their time zone. Time-zone differences may require you to hold meetings outside of normal business hours, such as late in the evening.

- **Don’t underestimate the importance of a local support team.** Building a “support team” in the foreign location not only helps you to accomplish the work vital to your research project, but it also helps to support your foreign co-investigator and encourages trust among the local residents.

  **Example:** Kazura conducted a study in Papua New Guinea on combating the parasitic disease elephantiasis. He needed to collect blood samples between 10:00 pm and midnight, due to the parasite’s nature. To collect the samples, he enlisted the help of local colleagues and public health workers to hold public meetings to explain the mission and carry out the important work.

**How to Manage Subcontracts & Foreign Subawards**

When you’re working with a foreign collaborator on an NIH-funded project, your off-site collaborator must operate as a subcontract to your grant. Sending your hard-earned grant money overseas can seem daunting, if not scary. But six preparatory measures will take the fear out of the subaward process.

1. **Prepare to provide up-front funding:** If your subawardee is from a resource-poor or developing country, you’ll likely need to provide some immediate funding to get started. “You’ll have to use your institutional funds to start the program on the foreign side,” says **Mike Blackwell**, subcontract manager in the University of Washington at Seattle’s Office of Sponsored Programs. Because this type of subawardee won’t be able to start the project without cash in-hand, you’ll need to find out whether your institution is willing to front the money, which is usually unlikely.
In some cases, you may need sponsor approval to make advance payments to the subawardee. There are, of course, risks to you and your institution. So to manage risks, you’ll want to ensure that you have invoice reconciliation of advance payments and provisions that you can take from future payments any disallowances. You’ll need to hold back a percentage of the final payment to ensure receipt of technical reports and financial reconciliation.

2. **Develop a strong personal relationship with the foreign PI.** You need to build strong connections to key stakeholders in the subawardee’s locale. You also must understand the people -- and the institution -- you’re collaborating with, says **Stephanie Endy**, director of the Office of Research and Sponsored Programs at Lehman College, City University of New York.

You need to develop this relationship before you get all parties at the table to discuss how you’ll allocate the project’s responsibilities. Try to spend at least a month overseas, especially if your subawardee is in a developing country, to build the necessary relationships and get the local people on-board. Develop a good government relationship, too – this is sometimes even more important than building the personal relationship.

3. **Build in extra time for additional bureaucracy.** When you’re dealing with projects that involve foreign subawards, you have extra levels of approval and red tape. For instance, NIH and NSF need State Department approval on your proposal when it includes foreign components. The State Department might then need to get approval from the foreign country’s embassy, all of which takes time -- usually several months. Other considerations include:
   - Obtaining a DUNS number and registering in the Central Contractor Registry for the foreign institution;
   - Researching and complying with the local laws regarding human or animal subjects; and
   - Applying for any necessary export control licenses.

4. **Circumvent dealing with currency issues.** Instead of trying to manage currency fluctuations -- which is extremely time-consuming -- ensure that your institution will write all foreign subawards and make all payments in U.S. dollars. Make payments via wire transfers for security, and then let the subawardee deal with conversions on his local currency.

5. **Solve language and cultural issues.** Language issues can range from having a “governing
language” for your contracts with foreign institutions (this should be U.S. English) to overcoming day-to-day language barriers when communicating with your overseas partners. Also, spend some time talking with your foreign subawardee about his country’s customs and culture to solidify your relationship and prevent any culturally-instigated project hiccups.

**Your Role as PI**

You have an important and varied role as PI when you’re working with foreign subawards. Your programmatic responsibilities involve the scope of work, compliance, approvals, performance risk assessment, progress monitoring and training. Here’s how to tackle the many elements of your role.

**Scope of Work:** The scope that you communicate to the subrecipient should focus on the subrecipient’s obligations, instead of the entire project’s general description, says Janet Simons, director of research policy at the University of Maryland, Baltimore. Include in the scope of work the specific aims, milestones, timelines and methods for the subawardee, as well as the technical and project reporting requirements. Ensure that the subawardee’s scope of work is consistent with the grant obligations.

**Compliance & Approvals:** As the PI, you must shepherd all compliance issues relating to your subawardee:

- **Human subjects** - If you have federal funding, foreign organizations engaged in human research must comply with U.S. regulations, and the subawardee must meet the minimum federal requirements and your IRB’s standards.

- **Animals** - Foreign organizations under federally-funded subawards must comply with U.S. regulations or have regulations at least as stringent as U.S. regulations. Your IACUC should review the subawardee’s regulations to ensure that they’re sufficient.

**Performance Risk Assessment:** For “higher-risk” (less-experienced) subawardees, you’ll need to provide a more detailed scope of work, more training and more frequent progress reporting requirements. You may need to restrict payments based on the completion of milestones or deliverables, and perform regular site visits and otherwise more closely monitor progress.
Progress Monitoring: You can monitor your subawardee’s progress informally or formally, or a combination of both. You can conduct informal monitoring through regular phone conversations, video conferencing and e-mails. Formal monitoring is a little more intensive and may include site visits and written progress reports.

Beware of 5 Pitfalls in Subcontracting

Whether you’re subcontracting with a foreign subawardee or someone in the United States, there are a variety of potential problems that can arise. Using subcontracts on federal grants can spark many problems even for the most seasoned PI, but you can avoid them by knowing the five most common mistakes that PIs make and how you can avoid them.

1. Failing to review protocols. Make sure that your subcontractor meets your required protocol approvals.

2. Hiring a subcontractor unfamiliar with cost accounting. Determine whether your subcontractor can handle his own expense reimbursement. Allowable expense determinations under a federal research grant is complicated, to say the least. Don’t issue a cost-redistribution contract to any subcontractor who doesn’t have a sophisticated enough accounting process. If your subcontractor has only basic accounting methods, offer a straight time and materials contract, and let the subcontractor determine how to pay for the extras.

3. Working with a subcontractor you don’t know. Ideally, you should work with subcontractors you already know and have a good reputation in their field, advises Marie Smith, grants administrator/compliance officer at the Cary Institute of Ecosystem Studies. Ultimately, you are responsible for the subcontractor’s research because it’s your proposal. So, make sure you trust the individual.

4. Misunderstanding whether you can keep the equipment. Know your rights on whether you can keep any equipment purchased under a subcontract. In general, private and for-profit entities can’t keep federally-funded equipment, but universities and non-profits can -- so always double-check.

5. Failing to work out distribution of royalties. To avoid potential conflicts between you and the
other PIs, draw up an agreement before the work begins for how you’ll distribute the royalties stemming from the research. You should work out a deal in which PIs completing equal work end up with equal shares of the royalties.

**Discover Your Institution’s Fee-for-Service Offerings**

Many universities offer certain services to PIs known as “fee-for-service.” These services can save you money and make it easier to access needed tools to get your research on the right track. Some universities offer some of these types of services for free, while others will charge a per-hour fee. Depending on what resources your institution has, fee-for-service offerings may include:

- **Administrative support** – Most institutions offers some type of grants administration or management services through a centralized office. Many offer assistance with grant account management, financial support and reporting requirements.

- **Data collection support** – Find out if your university offers help with set-up and maintenance for research data, clinical support and biomedical informatics. Some institutions also offer custom programming support to develop advanced database systems.

- **Clinical research resources** – Your institution may offer assessments, monitoring and other types of support for certain clinical research studies.

- **Man- and Woman-power** – At some institutions, fee-for-service offerings include a study coordinator pool or similar research staffing support. Experienced research staff may be available to help with start-up, implementation and close-out of research studies.

- **Clinical trials facilitation** – Another offering at some institutions is support and expertise for PIs who are conducting clinical trials. Services may include protocol development, assistance with IRB processes and advice on regulatory concerns.

- **Data safety monitoring** – Look into your institution’s services involving data safety and security,
whether within the IT department or in a separate fee-for-service office.

❖ **Space and equipment** — Among the most common fee-for-service offerings are desk, office and lab space, as well as the use of equipment.
CHAPTER III:
Compliance Issues You Can’t Ignore

From research misconduct to lab animal regulations to lab safety, you as the PI have a myriad of compliance issues that you’re responsible for addressing. Staying compliant with all the rules, regulations and laws -- from grantors’ requirements to federal mandates -- is crucial to staying out of hot water.

You’re probably well aware of the potential consequences of noncompliance, ranging from losing grant funding to civil penalties or even criminal charges that could lead to incarceration. You have some heavy responsibility on your shoulders, to say the least.

In this section, you will learn about your role in the following compliance areas:

- Research misconduct;
- Ethics training;
- Lab animal care and use;
- Human subjects;
- Financial conflicts of interest;
- Natural disasters and other lab crises.
SECTION 1:
Research Misconduct: What’s Your Role as PI?

Although many institutions have certain offices that handle training in the Responsible Conduct of Research (RCR), you as the PI are responsible for your lab’s compliance with these mandates. Both the NSF and NIH expect you to have a plan in place to provide and monitor RCR training.

Ever-increasing public scrutiny of RCR issues, combined with the mandates in the America COMPETES Act, has ratcheted up expectations for ethical research conduct. Therefore, planning for and ensuring that your trainees, students and post-docs receive the RCR training they need -- and that’s required by the federal granting agencies -- is more important than ever.

What is Research Misconduct?

The NSF defines research misconduct as:

- **Fabrication** (making up data or results and recording or reporting them);

- **Falsification** (manipulating research materials, equipment or processes, or changing or omitting data so that research is not accurately represented); and

- **Plagiarism** (appropriating another person’s words, ideas, processes and results without giving credit).

The punishment for research misconduct is potentially severe -- you could face career-ending civil or criminal charges, or both.

Although the NSF is a bit vague about your role as the PI in RCR training, the NIH is a bit more specific. NIH expects grantee institutions to provide proof of RCR training and increase faculty involvement in both formal and informal RCR instruction.
Your institution must have a plan in place, or the NIH won’t accept your proposal. You must submit your form stating that you’ve had the training when you apply for a grant. The NIH requires that you:

- Conduct RCR instruction face-to-face, with some supplemental online instruction allowed;
- Provide at least eight hours of RCR instruction at each career stage, or at least once every four years;
- Utilize faculty in both formal and informal RCR training as speakers, course directors and leaders; and
- Include a plan in your grant application for RCR training.

How to Create Effective RCR Training

Combine formal and informal instruction for the most impactful kind of RCR training, advises Wendy Reed Williams, PhD, Director at the Office of Responsible Research Training and Postdoctoral Affairs, The Children’s Hospital of Philadelphia. Informal instruction is unstructured learning about RCR that occurs in the lab every day. Informal training can also occur during clinical or behavioral research, in scientific groups, and during interactions with colleagues and mentors throughout the research training period.

**Best practice:** Try to incorporate RCR training into your daily practices -- ideally, creating a lab environment that promotes integrity, openness, honesty and communication. To carry out effective informal education, you can:

- Make yourself available and accessible to discuss RCR topics with your trainees;
- Provide daily guidance and listen to concerns;
- Weave RCR topics into discussions in the lab and in your lab meetings;
- Require trainees to attend RCR training, and monitor and track their attendance;
• Understand your funding agency’s specific RCR education requirements; and

• Stay current on RCR issues.

Formal training occurs a little differently, typically in a systematic and structured format. Formal RCR instruction should address the NIH’s specific guidelines for the instructional components, such as format, subject matter and faculty participation. You can perform this type of RCR training via seminars and lectures, workshops, case studies, and even small group discussions, Dr. Williams says.

Because granting agencies see both the PI and the institution as responsible for formal RCR training, you must ensure that not only you are doing your required part, but also that your institution can show its part in the training plan as well. Your institution must:

❖ **Show commitment** -- your institution can mandate RCR training for all junior faculty and other trainees; and

❖ **Commit resources** -- your institution can establish a centralized RCR training office, or appoint an individual trainer, team of trainers, faculty member or senior fellow, or member of administration who’s in charge of coordinating training.

What’s your role as the PI in providing formal RCR training? The NSF and NIH say that you should:

✔ Encourage your institution’s administration to support related education and RCR course development;

✔ Ensure that your institution has an RCR policy and training plan in place -- if not, draft them yourself or recruit colleagues to help you draft them;

✔ Involve yourself in the design and evaluation of an existing RCR course, or if your institution doesn’t have one, create one and sign on as the course director;
Act as an expert on RCR topics;

Volunteer to lead a discussion or give a seminar on an RCR topic;

Ensure that you have a formal ombudsperson procedure in place; and

Act as a cheerleader for RCR training at your institution.

How to Design RCR Training: Planning & Preparation

Developing an RCR course or training module takes more planning and preparation than anything else. But keep in mind that if you’re asked to participate in developing RCR courses, this is a huge boost for your career as an early investigator. Take the opportunity to show your initiative, motivation and commitment to ethical research practices.

While you’re in the planning phase, you must address the following key factors:

- What’s my timeline, and are there any milestones I need to meet?
- Who among the faculty or administration can help me with planning?
- What are the challenges I might encounter?
- What resources and content already exist that I could use? (Hint: Visit the NIH’s Office of Research Integrity website [http://ori.hhs.gov](http://ori.hhs.gov) to get RCR materials and course content)
- What’s my budget?
- How often will we offer this course?
- Who will teach the course?
- Will we make the course required or optional?

While you’re pondering these key questions, you must also define the major components of your RCR training. These include the scope, outcome, format, time, commitment, accessibility, technology, audience and goals.
Scope: You’ll need to determine what RCR topic or topics the course will cover. Because you can’t try to squeeze all the training into one course, you can choose one or two RCR topics.

RCR Topics

- Data management acquisition and sharing
- Research misconduct policy
- Use of human subjects
- Peer review
- Conflict of interest
- Animal care and use
- Collaborative science
- Responsible authorship
- Lab safety
- Publication practices
- Mentor/trainee responsibilities
- Ethical issues in biomedical research
- Environmental and societal impacts of research
- Intellectual property
- Scientist as a responsible member of society

Outcome: Craft a desired outcome statement or identify a measurable objective that specifies what the participants will learn from your course.

Format: What format is best for your institution? Should you conduct a semester-long course, a workshop or symposia, or a credited or certification-linked course?

Time: What time of day is best to hold the course? Consider the general schedules of the people who would attend the course.
**Commitment:** What kind of time commitment will trainees need to make in order to attend the course? Think about the ways you can deliver large amounts of content in a short period of time.

**Accessibility:** Do you have a meeting place to hold your face-to-face course that’s reasonably accessible for everyone who would need to attend?

**Technology:** Consider an e-learning course or online module, or a combination of both a traditional in-person course and a technology-based class.

**Audience:** Who will attend your course? What are their preferred learning styles? You may have mostly graduate students, undergrads, physician fellows, post-docs or a mixture.

**Goals:** What are your goals for the course -- what learning objectives do you have? Your course objectives should focus on the participants’ knowledge absorption and participation or performance, as well as these RCR training goals:

- ✓ Meet institutional requirements;
- ✓ Introduce RCR topics;
- ✓ Facilitate and promote understanding of federal policies and guidelines; and
- ✓ Provide best practices and examples.

**How to Design RCR Training: Implementation & Evaluation**

Learning is one thing, but taking that knowledge and applying it to the real world -- putting new knowledge into practice -- is the ultimate goal of any educational course. Knowledge application should be your overarching goal for RCR training, because you want trainees to convert the information into behavior changes, outreach, networking and correct practices, Dr. Williams says.

There are countless options for different course formats and learning environments that you can employ for RCR training. Some effective strategies include:
- **Case studies** - Choose a simple RCR case (preferably a real-life one) and discuss it with your trainees, walking them through the case and encouraging them to use problem-solving skills.

- **Independent study** - Require your trainees to study journals, reports or other ethics-related materials as part of your RCR training.

- **Interactive studies** - You can try conducting panels with faculty members, or even using role-playing, simulation and games.

- **Roundtable discussions** - A group of faculty and trainees sit a table and discuss each topic for about 10 minutes.

- **Lectures** - Have faculty lead lectures either singularly or as a panel.

- **Ethics partners** - Pair up trainees as ethics buddies.

- **Diversified educational offerings** - Tailor RCR training for different audiences, such as PI training programs.

Whatever implementation strategy you choose, ensure that the learning environment is positive and upbeat. Keep the trainees engaged, and allow plenty of time for questions and audience participation, Dr. Williams recommends. Also, pass out an evaluation to gauge the participants’ reaction to the course. Finally, be sure to track attendance.

For your evaluation, review the course content and the feedback from the participants. Ask yourself what worked and what didn’t, whether you met the objectives, and how you can improve the RCR course.

**Integrate Informal RCR Training with Expert Strategies**

Ask your staff to give you all raw data, and then review it regularly, recommends Debra M. Parrish,
P.C., of Parrish Law Offices in Pittsburgh. Let your staff know that you’ve set high standards of integrity by checking their work. Doing so helps to ensure transparency in your lab.

Dr. Jean-Claude Bradley, an associate professor of chemistry at Drexel University in Philadelphia, is an advocate of “Open Notebook Science,” or the sharing of data on the Internet. Bradley believes that reporting data online is a “good protection against research misconduct because it becomes very difficult to fabricate data.”

When it comes to protecting against research misconduct, one of the best things you can do is to lead by example. You don’t want your staff to think that they should get specific lab results at all costs, leading some employees to fudge the data.

Ensure that you aren’t sending this message to your staff or creating a environment in which they feel pressured to get certain results. Likewise, don’t let the pressure to nab funding and to publish impact your team’s work. Even if the data contradicts your claims, present the complete story and validate all results.

**Best practice:** Talk openly about ethics in your lab and elsewhere. Discuss ethical research and any publicized cases of misconduct with your staff. Promote an open, honest discussion, and then answer your employees’ questions about RCR issues.
SECTION 2:
Lab Animals: Heed Expert Tips on Staying Compliant

If you work with animals in your lab, staying compliant with institutional and governmental regulations is crucial. Your go-to resource is the Guide for the Care and Use of Laboratory Animals, issued by NIH and updated by the National Research Council. The Council recently completed the latest update -- the 8th Edition of the Guide.

Your institution is responsible for training and ensuring compliance with the veterinarians, but you should still understand the basic principles. The Guide sets forth a variety of recommendations, principles and best-practices, such as the “three Rs:”

1. **Replacement** - finding possible non-animal models to replace the animal model in research. Examples of alternatives could include
   - isolated cell and nerve preparations,
   - use of tissues from a slaughterhouse or grocer, or
   - computer simulations based on in vivo data.

2. **Refinement** - refining methods to minimize pain and distress in lab animals. Examples of alternatives could include
   - proper use of anesthetics and analgesics,
   - modifications in restraint, handling and blood collection,
   - increased sensitivity of monitoring devices and chemical assays, or
   - proper training of personnel.

3. **Reduction** - reducing the number of lab animals used. Examples of alternatives could include
   - adopting a more appropriate statistical design,
   - sharing animals, tissues or organs, or
   - examining new methods in testing.

The *Guide* also provides a framework for humane care and use of lab animals and expects your lab to be fully compliant. Taking a proactive approach to compliance is the best strategy, and not only when you’re
preparing for an inspection by the USDA, Institutional Animal Care and Use Committee (IACUC) or the Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC).

Although your institution must provide the training itself, you as the PI must ensure that your staff is well-trained in proper lab animal care and use, according to Laura Gallaugher, DVM, Dipl. ACLAM, assistant professor of veterinary preventive medicine at The Ohio State University and clinical laboratory animal veterinarian with the University Laboratory Animal Resources (ULAR). Crucial training areas include:

- Humane methods of lab animal care and experimentation;
- Alternatives to limit the use of animals in labs or to minimize stress on lab animals;
- Proper use of anesthetics, tranquilizers and analgesics;
- Proper pre- and post-procedural care;
- Aseptic surgical methods and procedures; and
- Reporting deficiencies in lab animal care and treatment.

Note: Your institution may require additional training on:

- Survival surgery;
- Species-specific handling, care and restraint techniques; and
- Facility orientation.

Another key compliance measure is maintaining an animal care manual, either as a computer file, paper file or both, Gallaugher says. You must update your manual regularly and ensure that it contains copies of all current animal-use protocols and amendments, up-to-date institutional policies and procedures, and veterinary
contact information. Your animal care manual should also chronologue all training documentation for all your lab personnel, including both institutional and in-lab training, as well as handouts that you can use for future training sessions.

**Keep These Records to Protect Yourself Against Compliance Problems**

Demonstrating your animal-research project’s compliance relies heavily on the quality of your record-keeping. Your lab records should act as a clear, permanent journal of your staff’s work and thoughts, available to everyone in your lab and anyone else who requires the information -- particularly auditors or inspectors from the IACUC and USDA.

Serving as a staff reference and evidence to support your research objective, your lab records should provide proof that your use of animals, surgery, drugs and anesthetics comply with your approved protocol and are appropriate. Keep your lab’s permanent record as a bound research notebook that’s indexed, catalogued, legible and well-organized, and written in permanent ink.

You can also keep your lab records in electronic form, but you must still have the hard-copy written documentation, including any analytical data, graphs and charts. You should keep your lab notebook in a secure location but accessible to everyone involved in the research, including you as the PI, post-docs, grad and undergrad students, and techs. Everyone involved in the research should enter their daily notes into the notebook, as well as the electronic form if you have one.

Whenever a lab staff member makes an entry in the notebook, she must sign off on the page or notation. Cross out any incorrect item in the notebook -- don’t erase it.

**Goal:** Your lab record should be clear, concise, complete, up-to-date and verifiable at all times. Remember that this notebook is the first go-to record that inspectors and auditors will check when they arrive at your lab. You must keep the record at least until publication of your work or termination of the supporting grant. Your institution’s policies may require that you keep the notebook for a longer period of time, however.
How to Maintain Proper Animal Medical Records

In addition to your lab notebook, you must also keep animal medical records. Although your veterinary team is primarily responsible for keeping these records, you as the PI must often contribute. Animal medical records typically include:

- Clinical findings;
- Health evaluations;
- Surgical monitoring;
- Diagnostic results; and
- Administered treatments.

Your attending veterinarian may also want documentation of any experimentally-induced disease or breeding.

Animal medical records should also comply with the mandates of The American College of Laboratory Animal Medicine (ACLAM) and, if the animal species falls under the Animal Welfare Act, the USDA Animal and Plant Health Inspection Service’s (APHIS) Policy 3, “Animal Health Records.” The ACLAM recommends that you include in your animal medical records:

- Identification of animals or groups of animals;
- Results of physical exams;
- Animal behavior, abnormalities, illness or distress, discomfort or injuries;
- Immunizations and other prophylactic treatments;
- Diagnostic tests;
- Potential research interventions;
- Prescribed or provided treatments, including outcomes and follow-ups;
- Descriptions of surgical procedures, pre- and post-operative care, anesthesia, and analgesia, including drugs administered with dosage, route and times;
- Control of pain and distress with descriptions of responses and items used to alleviate pain, including pharmacologic and non-pharmacologic;
- Euthanasia or disposition, including outcomes and descriptions; and
- Necropsy documentation and findings as appropriate.
APHIS Policy 3 requires that you maintain records that at a minimum include:

✓ Identity of the animal(s);
✓ Descriptions of illnesses, injuries, distress and/or behavioral abnormalities, including the resolution of any noted problem;
✓ All medically-related observations, examinations, tests and other procedures, with dates, details and results; and
✓ Dates and details of all treatments, including the name, dose, route, frequency and duration of drug or medication treatments.

Heed Special Considerations for Documenting Justifiable Pain & Suffering

If you’re performing research involving animal subjects, you have two main governing entities to abide by: the USDA’s Animal Welfare Act (AWA), and the NIH’s Office of Laboratory Animal Welfare (OLAW). The AWA governs lab use of all warm-blooded animals except for rats, mice and birds bred for research. OLAW enforces the Public Health Service regulations, which cover all animals that don’t fall under the AWA.

According to a recent USDA seminar, if your research involves AWA-covered species of animals, you must prove to the IACUC that you:

➢ “Considered alternatives to procedures that cause more than momentary or slight pain or distress to the animals;

➢ “Provided a written narrative description of the methods and sources (e.g., the Animal Welfare Information Center), used to determine that alternatives were not available,” and provided “written assurance that the activities do not unnecessarily duplicate previous experiments;”

➢ Perform procedures using appropriate sedatives, analgesics or anesthetics, unless you can justify in writing that withholding such agents bears scientific reason and that such procedures “will continue for only the necessary period;” and
➢ Will not use any single animal “in more than one major operative procedure from which it is allowed to recover” unless you justify doing so for scientific reason in writing.

According to D’Anna Jensen, technical information specialist with the USDA’s National Agricultural Library, you can meet these requirements governing AWA-covered species by following these key steps:

1. **Address alternatives to any painful procedures.** Can you conduct your experiments using any viable kind of alternative to painful or distressing procedures? Also, keep in mind that even if you start out your project using such alternatives, and then need to include painful procedures as your experiment changes, you are no longer exempt from the AWA’s requirements.

2. **Search for duplicative research.** Conduct a database search to find any similar experiments already performed in the past. When you compose your narrative description, include the names of the databases you searched, the date you performed the search, the period that the search covered and the keywords and/or search strategy you used.

   While conducting database searches for duplicative experiments, you must:

   ✓ Check the terminology, sources, strategy and search dates;
   ✓ Review the search before completing the protocol;
   ✓ Evaluate the alternatives found via the database searches;
   ✓ Prepare your reasoning to support the use or non-use of any alternatives in writing; and
   ✓ Retain a copy of your search strategy, the databases you searched and the years searched for future use.

   Additionally, when you’re searching for alternatives, choose a database or source that is most relevant to your area of research, advises Mark Suckow, DVM, Dipl. ACLAM, director of the Freimann Life Science Center and associate research professor at the University of Notre Dame’s Department of Biological Sciences.
Suckow offers the following useful sources and databases for conducting your search:

- Biological Abstracts
- PUBMED
- TOXNET
- NORINA
- ECVAM
- ALTBIB (offered by the National Library of Medicine)
- Current Research Information Service (CRIS)
- Animal Welfare Information Center (AWIC)

When you conduct the search, select appropriate keywords that are descriptive of the methods or aspects of your research that may produce pain or distress in animal subjects, Suckow says. Couple these keywords with search terms like “non-animal,” “in vitro,” “culture,” “alternative,” “substitute,” “pain relief” or “simulation.”

3. Prove that none of the “three Rs” is available to you. Finally, after you’ve completed your due diligence you must prove to your IACUC that you cannot minimize the number of animals used (reduction), employ techniques that reduce pain and distress (refinement), and/or substitute animals with non-animal methods or lower organisms (replacement).

You’ve met the AWA’s informational requirements “when you’ve addressed whether your research is duplicative,” Jensen says. Only then will the IACUC approve your protocol.

**Focus on Reduction: Justify the Number of Animals in Your Protocol**

One challenge for animal studies is demonstrating “reduction,” in terms of determining the fewest number of animals needed for your protocol. Not only do you need to figure out the least number of animals necessary for your protocol, but you also need to present your reasoning to the IACUC. To accomplish both goals, experts recommend using certain popular methods and sources, such as statistical power analysis, pilot studies and your own experience or literature findings from similar studies.

*Statistical analysis:* Statistical analysis is the gold-standard for justifying study group size, says Kim
Stocking, DVM, Dipl. ACLAM, PI at the biotechnology firm Amgen in Seattle. If you have statistics to show that you can see statistically significant differences between certain study group sizes, then you have the key to getting IACUC approval. But your subject group size (the n number) could be too large or too small if your calculations aren’t precise.

Strategy: Try power analysis software programs, which contain analytical and graphical tools to help you determine reliable sample sizes. For guidance on power analysis, visit http://www.nal.usda.gov/awic/newsletters/v7n1/7n1chamo.htm.

Then, provide a clear, easy-to-understand explanation of how the statistical analysis supports the particular number of animals you need, advises Cynthia Pekow, DVM, Dipl. ACLAM, chief of the Veterinary Medical Unit at Veterans Affairs Puget Sound Health Care System near Seattle. Ideally, IACUC members prefer that you consult with a statistician as well, she notes.

Pilot studies: Provide the IACUC with the results of a pilot study, conducted perhaps under the supervision of the veterinarian, using a small number of animal subjects. Then, use the results and data from that pilot study to demonstrate to the IACUC what differences you might see between different-sized subject groups, justifying how many animals you really need, Pekow suggests.

Experience & literature: You may also use previous literature or experience in justifying the number of animals in your study. Show to the IACUC similar experiments or pertinent literature about studies that utilized the same or similar study-group sizes, and then show how the minimum number of animals in relation to these past studies provided statistical validity.

If you don’t know the exact proper number of animals for your project, tell the IACUC upfront and explain how you’ll find out the right number -- through a pilot study or other means, Pekow recommends.

Bottom line: No matter what method you use to justify the number of animals you’d like to use in your research, ensure that you write the protocol in layman’s terms. Remember - IACUC members aren’t all scientists or statisticians, so make sure that you present the protocol and reasoning in such a way that they can understand it.
Focus on Refinement: Stay Compliant with Changes in Guide’s 8th Edition

When OLAW updated the Guide for the first time in more than 14 years, many of the significant changes involved the “refinement” principle. The changes that garnered the most comments from scientists, institutions and organizations included those involving caging and housing, research use of non-pharmaceutical-grade chemicals and substances, food and fluid restriction guidelines, and limits on the number of survival surgeries performed on each animal. The changes are effective Jan. 1, 2012 (see Appendix D for a table of cage space recommendations).

Caging & Housing Changes: The Guide’s 8th Edition increases many of the recommended minimum cage sizes for lab rodents housed in groups, including mice, rats, hamsters and guinea pigs, as well as rabbits. (See Appendix D for tables of cage measurements.) The Guide also sets forth certain factors that you should consider when planning for adequate cage space:

- The animals’ ages, sexes and body weights;
- The number of animals in cohousing arrangements;
- The duration of accommodation;
- The animals’ intended use, such as breeding versus experimentation;
- Cage volume and its relation to spatial arrangement;
- Space allowance for species-specific postural expression and other behaviors;
- Clearance for cage structures (feeders, water containers, enrichment devices, litter boxes, etc.);
- All performance indices (health, reproduction, growth, behavior, activity and use of space); and
- Special needs (obese, hyperactive, arboreal animals, etc.).

Additionally, OLAW also provides the following considerations when planning cage space:

- Animals housed singly or in small groups may require more floor space;
- Cage dimensions should increase when you have various breeding configurations with multiple adults, multiple litters or litters with varying sizes and ages in a single housing unit;
- Juvenile rodents typically require a larger cage space than adults, to accommodate their higher activity level;
Juvenile rodents may require larger cage dimensions than indicated by their size or weight, in anticipation of their full growth and adult size; and

Larger groups can thrive in slightly higher-density housing, but not in cage spaces smaller than the minimum recommended dimensions.

**Non-Pharmaceutical-Grade Substances:** In the 8th Edition, OLAW now requires that you gain approval from your IACUC if you plan to use non-pharmaceutical-grade chemicals or substances. OLAW requires the IACUC to base its decisions on the substance’s: purity; grade; sterility; acid-base balance; stability; pyrogenicity; osmolality; site and route of administration; compatibility of components; adverse reactions and side effects; pharmacokinetics; and storage.

**Food & Fluid Restriction:** OLAW wants your IACUC to evaluate your methods of food and fluid restriction and/or use of preferred foods upon:

- The level of food/fluid restriction and its potential adverse consequences;
- How you assess the health and well-being of the animals involved in food/fluid restriction activities;
- Maintenance of hydration, body weight, and behavioral and clinical health; and
- Whether the animal is receiving its minimal daily requirements of food and fluid.

**Multiple Surgical Procedures:** You must prove to your IACUC that performing multiple procedures on a single animal is crucial to your research, despite the negative effects on the animal’s well-being. Specifically, to perform multiple major surgical procedures on a single animal, you must prove that the procedures are:

- Necessary for clinical reasons;
- Scientifically justified; or
- Included in and essential components of a single research project/proposal.
Stay in Communication with Your Attending Vet, PAM Contact

You and your lab staff should stay in regular contact with your attending veterinarian(s), particularly when you’re considering a protocol amendment, Gallaugher advises. Likewise, if your institution has a formal post-approval monitoring (PAM) program, contact the person(s) in charge and request a consultation. The PAM contact can identify any deficiencies in your lab, allowing you time to correct any problems before an official IACUC, AAALAC or USDA inspection.

PAMs are excellent tools to keep your lab compliant and prevent problems at inspection time. PAMs provide the IACUC with some assurance that PIs are in compliance with their protocols and that the protocols themselves are compliant, says Louisa Gay, PAM officer at Virginia Polytechnic Institute and State University.

Although the federal government doesn’t mandate PAMs, many institutions are now developing these programs. If your institution has a PAM program, a typical visit would include a walk-through of your lab facility so that the PAM officer can observe your procedures and activities, Gay notes. Then, the PAM officer will compare these observations with the actual protocol, the regulations, the SOPs and your records.

PAM programs give you some distinct advantages with the IACUC:

- Ensuring documentation compliance - Your PAM officer can help you to ensure that your documentation is in order, particularly the note-taking required to show compliance with your approved IACUC protocol. “There’s an old saying, ‘If it’s not written down, it didn’t happen,’” Gay points out. Whoever is responsible for note-taking -- often your grad students -- the officer can double-check that the notes are accurate and detailed.

- Advocating on your behalf - Your PAM officer is a powerful advocate with the IACUC, and your relationship with the officer can weigh heavily on the IACUC’s decisions when problems arise in your lab, Gay notes. PAM officers will lobby on your behalf to the IACUC when you’ve been cooperative and have strived to stay compliant.

- Complying with regulatory details - PAM officers can help to alleviate the burden of regulatory details and allow you to focus more on the science, because they’re essentially experts in the law and tasked...
with assisting you with regulatory compliance, Gay says.

- Preparing for inspections - PAM officers tend to see things the same way as regulatory inspectors. The main difference is that, as opposed to inspectors, PAM officers are really your allies. They can catch problems and help you to correct them before the federal inspectors do.

Avoid the Most Common OLAW Compliance Pitfalls

Continuous open communication with PAM officers and your IACUC also falls inline with OLAW’s most significant recommendation for PIs. In a webinar, OLAW director Dr. Patricia A. Brown reviewed the top reportable issues to her agency from 2000 through 2009. Based on 3,925 cases during this time period:

- 29% resulted from animal study protocol issues, including conducting unauthorized procedures, failing to follow protocol, working before approval of the protocol and working on an expired protocol; and

- 14% involved animal husbandry, including food and water issues, sanitation problems, improper space and inadequate records or identification;

Of the 3,925 OLAW cases:

- 73% occurred at institutions of higher learning
- 14% at government institutions
- 4% at commercial facilities
- 9% at other types of institutions

Protocol issues: In the past decade, only rare cases involved intentionally ignoring protocol requirements, Dr. Brown reports. Most cases stemmed from not fully understanding protocol requirements,
confusing some protocols with those of similar procedures, and generally not understanding protocol approval and amendment processes. Lab team members who lack clear direction and even language barriers can contribute to these issues.

**Solutions:** You as the PI must fully understand your institution’s requirements for animal care and use, and all your staff must also understand their responsibilities. Maintain clear, written operating procedures that are easily accessible for all lab personnel. You may also consider appointing a single senior technical member of your lab team who is responsible for animal procedures.

**Animal husbandry issues:** Among the cases involving animal husbandry problems, most involved food and water. Usually, lacking animal care or animal neglect leading to injury or death is due to miscommunication or confusion within the research team or between the researchers and the animal husbandry personnel.

**Solutions:** Ensure that you add to the protocol all individuals who will come into contact with the animals. When you’re housing animals in your laboratory and your own researchers are providing care for those animals, provide clear instructions on the lab personnel’s responsibilities, preferably using task sign-off sheets. Post in your lab a list of phone numbers for back-up lab personnel and emergency contacts.

Ideally, whenever possible you should house research animals in a central facility where specially-trained husbandry personnel care for the animals. OLAW found that fewer food-and-water problems occurred in these types of set-ups.

Finally, work closely with your IACUC and take advantage of its training opportunities on animal care and use. After all, the number-one corrective action that institutions undertook in the nearly 4,000 OLAW cases was retraining personnel.

**Prevent the Top 6 Inconsistencies between Grant Proposals & Protocols**

Did you know that grants and protocols are supposed to match? If that’s news to you, you’re not alone. Many PIs don’t know that the two are supposed to match up, and when you have discrepancies between the two, you’ll run into delays with your IACUC approvals -- or worse.
Carolyn Connolly, director of the Office for Research Subject Protection at Harvard Medical School, finds the following inconsistencies as the most common:

1. You mentioned a pilot study in the grant, but not in the IACUC-approved protocol.
2. You misidentified the substances tested.
3. You named the incorrect species.
4. There are wide variations in the number of animals used.
5. There are inconsistencies in your descriptions of ways to minimize pain and distress.
6. You have inconsistent euthanasia methods.

**Causes:** The most common causes for these types of inconsistencies are typically that you didn’t keep track of the protocols and amendments, or that you wrote a grant a few years back and now want to apply that grant money to another protocol, Connolly says. But discrepancies between protocols and grants have serious potential consequences.

You can’t use federal grant money on unapproved work, Connolly warns. If you spend grant money on experiments that your IACUC didn’t approve and get caught, you’ll need to back out any charges related to that work.

**Solution:** Ultimately, you as the PI are responsible for your use of grant funds and work with animal subjects. You must keep track of any changes -- whether major or minor -- to ensure that the protocol matches the initial grant, and amend the protocol as necessary, Connolly advises.

Another solution is to conduct your own compliance self-audit. You can accomplish a self-audit by devoting one lab meeting each year to animal welfare compliance, says Larry Carbone, DVM, PhD, Dipl.
ACLAM, senior veterinarian and associate director of the Laboratory Animal Research Center at the University of California-San Francisco. Conducting this type of regular audit can help you to nip protocol discrepancies and other problems in the bud, before they get seriously out-of-hand.

At the annual meeting, Carbone recommends that you and your lab staff should:

- **Read each IACUC protocol line by line** with the individuals doing the work. Begin the audit by reviewing your approved IACUC protocols, and stress that everyone working with the animals should view the IACUC protocol as a firm contract with the institution. Reviewing the protocols line by line can help you find -- and correct -- noncompliance issues.

- **Check for outdated drugs and medicines.** Do you have a good inventory system? If you don’t have a designated staff member assigned to regularly check the lab work areas and cabinets for outdated drugs and other supplies, you may have more out-of-date medicines than you realize.

- **Discuss how the animals are.** Ask your students and lab staff: “How are the animals doing?” Review your surgical survival rates and anesthesia practices, as well as how well your animals are eating, moving around, and maintaining body weight and condition after procedures or as conditions develop.

- **Troubleshoot and modify practices as needed,** with the help of your staff and students, as well as your veterinarian and IACUC. If you find departures from protocols, modify your protocols as needed and contact your IACUC coordinator or chair immediately. You may face some reprimands, but keep in mind that you’ll likely also get some praise for proactively reviewing protocols to spot non-compliances.

**Handle Reported/Suspected Lab-Animal Abuse the Right Way**

Discrepancies and non-compliances with protocols in the lab are one issue, but handling reported or suspected abuse of your lab animals is a tough situation for most PIs who must face it. You have certain responsibilities in responding to reports of overt animal mistreatment, whether the mistreatment occurs at the hands of your own lab staff, another lab’s staff or the animal-care personnel.
According to the NIH’s Institutional Animal Care and Use Committee Guidebook, “mistreatment” is any wrongful physical or psychological treatment of an animal, which can include physical mishandling, taunting or otherwise presenting a threatening presence to animals, or withholding an important resource like food, water, environmental enrichment or therapeutic intervention.

The animal may have obvious signs of mistreatment, such as scrapes, bruises, lameness or tenderness, or a sudden change in behavior, Suckow says. Although these occurrences don’t necessarily always indicate abuse, ongoing observations and reports of these types of otherwise unexplained findings can -- especially when the episodes are linked to handling by a particular individual -- suggest mistreatment.

You must take reported or suspected lab-animal abuse seriously and respond swiftly, Suckow stresses. Take the following steps:

1. **Question the suspected individual without accusing.** Ask the individual to explain what happened and when it occurred.

2. **Ask a veterinarian to examine the animal(s).** Enlist one of the institution’s veterinary staff to examine the purportedly abused animal(s) and provide any needed medical care.

3. **Notify your IACUC immediately.** Understand your institution’s specific policies and procedures for reporting suspected animal abuse, and follow them closely.

4. **Work with the IACUC as the panel investigates.** Provide all the information you can, and assist the IACUC in answering:

   - *Was the animal’s injury the result of the individual working in haste?* A staff member may become frustrated while trying to perform a procedure and lash out at an uncooperative animal.

   - *Was the animal’s injury the result of insufficient training or technical inaptitude?* A staff member’s lack of understanding of a particular species’ behavior could lead to inappropriate handling. Also, a staff member’s lack of expertise in performing a procedure could injure the animal. **Likely resolution:** In this situation, the IACUC will likely require the individual to get additional training, or it may recommend that you
assign a more qualified staff member to handle the tasks.

- **Did the animal bite or scratch the suspected individual, causing the person to lash out?** A staff member may retaliate when an animal bites or scratches him.

Depending on the nature of the mistreatment and the factors involved in the incident(s), the IACUC will usually require additional training for the individual, Suckow notes. But if the staff member refuses additional training or refuses to accept responsibility for the mistreatment, the IACUC can bar the person from continuing to work with animals. Of course, the IACUC can also work with you and your HR department to terminate the individual’s employment at your institution.
SECTION 3:
Adhere to Human Subjects Regulations, Protections

If you’re planning to use human subjects in your proposed research project, the NIH requires that you add quite a bit of extra documentation to your grant proposal. You must include the following separate documents:

- Protection of Human Subjects
- Inclusion of Women and Minorities
- Targeted/Planned Enrollment Table
- Inclusion of Children

Key Points for ‘Protection of Human Subjects’

**Risks to Human Subjects:** Divide this portion into three sections, adding a fourth for “Data and Safety Monitoring Plan” if your research includes a clinical trial. The three main sections are:

1. Human Subjects Involvement, Characteristics and Design

*Describe and justify:*

- The proposed involvement of human subjects in the work outlined in your Research Strategy;
- The subject population’s characteristics, including anticipated numbers, age range and health status (if relevant);
- The sampling plan;
- The recruitment and retention strategies, as well as the criteria for including or excluding any subpopulation;
- Your rationale for involving vulnerable populations, such as fetuses, neonates, pregnant women, children, institutionalized individuals or prisoners;
- The procedures you’ll use for assigning individuals to a study group, as well as for selecting an intervention’s dose, frequency and administration (if relevant); and
- Any collaborating sites where human subjects research will be performed, including the site’s role and data considerations.
2. Sources of Materials

Describe:
- The research material that you’ll obtain from living individuals, such as specimens, records or data;
- Any data that you’ll collect from human subjects for the proposed project;
- Who will have access to individually identifiable private information about the human subjects; and
- How you plan to collect, manage and protect the specimens, records and/or data, as well as whether you’ll specifically collect material or data that include individually identifiable private information.

3. Potential Risks

Describe:
- The potential risks to the human subjects, including physical, psychological, financial, legal or other, and their likelihood and seriousness; and
- Any alternative treatments and procedures, including any risks and potential benefits to the human subjects.

Adequacy of Protection Against Risks: Divide this area into two sections.

1. Recruitment and Informed Consent

Describe:
- Your plans for recruiting subjects and the process for obtaining informed consent;
- The process for meeting parental consent and child assent requirements (if your project will use children);
- The circumstances under which you’ll seek and obtain consent, who will seek it, what information you will provide to prospective subjects and how you will document consent; and
- Your justification for a waiver, if you will seek a waiver of some or all of the informed consent elements.

2. Protections Against Risk

Include:
- Planned procedures for protecting against or minimizing potential risks, including risks to the privacy of individuals or confidentiality of data, and assess their likely effectiveness;
- Research involving vulnerable populations;
Additional protections for pregnant women, human fetuses and neonates;
- Additional protections for prisoners;
- Additional protections for children; and
- Plans for ensuring necessary medical or professional intervention if subjects suffer an adverse effect (when appropriate).

**Potential Benefits of the Proposed Research to Human Subjects and Others:** For this section, provide:

- The potential benefits of the research, not only to participating human subjects, but also to others; and
- Why the risks to subjects are reasonable compared to the anticipated benefits to research participants and others.

**Importance of the Knowledge to Be Gained: Provide details on:**

- The importance of the knowledge gained or to be gained as a result of the proposed research; and
- Why the risks to subjects are reasonable when compared to the importance of the expected resulting knowledge.

**Data and Safety Monitoring Plan:** If your proposal includes a clinical trial, you must include this section. Provide these details:

- A general description of your monitoring plan for data and safety. Describe the entity responsible for monitoring and the process by which adverse events (AEs) will be reported to your institutional review board (IRB), the funding ICO, the NIH Office of Biotechnology Activities (OBA), and the Food and Drug Administration (FDA) in accordance with Investigational New Drug (IND) or Investigational Device Exemption (IDE) regulations.
- The frequency of monitoring, depending on potential risks, complexity and the trial’s nature. Therefore, you will have a number of options regarding monitoring trials, which can include, but should not be limited to, monitoring by a:
a. PD/PI (required)
b. IRB (required)
c. Independent individual/safety officer
d. Designated medical monitor
e. Internal committee or board with explicit guidelines
f. Data and Safety Monitoring Board (DSMB)
o. A detailed Data and Safety Monitoring Plan to your IRB and subsequently to the funding ICO for approval prior to accruing human subjects.

**What to Document for ‘Inclusion of Women and Minorities’**

A Scientific Review Group (SRG) will review your application to decide whether it’s acceptable or unacceptable, specifically regarding your inclusion of women and minorities. The big sticking point is the NIH mandates that cost is not an acceptable reason for excluding women or minorities, except when the study would duplicate data from other sources.

In this section, you must address four main points:

1) The targeted/planned distribution of subjects by sex/gender and racial/ethnic groups for each proposed study or protocol using the format in the Targeted/Planned Enrollment Table.

2) The subject selection criteria and rationale for selecting sex/gender and racial/ethnic group members in terms of the scientific objectives and proposed study design.

3) A compelling rationale for excluding any sex/gender or racial/ethnic group.

4) Proposed outreach programs for recruiting sex/gender and racial/ethnic group members as subjects.
**What’s the ‘Targeted/Planned Enrollment Table?’**

The NIH created a form called the Targeted/Planned Enrollment Table (see Appendix F), which you must use to report the targeted/planned distribution of subjects by sex/gender and racial/ethnic groups for each proposed study or protocol. You also need to submit the table even if your human research is exempt.

When reporting this information to NIH, you should include the following:

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

You can also list any proposed racial/ethnic subpopulations below the table. Subpopulations can include those limited by geographic origins, national origins and/or cultural differences.

**Address 3 Points for ‘Inclusion of Children’**

When you plan to include or exclude children (ages 0 – 21 years) in your proposed research project, you must provide the following information:

- A description of the plans to include children, or if children will be excluded from the proposed research, application or proposal, present an acceptable justification for excluding them.

- A rationale in the plan description for selecting a specific age range, if you’re including children. The plan also must describe the investigative team’s expertise for working with children at the ages included, of the available facilities’ appropriateness to accommodate the children, and the inclusion of sufficient children to contribute to a meaningful analysis relative to the study’s purpose.

- Address additional protections placed for children’s safety in the Adequacy of Protection Against Risks section within the Protection of Human Subjects document.
SECTION 4: Avoid These Conflicts of Interest

The past few years have yielded a big push in promoting objective research that isn’t influenced by conflicts of interest (COI) – financial or otherwise. New federal regulations govern a wide range of scenarios, including your consulting activities and any other financial interest that may present a COI.

In August 2011, the NIH issued a final rule that made substantial revisions to the 1995 regulation on objectivity in research, “Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors.” The regulation covers all research activities funded by (or seeking funding from) any PHS agency, including the NIH, FDA and all others.

The 1995 regulations were pretty loose and didn’t provide much specific guidance on the responsibilities or expectations of the investigator and the institution. But the 2011 update to the regulations is far more rigid. And by August 2012, your institution must be in compliance with the final rule and all of its revised regulatory requirements, according to the NIH.

Comply with the COI Regulatory Changes

Significant Financial Interest (SFI) Threshold: The 1995 regulations set the minimum threshold at $10,000 for disclosure, generally applying to payments or equity interests. But the 2011 final rule lowers the minimum threshold to just $5,000. FCOI disclosures generally apply to payments for services and/or equity interests, including any equity interest in non-publicly traded entities.

SFI Disclosures: Once the threshold is met, the old regulations stated that you needed to disclose “only those SFI the investigator deems related to the PHS-funded research.” In the revised regulations, however, you must disclose all SFIs related to your institutional responsibilities, not just the PHS-funded research.

Disclosure Requirement Exclusions: The 1995 regulations excluded from disclosure any income from seminars, lectures or teaching, as well as any service on advisory committees or review panels, for public or nonprofit entities.
The new regulation expands these disclosure exclusions to “income from seminars, lectures or teaching engagements sponsored by and service on advisory or review panels for a federal, state or local government agency, an institution of higher education as defined at 20 U.S.C. 1001 (a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.”

**Types of SFIs Excluded:** The 2011 final rule excludes SFIs like income from investment vehicles, such as mutual funds and retirement accounts, as long as you do not directly control the investment decisions made in these vehicles.

**Travel Reimbursement/Sponsored Travel:** The old regulation didn’t specifically mention travel reimbursement, but also did not exclude it from the SFI definition. The new regulation is more explicit: “Disclose the occurrence of any reimbursed travel or sponsored travel related to institutional responsibilities (including purpose of trip, sponsor/organization, destination and duration).”

You do not, however, need to disclose travel reimbursed or sponsored by a federal, state or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education. The new regulation tasks your institution with determining whether any travel reimbursement or sponsorship requires disclosure.

**Reported Information on FCOIs:** The old regulations required only basic information that you would need to report to the PHS-awarding component when you had an identified FCOI. Now, you must issue two different reports -- an initial report and an annual report -- on the FCOI.

**Initial Report:**
- Grant/contract number
- PD/PI or contact PD/PI
- Name of investigator with FCOI
- Name of the entity with which the investigator has a FCOI
- Nature of FCOI, e.g., equity, consulting fees, travel reimbursement, honoraria
- Value of the financial interest, identified in the following monetary brackets:
New and Early Stage Investigators Toolkit: All the Tips & Strategies You Need to Launch a Successful Research Career

- $0 - $4,999
- $5,000 - $9,999
- $10,000 - $19,999
- $20,000 - $100,000 in increments of $20,000
- $100,000 or more in increments of $50,000
- Or include a statement that the value cannot be readily determined

- A description of how the financial interest relates to PHS-funded research and the basis for the institution’s determination that the financial interest conflicts with such research
  - Whether FCOI was managed, reduced or eliminated
  - Key elements of the institution’s management plan for the FCOI

Annual Report:
- Status of the FCOI
- Changes to the management plan

**Subrecipient Institutions/Investigators:** The new regulations also changed the FCOI reporting requirements for grant subrecipients. In the old version, your institution “must take reasonable steps to ensure that investigators working for subs comply with the regulations by requiring those investigators to comply with the institution’s policy or by requiring the entities to provide assurances to the institution that will enable the institution to comply with the regulations.”

But in the new regulations, your institution must have a written agreement that incorporates the terms that establish whether the institution’s FCOI policy or the subrecipient’s policy will apply to the subrecipient and its investigators. The written agreement must also include time periods to meet disclosure and FCOI reporting requirements.

If the subrecipient relies on its own FCOI policy must report identified FCOIs to the institution “in sufficient time to allow the awardee institution to report the FCOI to the PHS-awarding component (e.g., NIH through the eRA Commons FCOI Module) to meet reporting obligations,” the new regulations state.

**Public Accessibility:** The 2011 regulation revisions included a new public-accessibility requirement. For
all FCOIs held by senior or key personnel, you must make this information available via a publicly-accessible website or by a written response to any requestor within five business days of the request, and update the information as specified in the final rule.

At a minimum, the publicly-reported information must include:

- The investigator’s name;
- The investigator’s title and role with respect to the research project;
- The name of the entity in which the investigator has the SFI;
- The nature of the SFI; and
- The SFI’s approximate dollar value, or a statement that the interest’s value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

**FCOI Training:** Another new requirement in the 2011 regulations is for FCOI training. Specifically, each investigator must complete FCOI training prior to engaging in research related to any PHS-funded grant or contract. You must complete the FCOI training again every four years, as well as any time that:

- Your institutional FCOI policies change in a manner that affects investigator requirements;
- An investigator is new to an institution; and/or
- The institution finds an investigator noncompliant with the FCOI policy or management plan.

**Mitigation Plan (“Retrospective Review”):** The third new requirement in the 2011 final rule is the mandate of conducting a retrospective review or mitigation plan. When a case of noncompliance arises, the institution must conduct a retrospective review and notify the PHS-awarding component promptly. In the notification, the institution must submit a report to the PHS-awarding component in cases where bias is found. This report should address the bias’s impact on the research project and the actions the institution has taken or will take to eliminate or mitigate the effect of the bias -- the “mitigation plan.”

**Try These COI Prevention Strategies**

PHS granting agencies don’t require much in the way of preventing FCOIs, but instead tend to focus on managing these conflicts after they arise. But some institutions are taking a more proactive approach, deciding
that prevention is far easier than the damage control after-the-fact.

**Example:** The research arm of the North Carolina State University (NCSU) employs a “pre-approval program,” an entirely automated process that spots potential COIs before they actually occur. PIs at NCSU must file for permission to perform consulting or other outside activities at least 10 days prior to the engagement, according to **Matt Ronning**, Associate Vice Chancellor and Director of Research Administration at NCSU in Raleigh.

PIs use an automated system drive by logic written into the program, Ronning explains. The program asks the PI a series of questions designed to detect potential COIs.

The PI’s immediate supervisor -- usually the department chair -- reviews the outside activities, checking them against the PI’s COI disclosure and their sponsored program portfolio. “If the affected PI doesn’t have any conflict of interest already disclosed or discovered through how they answer our questions, then [the review process] stops at the immediate supervisor level,” Ronning says. But if a potential FCOI exists, the permission application routes to the dean or second-level authority above the immediate supervisor.

**The Keys to a Pre-Approval Program**

Although a pre-approval process doesn’t need to be automated like the one at NCSU, you can use some simple strategies to build a program of your own. For instance, utilize some basic parameters for detecting potential COIs in outside activities:

- **Relation to university work.** All outside activities should be a separate as possible from the investigator’s research work for the institution.

- **Compensation amount.** Use the final rule’s compensation limits of no more than $5,000 per year for consulting fees, honoraria or other types of payments for outside activities.

- **Agreement’s specificity.** Stanford University requires that the consulting or other outside activities’ scope is “very specific.” Having specific terms in the agreement is important because this can help to prevent
granting the outside entity access to work outside the agreement. Specificity in the agreement also prevents interference with the intellectual property (IP) disclosure and publications from the faculty member’s academic work or sponsored research.

- **Licenses, titles and patents.** The outside agreement should conform to your institution’s policies regarding licenses, titles and patents.

- **Access to information, ideas and research.** The outside agreement should not allow exclusive or early access to the investigator’s research findings, unless the findings are from the results of research sponsored by the outside entity and not by a PHS-awarding component.

- **Publication restrictions.** The agreement itself must not prohibit or delay publications relating to research findings from the investigator’s work at the institution.

- **Equity interests and IP rights.** The pre-screening system should flag all potential COI situations, including equity interests, as well as IP rights and the royalties derived from these rights.

### Scenarios: Look for FCOI Red Flags

Although some FCOIs are obvious to even the beginner’s eye, others may have more subtle elements that indicate potential conflicts. Test your own FCOI know-how by studying the following examples and scenarios.

*Scenario:* This hypothetical case comes from the California Pacific Medical Center (CPMC). One of CPMC’s endocrinologists who has a large clinical practice expects to receive funding from a pharmaceutical company for a Phase III clinical trial. The trial involves a drug that has shown some promise in preventing peripheral neuropathy in advanced diabetes.

The endocrinologist has been a member of the same pharmaceutical company’s speaker’s bureau and has provided consulting services for the company. The endocrinologist has lectured and consulted on diabetes treatments -- in the last year, receiving from the pharmaceutical company about $5,000 in honoraria and consulting fees for her work.
This is a FCOI that requires a mitigation plan. When the endocrinologist applies for IRB approval of the study, she discloses the honoraria and consulting fees from the study’s sponsor. She must disclose these payments to the research institution, the IRB and the human subjects prior to enrolling them in the study.

**Example:** Another scenario comes from the University of Michigan’s research department. Company A wishes to sponsor university research under Professor Z’s direction. Company A and Professor Z wish to have an ongoing consulting relationship. The research project would involve subject matter that’s clearly unrelated to the focus of the consulting relationship.

First, this situation would require that Professor Z disclose to the institution’s COI review committee the consulting arrangement and its relationship with the research project. If the sponsored research project would involve university support for one grad student research assistant under Professor Z’s supervision, this is unallowable and would require a FCOI mitigation plan that would:

- Appoint another faculty member with no connection to Company A to serve as the student’s thesis advisor, particularly if the thesis’s focus is based on the research project; or
- Have Professor Z serve as co-thesis advisor with another faculty member who has no connection to Company A.

If the proposed research project were directly related to the work that Professor Z conducts as a consultant for Company A, this would be a significant FCOI risk and would require more extreme mitigation measures. The measure might include appointing a different faculty member with no connection to Company A as the project’s PI, but still allow Professor Z to participate in the research as a company representative or even as the co-investigator.

**Case Study:** The Council on Government Relations (COGR) provides yet another example. Chairman of Cardiology Dr. Gray consults for PharmaCo. Dr. White works in Dr. Gray’s department, and through Dr. White’s research he has developed a gene therapy to a deadly congenital heart defect in newborns. Now, PharmaCo wants to license the gene therapy technology.

Is Dr. Gray’s consulting relationship with PharmaCo a FCOI or otherwise an issue that the institution should consider in the proposed license agreement? Depending on your institution’s policies, you may decide that if there’s no equity included in the license and no related financial interests with other institutional decision-
makers or trustees, there wouldn’t be any COIs to manage or mitigate. This is excluding, of course, the usual issues of the Technology Transfer staff’s oversight of the licensee’s performance, COGR states.

Or you might decide that because a license poses the possibility for future royalties, the financial interest does in fact constitute a potential FCOI that requires mitigation. Also, Dr. Gray would have to recuse himself from any institutional COI deliberations due to his consulting role, particularly if his payments from PharmaCo exceed the de minimus threshold.

The COGR takes this case study a step further, posing the scenario in which PharmaCo becomes the technology’s licensee and wants to conduct Phase I clinical trials. In this case, Dr. White would likely be precluded from serving as the PI for the Phase I trial. Also, the dean’s office may want to review Dr. Gray’s consulting agreement with PharmaCo to ensure that his consulting activities don’t interfere with or involve the evaluation of the trial’s study data.

**How COCs Can Reveal Underlying FCOIs**

Many institutions have policies on “conflicts of commitment” (COCs), which tend to become intertwined with COIs. When it comes to consulting agreements or other outside activities, the biggest red flags at Wake Forest Baptist Health in Winston-Salem, NC usually involve situations that are more COCs than FCOIs, according to *Teresa Anderson*, Wake Forest’s Conflict of Interest Director.

Anderson offers the following list of COC and COI red flags that she commonly finds in outside agreements:

- Language about the **sponsor owning IP rights** to IP resulting from the consulting relationship;

- The **investigator’s business address** listed as the institution’s instead of her personal address;

- Language stating that the faculty member will carry out the consulting work at **her “principal place of business”** (the institution);
• **Non-compete provisions**, which aren’t usually in the faculty member’s best interest and could lead to COI issues;

• **Promotional or marketing activities** as part of the consulting work;

• **Indemnification language** that many faculty members might not understand completely; and

• Statements that the investigator is to perform “research” under the consulting agreement, which would need to go through the proper channels at the institution, budget for F&A and fall under the investigator’s primary employment role at the institution.
SECTION 5:  
Safety: What to Do When Your Lab is in Crisis

Crises can come in many different forms, especially in labs. From natural disasters to infection outbreaks to select agents, as the PI you must be ready to handle any crisis that comes your way. Not only do you need to lead your staff through the crisis, but oftentimes you also have to ensure compliance and safety in your lab.

In any type of crisis, as a leader you must project strength, show confidence in your team and keep all your team members focused on solving the problem. Effective leadership during a crisis enables you to mobilize your lab team to react appropriately. The “three C’s” of effective crisis communication are that the leader must appear Confident, Competent and Compassionate, according to Jonathan Bernstein of Bernstein Crisis Management consulting in Sierra Madre, CA.

**Competent:** Your lab staffers want to believe that you’re fully competent as their leader to guide them through the crisis. If they begin to doubt your competence, you’ll lose their buy-in and slow down your preparations and recovery plan.

*What to say:* “We’ll meet back in an hour, and I’ll explain our plan of action.” This kind of statement not only inspires confidence, but it also demonstrates your competence. Formulate a plan, begin to mobilize resources, and identify individual roles that each staff member can play. Meet back with your staff at the promised time and present your action plan.

**Confident:** Your leadership skills during a crisis in your lab should inspire confidence among your staff members. If your lab employees aren’t confident in your leadership during a crisis, morale will plummet and fear will proliferate.

During a crisis, the best thing that you can do as a leader is to “radiate calm,” says John Baldoni, leadership development consultant at Baldoni Consulting, LLC in Ann Arbor, MI. “There will be lots of noise in the room. But you need to speak in your normal voice and not get drawn into the emotional aspects of it.”

*What to say:* “Here’s the plan, and I believe in it.” Establish the basic plan with some flexibility to make any necessary adjustments, and express your confidence in the plan to reassure your staff that you will lead...
them through the crisis.

**Compassionate:** Compassion is particularly important during a crisis, because your team members may feel anger, anxiety or other negative emotions. And if you don’t show compassion for their feelings, “they won’t listen to the facts -- or follow you as leader,” Bernstein warns.

**What to say:** “I have confidence in you to ...” or “I need you to do this. Can I count on your help?” Because people tend to have a strong psychological need to help during a crisis, you must focus on your individual staff members’ skills and talents. Doing so will motivate your staff and show that you have confidence in them, Baldoni says.

**How Your Lab Can Weather a Natural Disaster**

Among the many different types of crises that your lab may face, natural disasters are one of the most common -- especially if your lab is located in a hurricane-prone area or earthquake hotspot. Whether you’re worried about tornadoes, tsunamis, flooding or another type of natural disaster, getting through such an event is all in the preparation.

If you haven’t looked at your lab’s disaster preparedness plan in awhile, there’s no time like the present. Reviewing your plan keeps everyone in your lab on the same page, says Adam Montella, vice president of Homeland Security and Emergency Management at Animus Technology.

When you’re reviewing your disaster preparedness plan, consider taking the following key measures to ensure that your lab survives:

- **Plan for a shortage of maintenance resources.** When a natural disaster strikes, your lab will undoubtedly need to compete for maintenance resources, which will be spread thin throughout the institution while repairing windows, restoring power and fixing other problems around the buildings. But if you need to decontaminate your lab before the maintenance crew can come in to repair your broken windows, you’ll have even more delays and headaches in getting your lab back up and running.
**Strategy:** Some universities in hurricane zones, like the University of Texas Medical School at Galveston, begin to shut down their labs before a hurricane hits. This way, at least some of the decontamination work is completed before the storm, allowing access to the labs after the hurricane to make repairs.

- **Back up your paper documents.** Sure, you probably have data backups for your computer files, but many labs fail to back up their paper documents. When a natural disaster descends on your lab, you won’t get those paper documents back. In addition to your digital backups, ensure that you have copies of your paper files.

  **Solution:** Assign a staff member or administrator to scan all your paper documents so they are duplicated in electronic form, Montella advises. Save the electronic files to an off-site storage to ensure their safety.

- **Perform emergency action drills.** You can practice your disaster preparedness plan using emergency action drills, which are exercises that give your staff somewhat of a simulation that they can draw from when a real emergency arises. Drills can also help you to realize flaws in your plan that you wouldn’t otherwise anticipate, says Heather Case, DVM, MPH, director of the American Veterinary Medical Association’s Scientific Activities Division and coordinator of the Emergency Preparedness and Response team.

  **Example:** Case recalls a drill in which a lab-animal evacuation team realized that their transport cages didn’t fit into some of the evacuation vehicles. You don’t want to uncover that kind of issue during an actual evacuation.

**Take These Precautions to Prevent Infection Outbreaks, Select Agent Risks**

In addition to natural disasters, labs that use certain contaminants in their experiments face unique risks to staff safety. Lab-based contamination cases have increased, with the Centers for Disease Control and Prevention (CDC) reporting 73 cases of laboratory-linked human Salmonella typhimurium infections in 35 states between August 2010 and March 2011.

Also, research involving the use of select agents poses serious health risks. These are hazardous biological agents and toxins that can potentially pose a severe threat to public health and safety, or to animal and
plant health or products. Note: Most precautions are mandated by your institution, with yearly inspections.

**Infectious Substances:** Safety inspectors want to know that your lab is meeting or exceeding the bar when it comes to protecting against outbreaks of lab bacteria and other infectious substances. Markus Schaufele, assistant director and Safety/Chemical Hygiene officer at Northwestern University, says that safety inspectors will specifically look for proof that you and your lab staff:

- Have completed all required training;
- Follow all safety procedures regarding engineering and administrative controls, as well as personal protective equipment (PPE);
- Adhere to the shipping and receiving procedures for pathogens and hazmats;
- Have proper procedures and records for materials disposal;
- Have proper laundering procedures; and
- Maintain proper containment equipment and procedures in your lab.

Safety inspectors aside, no PI wants to deal with a contamination issue in the lab. You can follow three simple steps to ensure that your lab is taking the proper precautions against infection outbreaks:

1. **Check your existing controls.** Double-check your safety procedures and personal protective equipment. Is everything in order? For example, are the fume hoods properly fit-tested? Also, examine your engineering controls to verify that your equipment and tools are still working properly. Finally, check your administrative controls. For instance, are your lab employees using “safe” amounts of harmful bacteria or chemicals, or are they taking more from storage than they need?

2. **Perform routine monitoring.** Quietly observe your lab staff as they perform research procedures to look for safety compliance. Also, reinforce safety procedures with your staff members on a routine basis to ensure that they’re taking the necessary precautions. For example, are your lab employees washing their hands after touching bacteria and before touching anything else, even mid-experiment?

3. **Look at your high-hazard areas.** Think about what your staff bring in and out of the lab that could transmit pathogens. What about mp3 players, pens and pencils, flash drives, and cell phones? Remind your employees of proper procedures and that contamination can originate from low-risk areas -- not just the highest-
hazard areas in your lab.

Select Agents: If you’re using select agents (see the CDC’s list at http://www.cdc.gov/od/sap/docs/salist.pdf) in your lab, you must write into your grant application that you’ve considered and prepared for safely handling the dangerous substances beyond the standard regulations. Follow these four steps to prove that you’re prepared to handle select agents in your lab:

1. **Go beyond the “boilerplate” answers.** Your institution can likely supply you with some standard answers, including its CDC registration numbers, policies on shipping and receiving, bio-safety policy, and federally-compliant containment and research facilities. You’ll need all of these things for your grant proposal, but reviewers already know the “boilerplate” answers, says Chuck Putney, a trainer/consultant based in Bennington, VT, who represents the Grantsmanship Center in Los Angeles.

   **Mistake:** Don’t simply regurgitate the standard language. Be more specific. For example, don’t say, “All researchers who will handle select agents will be trained according to the institution’s biosafety policy and federal regulations.”

   Instead, tell grant reviewers exactly who will handle select agents and how you will determine that they’re prepared to handle them. Address the specific circumstances, even just one or two sentences, to strengthen your case, Putney advises.

2. **Demonstrate your IT security.** Because many select agents have the potential for use in bioterrorism, reviewers want to know that you have tough IT security to protect sensitive information that could become dangerous in the wrong hands. Discuss with your institution’s IT department the need for tough information-handling procedures, and ensure that your IT security is top-notch.

3. **Address the “what if” scenarios.** Grant reviewers have “worked at institutions, universities and hospitals, and they know how and where things went wrong at their own institutions,” Putney says. So they want to know that you’ve considered the potential problems. Provide a short description addressing common problems to establish your credibility and explain your backup plans for those “what if” scenarios.

4. **Show your institution’s existing equipment, facilities and experience.** The NIH doesn’t want
to pay for your learning curve or for expensive facilities necessary for handling select agents. “It’s better to say we’ve done this before, that we have all the facilities and containment procedures,” says Dr. Charles Howard, a grant-writing consultant for GrantsCrafter Consultancy in Salem, OR.

**Best bet:** In your grant proposal, focus on the facilities, containment, training programs, equipment, security and safety measures, and PPE that already exist at your institution, Howard recommends. Also, highlight your institution’s history of handling similar agents.
CHAPTER IV: Starting Your Professional Career

As a PI, you want to become a leader, not a “manager.” Leaders have certain traits and skills that managers lack. Further, leadership is a character trait learned over time and honed with experience. Nobody is born a leader, just as nobody is born destined to never become a leader.

Leaders share key characteristics that you might already recognize in yourself. A leader is:

- Forward-thinking yet reflective;
- Empowering, energizing and encouraging;
- Assertive when necessary;
- Emotionally intelligent; and
- A listener and approachable.

In this chapter, you will learn:

- Leadership and employee-management skills;
- Project-management techniques;
- Proper delegation tactics;
- What you need to know about foreign visas and export controls; and
- Time management and organizational skills.
SECTION 1: Master Leadership & Employee Management Skills

Stepping into a leadership role in the lab isn’t easy for every new PI. Effective leaders in the lab have several key traits and skills that usually don’t come naturally for new PIs. Being assertive, boosting morale, giving appropriate feedback and delegating are among the top skills you’ll need to lead your lab team to success and keep everything running smoothly.

Beginning your career as a PI, you’ll need specific tools and know-how to run your lab team effectively. For each key leadership and management goal, experts offer several proven strategies.

Top 10 Tips to Lead Your Lab to Success

1. **Communicate your management style.** Tell your lab employees upfront about your management style, whether you have a “hands-off” approach or you are a micromanager. Be prepared to adjust your style to fit the needs of your staff.

2. **Hold weekly lab meetings.** Keep a productive agenda for your weekly lab meetings, but encourage everyone to speak up by asking them questions or assigning them part of the agenda to discuss.

3. **Voice your expectations.** When you hire an employee, tell them right away what your expectations are and what responsibilities he will have. Don’t rely on “unspoken expectations.”

4. **Provide regular staff evaluations.** Keep your lab employees accountable and catalog a documented performance record with regular -- annual or semiannual -- performance evaluations.

5. **Distribute written policies.** Provide every staff member in your lab with written policies on lab notebooks and other organizational matters, vacation time, working hours, and other issues specific to your lab. Written policies promote fairness and help to prevent conflicts.
6. **Celebrate achievements.** Plan social interactions outside the lab, public praise and smaller celebrations inside the lab to recognize your employees’ individual and group victories or special events.

7. **Nip problems in the bud immediately.** Don’t let problems fester. Learn to recognize the warning signs for employee problems, such as chronic tardiness, withdrawal, outbursts or a sloppy appearance. Talk privately with the employee to determine the root of the problem, and give him a set time to make improvements.

8. **Give firm reminders.** For more minor issues, such as sloppiness with lab notebooks or data recording, issue firm verbal and written reminders to keep your staff on-track.

9. **Do some self-reflection.** Whenever a morale problem arises in your lab, examine yourself to determine whether you could be contributing to the low morale. You might be the problem if you tend to use intimidation with your staff, if you rely on only one or two employees, if few team members come to you with questions or concerns, or if staffers don’t readily speak up in meetings.

10. **Know when to terminate.** Use your periodic performance evaluations to work with your HR department when you’re considering terminating an employee.

*Sources: Dr. Kathy Barker, former PI and author of “At the Helm: Leading Your Laboratory;” Dr. Bruce J. Mayer, associate professor of genetics/developmental biology at the University of Connecticut Health Center at Farmington; Dr. Steve Koch, assistant professor of biophysics at the University of New Mexico.*

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**Goal: Empower Your Staff to Get the Job Done**

*Strategy:* Outline the details of each and every employee’s job duties, including the results when they don’t accomplish their tasks.
Getting your employees to work effectively and efficiently as a team is not always an easy task. Your staff members don’t necessarily come to your lab with the habits and understanding to work the way you want them to in your lab. That’s why you can get your lab team to run efficiently by outlining each employee’s tasks and responsibilities.

You can even list each person’s responsibilities in a lab manual or post the tasks and who is responsible for them in your lab, suggests Patricia Evans, found of the Evans Interpersonal Institute in California. Always be honest and clear about your expectations, and outline the expected goals for each employee.

When an employee fails to meet a goal or expectation and this failure affects the rest of the team members, meet privately with the individual first. Find why she failed and decide whether to reassign the task or reaffirm that you expect her to complete the assignment. Then, without naming the individual, during a staff meeting explain how you’ve handled the issue.

**Strategy:** Lead by example, and be assertive.

Assertiveness doesn’t come naturally to all leaders -- and many new PIs struggle with being assertive. Assertiveness often relates closely with being honest and upfront about problems, as well as facing the problems head-on and immediately after they occur.

When a problem arises, don’t ignore it or dwell on it. Instead, act decisively, advises Beth Parker, PhD, head of the exercise physiology lab at Hartford Hospital in Connecticut. Be direct, and don’t get emotional. “When you are clear about what needs to be done, that you know what’s happening and are taking action, you shut the door for disagreement,” she says.

**Tip:** New and early PIs benefit greatly from observing a well-run lab headed by senior PIs. Take the time to observe and learn from labs that operate smoothly, win grants and make discoveries. Look for senior PIs who get results from their lab employees without being emotional.
**Strategy:** Give effective feedback.

Provide performance feedback as soon as you can after a problem arises. Waiting a week or more after a problem to discuss the situation with your employee won’t be as effective, because you’re likely to forget the details and key points that will truly help. Providing feedback that will actually make a difference in your employee’s performance is a three-step process:

1. **Encourage self-evaluation.** Before you give your own thoughts on the situation, get your lab employee to assess her own performance, advises Tracy Ellig, director of communications at Montana State University. Usually, employees will pinpoint their own weaknesses and are able to identify where they went wrong. What to say: “Tell me what happened, why it happened and how it affected your team.”

2. **Fill in the gaps with your own perspective.** Oftentimes, an employee won’t detail every issue relating to the problem in her self-evaluation. When your lab staffer leaves out a key element -- such as how her behavior affected her team members -- explain what she overlooked, and be sure to provide specific examples, Ellig recommends.

3. **Collaborate to avoid future problems.** To ensure that the problem doesn’t arise again in the future, you will probably need to delve deeper and find the source of the issue. Although this can go in many different directions, some common ones include that the employee underestimated the amount of time to complete the work, had difficulty juggling the task with other duties, or didn’t understand the directions.

**Goal: Keep Lab Morale High**

*Strategy:* Celebrate achievements, birthdays and other milestones.

Boosting your lab morale will not only keep your staffers happy, but it will also stimulate smoother workflow, more discoveries and better collaboration. A key way to boost morale is to celebrate your employees’ birthdays, achievements and other milestones, according to Pam Soltis, PhD, curator of the laboratory of molecular systematics and evolutionary genetics at the Florida Museum of Natural History.
You can throw a small party, have a cake in the break room or pass around a card for everyone to sign when a lab team member has a birthday, gets through his orals, gets a grant, has an anniversary or another notable event. Engagements, marriages, births, published papers and other professional or personal milestones are also a great opportunity for a morale-building celebration.

Another way to mention achievements is to announce them at the beginning of your team meeting, so everyone can congratulate their colleague. This stimulates camaraderie among your lab staffers.

**Strategy:** Organize social events outside the lab.

Socializing outside the lab can also help to boost morale among your staff. These outings are a way to encourage better personal and professional relations among your lab employees, says Greg Ball, PhD, vice dean for science and research, and professor in the psychological and brain sciences department, at Johns Hopkins University in Baltimore.

At least once each year, organize social gatherings outside the lab for which everyone is invited. Try to select an activity that fits your team’s personalities and preferences. You could get together for a cookout at your house, enjoy a meal at a restaurant, go to a ballgame or go bowling.

Of course, you may need to spend some of your own money to have this outside social gathering, Ball says. “It is sort of the cost of doing business, so to speak.”

**Goal: Lead a Generationally-Diverse Team**

**Strategy:** Understand the unique needs of Gen-Xers.

Generation X employees (30 to 46 years of age) in your lab tend to crave a sense of “community” in the workplace. GenXers tend to share certain key traits that make managing them a little different from Baby Boomers and other generations, says Robin Matross Helms, founder of the consulting firm Hibari Connection, Inc. Helms authored a recent Harvard study on GenXers in the workplace, New Challenges, New Priorities: The Experience of Generation X Faculty.
GenXers tend to enjoy interdisciplinary work and value collegiality over competitiveness. They focus on building relationships to broaden opportunities, Helms says. They want to create a close-knit community with their colleagues and will often remain at the same workplace if they’ve achieved this sense of community.

Some GenXers, however, will achieve this community not in the workplace, but instead elsewhere, such as with family or their church. GenXers who have a community outside of work are typically more defensive about their home life and want to defend their private life. For these GenXers, keeping meetings on-topic and avoiding assigning them tasks that they’ll perceive as a waste of time will keep them satisfied and productive.

For most GenXers who crave community in the workplace, you can create this community as the best motivational and retention tool for this particular generation, says Kiernan Mathews, Director of Collaborative on Academic Careers in Higher Education (COACHE) at the Harvard Graduate School of Education.

**Strategy:** Understand the unique needs of Millenials.

Millenials -- individuals born in the 1980s and 1990s -- are often different to manage than GenXers and other generations. Millenials are usually tech-savvy, enthusiastic learners and team-players, says Ed Tywoniak, EdD, communication professor at St. Mary’s College of California. They’re also particularly gifted with social media.

But Millenials tend to have unique needs, due to their immersion in high-tech communications and the Internet. Here are some tips to keep your lab team’s Millenials on-task and thriving:

- **Help them stay on-task.** Millenials are often easily-distracted and want instant gratification, due to their fast-paced, technology-driven world. You may need to help them to stay focused and task-oriented. Clarify your lab’s mission and how your project specifically relates to that mission. Moreover, show your staffer how she fits in with the project and the overall mission. Explain how her specific tasks fit in as well.

- **Give them a balance of structure and autonomy.** Break down the larger projects into smaller tasks for Millenials, but then hang back and allow them to perform the tasks themselves. Millenials tend to struggle with bigger projects and instead perform better with smaller assignments, Tywoniak says.
➢ Don’t assume that they know everything about technology. Despite Millenials’ tech-savvy, they may not know a lot about the specific technological training that your project requires.

➢ Help them to understand the difference among data and opinion. Because Millenials are accustomed to “information overload,” they tend to have difficulty discerning between hard data and opinion.

Goal: Avoid & Resolve Personal/Professional Conflicts

Strategy: Embrace the right kind of conflict.

Although most people view conflict as negative and try to avoid it at all costs, there are some fundamental advantages to encouraging conflict -- as long as it’s the right kind of conflict. You can have conflict, but the key is respect. Respect is what most people want.

Sometimes, your lab may seem to be running smoothly, but you can sense and underlying discontent among your staff. This is a situation where conflict is healthy, because it airs problems, according to Howard Gadlin, PhD, ombudsman and director of the NIH Center for Cooperative Resolution.

Healthy conflict also allows dissent to surface, encouraging your staff to think independently and produce better, stronger ideas, Gadlin says. You also want to bring to the surface any discontent among your staff, because you don’t want it to fester until the discontent affects workflow or staff morale. Finally, healthy conflict stimulates positive change.

People tend to handle conflict in different ways, according to their conflict “styles.” Individuals who are “competitors” tend to look for a resolution to a conflict in which they win and the other person loses. “Spites” allow conflicts to degenerate to the point where both sides lose, while “accommodators” will naturally self-sacrifice to avoid conflict altogether.

But “collaborators” look for the real win-win outcome to conflict, Gadlin says. They will work hard to find a solution to the problem where both sides can get positive results.
**Strategy:** Utilize conflict to bring about positive changes.

Fostering the right kind of conflict isn’t always easy, but you can do so by:

- **Differentiating between disagreement and hostility.** Hostility is often personal, emotional and therefore unproductive. Professional disagreement is healthy. Although personal conflict is harmful to your lab environment, disagreement is essential to science. “Disagreement is conflict about intellectual and scientific ideas,” Gadlin notes.

- **Encouraging a response of curiosity toward any sort of conflict.** When conflict arises in your lab, ask questions and remain curious. Not only will doing so help to diffuse any anger, but it will also promote better understanding of the issues at-hand.

- **Avoiding bad compromises.** Compromise isn’t always a good thing. In fact, only one type of compromise -- the win-win -- produces an optimal result. Bad compromises are those that yield results where one side loses and one wins or both sides lose.

**Goal: Perfect Your Project-Management Skills**

**Strategy:** Assign employees’ roles and responsibilities.

If your lab team members don’t know their specific responsibilities and roles in the project, tasks will inevitably fall through the cracks. When you don’t assign roles, your team will likely do it for you -- informally and with little communication. Clarify each and every team member’s role, stresses **Stanley Portny**, independent project-management consultant and author of Project Management for Dummies.

**Strategy:** Encourage ideas, but don’t be afraid to kill projects.

You and your lab team will undoubtedly have many great ideas, but you can’t pursue all of them. Don’t be afraid to kill projects or table ideas for later consideration, says **Adam Schayowitz, PhD**, director
of business development for Biomarker Strategies, a cancer-diagnostics biotech company. You don’t want to discourage your team from coming up with new ideas, but you’ll need to strike a balance, he explains.

Every time you and your lab team are considering a new idea, ask the key questions:

- Will this idea help our team move in a positive, productive direction?
- Do we have enough resources and time to pursue this idea?

**Strategy:** Try “rolling wave” planning.

Because you’re attempting to discover something that is unknown, planning ahead in the lab environment is challenging -- if not impossible at times. That’s why “rolling wave” planning is an excellent strategy for labs, Portney says. You can essentially make a series of short-term estimates of the time and resources you need to complete specific tasks or steps in the project.

Instead of planning each and every phase of your project in advance, “rolling wave” planning forces you to plan in increments, so you can allow for any unexpected results or changes in direction for your project.

“Rolling wave” planning allows you to measure your successes in increments, so you can review your results and revise your plan based on what you’ve learned at each step in the project. For researchers, this type of planning provides structure and more control over the project, Portny explains.

Inline with “rolling wave” planning, distinguishing between the known and unknown elements of your project can also help to keep your lab running smoothly. In your time and budget estimates for the project, separate the “knowns” and “unknowns,” Schayowitz recommends. Plan for all the known elements first, and then work on building the unknowns into your project planning using the “rolling wave” strategy.
SECTION 2: Overcome Common Management Hurdles

There are many different roadblocks to effective leadership and lab management -- some of which you might not even be aware of until it’s too late. Whether your management hurdles are internal or external, you can overcome them with expert strategies and tips.

Hiring 101: How to Pick the Cream-of-the-Crop

Hiring is one of the most daunting tasks for new investigators, and whittling down a large pile of applications to pick out the best few candidates to interview can seem overwhelming. More experienced PIs tend to use certain tried-and-true strategies for putting together the short list of interviewees:

1. Encourage self-screening. One strategy that experienced PIs use is weeding out less-qualified or less-interested candidates by forcing prospective applicants to “self-select.” To do this, you simply raise the bar for applying.

   For example, you can ask for letters of reference -- not just reference names -- upfront to ensure genuine interest in the position. Candidates will need to weigh their interest in the job to get those letters of reference in order to apply for the position.

2. Don’t Use Online Applications to ‘Prescreen.’ Using your HR department and regular online applications to help save time and prescreen some applicants may seem like a good idea, but you might also inadvertently weed out some of the best candidates.

   If you have candidates applying online or through HR, their resumes are screened by an algorithm supported by a keyword-based search method. And online forms encourage frivolous applications, which only add to your stack.

3. Prescreen the right way. If you have a grad student or post-doc on your staff already, you can have her help you perform the initial screening by simply removing the most unqualified applicants. If you’re
performing all the screening yourself, you can do this yourself.

After you weed out the most unqualified candidates, the next part of prescreening is to pick out the applications that show some way of meeting any specific needs you have for the position, such as previous experience in a certain type of computer software or strong interest/experience in autism spectrum disorders.

4. Decide on the “middle-of-the-road” candidates. Your hiring task would be easy if all you had to do was divide resumes into two piles -- one for flat-out rejections, and one for definite interviews. But that’s not really the case, and you’ll likely end up with three piles -- the third being your “maybe” pile.

You can deal with your “maybe” pile in two ways: 1) call the candidate for more details on her goals and what she could bring to the table, inquiring specifically about the skills she hasn’t yet developed; or 2) send the candidate a written test (e.g., review a published article) via snail mail to gauge how serious she is about applying and how enterprising she is.

Are You an Introvert? Tips to Manage Effectively

One internal management hurdle that many PIs face is shyness. But many famous leaders like Bill Gates and Warren Buffett are notorious introverts. How did they succeed? How can introverts overcome their shyness and lead effectively? Here are the secrets to success:

1. Speak up -- and learn to say “no.” Introverts tend to have difficulty saying “no” or asking for help, says Jennifer Kahnweiler, executive coach and author of The Introverted Leader: Building on Your Quiet Strength. This can lead to becoming quickly overwhelmed by deadlines or projects, as well as to a perception that you’re a micro-manager or mistrustful of your staff.

Don’t wait until there’s a crisis before you begin communicating. Speak up early and often, to redistribute the work and avoid taking on too much. You may need to force or train yourself to speak up, but eventually it’ll begin to feel more natural, Kahnweiler says. Learn to say “no” and eliminate destructive patterns of “self-talk.”
2. **Pace yourself with people interactions.** Introverts often feel relieved when interactions with others are finished and sometimes even feel drained after these interactions. Extroverts, on the other hand, feel energized by positive interactions with others.

If you’re an introvert, don’t be afraid to allow extra “alone time” in your schedule, and build in time between meetings or interactions to decompress and allow yourself time to think. You need this time to organize your thoughts and recharge for the next meeting or interaction.

3. **Don’t rely on e-mail as a primary mode of communication.** Sure, e-mail is safe and sometimes less “draining” to communicate with others. But e-mail is also often harmful and counterproductive as a personal management tool, Kahnweiler warns. You should not use e-mail for:
   - Saying anything that you wouldn’t say to the person directly;
   - Resolving conflicts; or
   - Management tasks like discipline.

Also, if you exchange more than three e-mails with someone on a single subject, pick up the phone and call him. E-mail doesn’t relate the nuances you get from voice and face-to-face communication. “E-mail is a multiplier of misunderstanding,” Kahnweiler says.

4. **Accentuate your positives.** Introverts have certain distinct characteristics that are great strengths in managing others:

   - A calming influence -- Stressed-out lab employees will benefit from an introvert’s low-key demeanor, coupled with a PI’s tendency to be well-prepared.

   - Thinking deeply first, then speaking -- Introverts tend to think carefully before they speak up. This leads to more insightful and well-prepared problem solving.

   - Meaningful interactions -- Introverts desire more meaningful interactions with others, cutting down on the small talk and making the most of lab meetings.
Don’t Lead Through Intimidation: 5 Signs for Self-Assessment

Although introverts are less likely to lead through intimidation than other personality types, many PIs can unknowingly intimidate their staff. This is a very harmful and unproductive -- and possibly toxic -- management style. Are you unknowingly intimidating your staff? Ask yourself five key questions:

1. **Do you rely on one person or only a few people?** If you answered yes, you’re creating a perception of favoritism. You may inadvertently block out the other lab employees. Solution: Broaden your communication efforts over a few months, and try to make it a habit to speak to each employee the same amount and delegate the same level of tasks to each lab staffer.

   Of course, if you have just a few lab team members, relying on the one or two people all the time is unavoidable. This really depends on the size of your lab.

2. **Do your employees not speak up at meetings?** If your lab staffers aren’t speaking freely during meetings, they’re most likely too afraid to do so. Solution: End each meeting with an open-ended question, such as, “What are you going to do differently as a result of this meeting?” Then, give each employee a chance to speak.

3. **Do your employees give in too quickly to your opinions?** Again, if your employees are quickly agreeing with your opinions, it’s probably because they’re too afraid to disagree with you. Solution: Say something like: “You’re accepting my idea that easily? What about...” Argue the other side to indicate that you want everyone to speak their minds freely and that you’re open to -- and encouraging -- opposing ideas.

4. **Do your employees seem like they lack confidence?** Do your lab staffers seem to wait for you to reject their ideas? This lack of confidence tends to happen when you make it a practice to poke holes in their ideas or arguments right away. Solution: Finish or “complete” their idea for them, or take the idea to the next level. Your employees will feel pleased that you not only understood, but also you helped them understand their own thinking better.

5. **Do few people come to you with issues or concerns?** This is a huge red flag that tells you about how your staff feels about you as their leader and supervisor. Solution: Maintain an “open-door” policy, both
literally and figuratively. You may even need to set aside specific time for each employee to voice his concerns, problems and issues.

Of course, there are times when a more authoritative and intimidating leadership style is appropriate. Typically, these times are only those of crisis. A “command-and-control” management style is appropriate for emergency situations, such as an accident in the lab. This management style involves you making the decisions and telling your staff how to carry them out in a very direct manner.

In less dire situations, you can use a “command-and-execute” management style, which involves you needing to take over a task that you originally delegated to one of your employees. This style is appropriate when a lab employee lets you down at crunch time, and you need to step in and redo his work. If you have to use this technique, make sure that you offer coaching and encouragement after the crisis is over -- otherwise, this tactic is demoralizing and intimidating to your staff.

Another management style is “consensus-building,” where you communicate a vision and want your team to help in deciding what goals to set and the best ways to achieve them. As the PI, you act as the facilitator and make your decisions based on consensus.

“Coaching” is a management style involving one-on-one mentoring to help your lab employees develop important skills. You study each employee’s performance, and then offer advice and suggestions for improvement in a positive, supportive manner.

**Recognize Burnout in Your Lab: 9 Signs**

Burnout is a serious issue in lab environments, and not just for you, but for your staff as well. Often, awareness is the key issue to addressing burnout, says Alan H. Rosenstein, MD, MBS, medical director at Physician Wellness Services.

“If you’ve worked under stressful conditions for your entire career, you may not even recognize that it’s influencing your behavior,” Rosenstein notes. “And even if you do, you may react by saying you know how to handle it.” Burnout is sometimes confused with depression, but duration can determine the difference -- burnout
is usually a short-term condition, while depression can last weeks, months or longer.

Intensity is another determining factor. “With burnout, there are things you want to do, but you can’t make yourself do them. With depression, you don’t care at all,” explains Shari LeDonne Frisinger, president of CornerStone Strategies, LLC.

Here are the nine major signs that can indicate burnout:

1. **Disinterest in tasks and activities that are normally of great interest.** “Burnout itself is a feeling of extreme fatigue and disconnection brought on by a period of over-commitment, and it often manifests as a lack of interest in the things you used to love,” says Jay Forte, head of the management consulting firm Humanetrics in Louisville.

2. **Disengaged and disconnected from family, friends and things that used to be important to you.** “Self-preservation kicks in when you’re dealing with burnout, and takes over your rational mind,” Frisinger explains. “There’s apathy where there was once passion and excitement, because you become resigned to the status quo.”

3. **Trouble staying focused on conversations, activities and tasks.** For example, you find yourself reading the same passage in a grant proposal over and over – and you never do fully understand what it says.

4. **Irritability about normally inconsequential events.** Conversely, you might see apathy for things that should get your irritated or angry, Frisinger says.

5. **Symptoms of chronic fatigue without any specific contributing event.** That might explain why a lab assistant who isn’t working longer hours still just can’t seem to stop yawning during your morning meetings.

6. **Feeling helpless and loss of control.** Your funders are going to decide whether to continue your grant based on their own selfish motives and not based on the quality of your work, it suddenly seems. It’s all just politics, right? So why bother, right?
7. **Reduced resistance to colds and the flu.** It may not be “the season.” It may be that your burnout-addled body just can’t fight back like it used to. Your mind and body can only handle so much stress and hard work. When you put too much pressure on yourself for long periods of time, your physical and mental selves may ultimately have no choice but to push back.

8. **Sleeplessness and dreaming more – and more vividly – than before.** This is your subconscious telling you that you’re overwhelmed.

9. **Loss of taste in eating.** Although there can be many physical symptoms of stress and burnout -- including loss of appetite -- chronic health conditions that are out of the normal range, “such as chronic sore throat, joint pain, stomach or abdominal pain, headaches, angina, or vision challenges,” are not burnout, Forte warns. These types of ongoing, persistent symptoms could indicate a serious health problem.

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**Delegate Your Way to Success**

Delegation -- like leadership -- is a bit of an art form. Mastering the art of delegation will not only help you to achieve greater success in your lab and personal career, but it will also create a team atmosphere that utilizes the unique talents of each lab staff member. Delegating effectively enhances lab productivity, ensures timely data collection and prevents rushing to meet deadlines.

According to **Bryan Helwig, PhD**, the art of delegating has three critical components:

1. **Internal collaboration.** You must create an environment in which you and your staff scientists work together.

2. **A “team” mentality.** Get all your lab staff members to participate actively in shaping the project.

3. **Evaluation.** An evaluation component is important throughout the project and after completion. Involve all lab staffers and yourself in the evaluations – but keep the evaluation component focused on the work itself, not the individuals.
Delegating Vs. Micromanaging: How to Tell the Difference

Because science depends on “controls,” many PIs will tend toward controlling projects and lab teams. PIs who are too afraid to let go of this control and delegate will instead micromanage. When you’re micromanaging, you are:

- Hovering;
- Taking back delegated tasks;
- Not trusting your team; and
- Asserting control over the project.

Conversely, when you’re delegating, you are:

- Clear;
- Available;
- Breaking projects into sections;
- Setting goals and key due dates; and
- Tracking progress.

Delegating effectively takes some fundamental understanding of your institution’s expectations and your own vision for the lab. Understand your institution’s expectations concerning grants, committees, manuscripts, internal deadlines, reports, service-to-science and teaching, so that you can communicate these goals clearly to your lab team, Helwig says.

Also, clearly communicate your vision for the lab to your team. Write down the vision, and ensure that each staff member understands the purpose of your work. Then, you can set out your goals and action plan. You might take these goals and actions from your grant proposals and project objectives.

Finally, create a feedback loop, Helwig advises. Encourage and solicit feedback from your lab team continuously throughout the project. Effective delegation depends on open communication and proper feedback.

**Remember:** Your feedback loop is an integral part of your “open-door” policy.
8 Steps to Delegate Effectively

If you often struggle with delegating -- or too often find yourself doing much of the work yourself -- a few simple steps can help you to hone your delegation skills. Helwig recommends the following eight steps to master the art of delegation.

1. **Identify what you can and can’t delegate.** Don’t delegate tasks or responsibilities that require your specific expertise, that relate to patents or exclusive knowledge, that involve seniority or authority issues, or that involve regulatory guidelines. But consider delegating all other tasks, including all those that you feel one of your lab team members can handle just as well -- or better -- than you.

2. **Choose the right employee for the task.** To delegate properly, you must take the time to thoroughly understand your lab employees -- particularly their strengths, weaknesses and unique skills. Based on your understanding of your team, delegate tasks to the right people. And don’t underestimate your employees’ potential, and instead always give your staffers just a little more than you think they can handle.

3. **Delegate whole experiments, instead of piecemealing.** Assign a whole experiment to your employee, instead of delegating single experiments of a protocol. Doing so helps to boost your staff’s feelings of contribution, autonomy and recognition.

4. **Set clear due dates and end points.** Give firm due dates, but remain flexible in adjusting those due dates and end points to allow for unforeseen circumstances. Explain to your employee why you need a task completed by a certain date and how this pertains to the bigger picture. Help your researcher to prioritize the task among his other responsibilities.

5. **Clarify responsibilities.** Clearly explain the who, what, when, where and why of the task or goal. Provide these details in both verbal and written form. You can even create “assignment sheets” for your staff to boost understanding. Also, ensure understanding by offering visuals, asking the employee to summarize the task, relating the task to the larger goal and explaining the theory behind the project.

6. **Keep an “open door” policy.** As part of maintaining a feedback loop, you must be available and approachable to your team. Arrange weekly lab meetings to track progress and get feedback without
micromanaging. Also, utilize a centralized lab tool like an electronic calendar to keep all staff members in the loop on due dates, end points, task assignments and other details.

7. **Handle problems in real time.** Problems will inevitably arise, so address concerns immediately. Allow some leeway for failure, considering the nature of science as hypothesis-driven and unpredictable. At the same time, hold your staff accountable for missed deadlines or poor work performance. Be assertive but fair and diplomatic. Also, evaluate results continuously to pinpoint not only where failures occurred, but also what worked well.

8. **Acknowledge and reward.** Ensure that you make your team feel appreciated and recognized for their work. You can reward your team using a simple “thank you,” bringing lunch to the lab or arranging a small get-together.

**Understand the Unique Delegation Pitfalls for Each Lab Employee**

You likely have several lab staffers who play certain roles in your lab team. Each position carries its own inherent dangers when you’re delegating. For example, your lab coordinator is easy to overload with work. Your project leader -- whether he’s a post-doc, senior grad student or lab technician -- often feel a time crunch. Bench scientists need intellectual challenges, while new employees benefit from hands-on learning.

Pay attention to these individual concerns, looking for warning signs that your lab team members are feeling some boredom, stress or nervousness. You must delegate fair and equitable workloads to your team members. Learn to sense when you’re overloading an employee by looking for signs like missed deadlines, poor performance, tension and stress, and resistance to delegated tasks.
SECTION 3: What You Need to Know About Foreign Visas & Export Controls

As the leader of your lab staff, you can’t just rely on your HR department to stay up-to-date on immigration laws. Many labs have foreign post-docs and grad students who are working in the United States while on visas. Staying current on what’s happening with immigration and visas can help to ensure that you don’t lose one of your staff members before their work is finished.

Visas are divided into two major categories: non-immigrant and immigrant, according to immigration-law attorney Adam Frank, with the firm Leavy, Frank, & Delaney, LLC, based in Bethesda, MD. Key issues to stay abreast of include visa changes, updates, waivers and backlog adjustments. (See Appendix E for a table of visa types.)

Non-Immigrant Visas

J Visas: The J-1 Exchange Visitor visa is for students, as well as for short-term scholars, professors, researchers and specialists. This visa has a five-year maximum stay with a two-year home residency requirement. This means that a foreign scientist or student in the United States on a J-1 visa can stay for no longer than five years and must go back to his home country for at least two years at the end of his stay.

But there is a waiver that can eliminate the residency requirement. The waiver applies to individuals who:

• Receive money from the U.S. government, their home country’s government or an international organization in order to come to the United States on a J-1 visa;
• Have a skill they’re working on or an area they’re working in that’s on their home country’s “skills list;” or
• Are coming to the United States for graduate medical education.

O Visa: The Person of Extraordinary Ability O-1 visa (and the Accompanying Personnel O-2 visa) is typically tough to get but doesn’t have the same home-residency issues as the J visas. The initial visa is valid for
three years, and then the visitor can renew the O-1 visa in increments of one year.

The O-1 visa is for foreign nationals who have “extraordinary ability in the sciences, arts, education, business or athletics.” They must prove this “extraordinary ability” by proving they’ve “sustained national or international acclaim.”

**TN Visa:** The Trade NAFTA TN visa is specifically for citizens of Canada and Mexico who are coming to the United States to perform professional services for a sponsoring employer in a specific position for a fixed time period.

**H Visas:** H visas are perhaps the most common for the foreign students and scientists you work with. In particular, the Temporary Worker in a Specialty Occupation H-1B visa is the top visa type. The H-1B visa allows foreign nationals to come to the United States to perform professional services for a fixed time period with a sponsoring employer.

The H-1B visa lasts for just three years, with an option to extend it for another three years. Further extensions are sometimes possible, but the standard is a six-year maximum stay.

**Immigrant Visas**

**EB Visas:** These are immigrant visas and include EB-1 through EB-5 (First Preference through Fifth Preference). EB-1 visas are reserved for “persons of extraordinary ability,” similar to the non-immigrant O-1 visa.

**Your 4 Biggest Foreign-Visa Challenges**

Although your HR department will likely handle much of the paperwork and most of the nuts-and-bolts of foreign visas at your institution, you as the PI will face several challenges. Certain problems can seriously slow down visa processing, leading to delays in getting much-needed help in your lab.
1. **Prevailing Wage:** When you write the foreign visitor’s job description, keep in mind that the U.S. Citizen and Immigration Services (USCIS) is reading it to determine whether the person qualifies and whether the prevailing wage is correct or should be higher. Therefore, you need to write the job description as easy to read as possible, in layman’s terms, so that it doesn’t look more complex than the job actually is. If the job is an entry-level position, say so.

2. **Visa Caps:** The H-1B visas are capped at just 65,000 per year, but this cap typically does not apply to universities, government research organizations and qualifying non-profits. What you need to be careful of is when you have a foreign national working at your institution who is also working at a private, for-profit company or with a contractor, both of which are likely subject to the cap. Also, an individual on an H-1B visa cannot transfer from working at your cap-exempt institution to a cap-subject employer.

3. **Background Checks:** The process for background checks and the required in-person interview takes weeks, if not months. So when you’re planning work for a foreign national who is in the process of applying for a visa, you need to ensure that he’ll arrive to work at your institution on-time.

   Unfortunately, background checks -- especially Visa Mantis Checks and Visa Condor Checks for individuals from certain countries -- often slip through the cracks, particularly when an embassy submits a background check to the FBI and CIA but fails to follow up on it. Months can go by before the embassy thinks to follow up, so you have to stay on top of the process and contact the embassy to ensure that everything is moving along smoothly.

4. **Export Controls:** Export controls deal with the transfer of certain information or technologies -- “deemed exports” -- to other countries. The reason why you need to worry about export controls is that under federal law, giving a foreign scientist information or access to technologies is the same as giving it to his country of origin.

   Export-controlled items are typically those with military purposes or those that have potential terrorist uses, such as bombs and deadly viruses (or the information to create or use these items). Export-controlled countries are typically those that the U.S. government considers “state sponsors of terrorism” or the “T5” countries -- Iran, Cuba, the Sudan and Syria.
If you have a scientist coming from a terrorist or terrorist-supporting country, or if you work with any export-controlled technologies or items, you may need a government license to proceed with the visa process.

Multiple federal agencies regulate export controls:

- U.S. Department of State -- Directorate of Defense Trade Controls (DDTC)
- U.S. Department of Commerce -- Bureau of Industry and Security (BIS)
- U.S. Department of Treasury -- Office of Foreign Assets Control (OFAC)
- U.S. Department of Defense, Department of Energy, Department of Homeland Security, Nuclear Regulatory Commission and Customs

Export controls vary on the type of sanctions involved. For example, OFAC sanctions include “comprehensive” for countries like Cuba, Iran and the Sudan, or “regime-based” for the Balkans, Belarus, Iraq, Liberia and Zimbabwe.

Other sanctions are “limited programs” for Burma, Syria, North Korea, Cote d’Ivoire and the Democratic Republic of the Congo. Still others are “list based,” such as for Specially Designated Nationals, embargoes, “denied lists,” and so on.

Why You Should Care About Export Controls

For exports and “deemed exports,” PIs tend to face the greatest risk in certain areas of concern. These include:

- **Collaborations or discussions with professional colleagues** — Of course, most of your activities on campus aren’t “controlled” under the export regulations, but if you’re having discussions about information or technologies that involve export controls, that’s a potential problem.

- **Sharing data, materials or software** — If the items are controlled and not available in the public domain.
• **Transporting or shipping items or transferring technology that is controlled to a foreign country** — If the PI is conducting fieldwork in a foreign country, even taking a laptop can become problematic if it contains data or software that is controlled.

• **Peer reviews for foreign nationals from sanctioned countries** — This is an issue for only a few countries, usually terrorist-supporting countries like Iran or Syria.

• **Performing defense services** — This includes providing assistance including training to foreign persons in the design, development, engineering, production, manufacture, assembly, testing, repair, maintenance, modification, pre-militarization, construction, processing or use of a defense article.

• **Visiting scientists from foreign countries** — You must have protections in place to ensure that these visitors don’t inadvertently have access to any export-controlled or sensitive work.

• **Travel to foreign countries, including fieldwork** — Be especially concerned with what you take with you to certain foreign countries. For example, researchers may need a license to perform work in countries like Iran or the Sudan, as well as a license to take the needed equipment. Even simple GPS devices are problematic in some countries.

• **Technology and materials transfer** — Anytime you ship something abroad, take technology out of the country or deliver it to a foreign national within the United States who then returns to his home country, you can have an export-controls problem.

• **Faculty startup companies** — If you have a connection to a startup company, the information is more proprietary and not necessarily in the public domain. Especially if the company’s work is defense-related, you may have an export-controls issue.

Thankfully, there are several major exclusions from the export controls that tend to untie your hands: the fundamental research exclusion (FRE), the educational information exclusion, public domain/publicly available information, humanitarian activities, national security, and full-time employees.
**Educational Exclusion:** This applies when the information consists of general scientific, mathematical or engineering principles commonly taught in universities and in your university’s catalog courses.

FRE: Under this exclusion, “fundamental research” is defined as: Basic and applied research in science and engineering, the results of which ordinarily are published and shared broadly with the scientific community, as distinguished from proprietary research and from industrial development, design, production and product utilization, the results of which ordinarily are restricted for proprietary or national security reasons.

If you need to prove that the FRE should apply to your situation, you must show documentation of your due diligence in determining that the information qualifies as basic research. Even if you don’t need any licenses, you’ll need to document the following:

- The funding source;
- Access to proprietary and controlled information;
- Foreign collaboration, travel, fieldwork, etc.;
- Solicitation requirements; and
- Contractual terms and conditions of the award.

**Public Domain Exclusion:** This exclusion allows you to share information with foreign individuals and entities, if the information is publicly available and accessible. This information can include technology or data found in patents that are publicly available in any patent office, conferences that are generally accessible to the public, publicly accessible libraries, and foreign patent applications filed after a U.S. patent.

**Bona Fide Employee Exclusion:** This excludes certain foreign faculty members, primarily “foreign individuals who are full-time regular employees of U.S. institutions of higher education with permanent abodes in the United States throughout their employment,” the regulations state.

The bona fide employee exclusion does not apply to foreign nationals from prohibited countries, such as Iran, the Sudan and other terrorist-supporting countries, as well as China. The exclusion also doesn’t apply to defense services (category XV spacecraft systems, software source code, controlled technical data, etc.) and foreign graduate students.
For ongoing compliance with export controls, you should alert your institution’s export control office or sponsored projects officer when there is a change in the project’s scope, change in the project personnel or parties or an invention disclosure. Also, notify your export control office if there are plans for foreign travel, if you’re expecting a visiting foreign scientist, or if you plan to ship export-controlled equipment, material or software overseas.
SECTION 4:
Develop Your Presentation Skills for Career Success

Giving talks and presentations is an essential -- and unavoidable -- part of your work as a PI. But strong presentation skills don’t come naturally for most people, and you’ll likely need to work on these skills diligently and over time.

There are numerous advantages to becoming a skilled presenter, including benefits for your career, research and lab, says Dr. Heather Duffy, an award-winning speaker and assistant professor of medicine at Beth Israel Deaconess Medical Center. Strong presentation skills enable you to communicate your research to others in a clear and exciting manner, as well as encourage scientific collaboration and interaction with your colleagues, industry stakeholders and grantors.

The most important part of giving a great presentation is proper preparation. Follow six crucial steps to preparing for an excellent talk:

1. **Understand your audience.** Your audience demographics will determine how you frame your talk, present your data and pace your presentation. For most scientists, oral presentations fall into one of three major categories:

   - *Departmental works in progress* -- include an audience consisting of your colleagues, usually working within your discipline, such as division or department chairs, students, post-docs and lab technicians.

   - *Invited faculty talks* -- include an audience consisting of more distant colleagues, sometimes outside your discipline, who may be potential collaborators and grant or paper reviewers, or students, post-docs and lab technicians who might work for your lab someday.

   - *Conference presentations* -- involve similar audience demographics as invited faculty talks, but also tend to include audience members who are less knowledgeable about your discipline, or sometimes science in general.
2. **Specify your message.** Each presentation should have a single main message. State this message clearly within the first or second slides. This will capture the audience’s attention and fascination with your topic. In addition to clearly stating the main message of your presentation, your title slide should include your full name, position title and affiliation.

If you’re giving a conference talk in which the audience might include non-scientists, use the next few slides to outline some background information, bringing some context to your main message. In subsequent slides, dive right into the data. Don’t talk about the methods first, but instead discuss the methods as you present the data to keep your presentation interesting and stimulating at all times.

*Mistake:* Don’t use text-heavy paragraphs or small font sizes in your data and text slides. Your audience will become distracted, and audience members toward the back of the room probably won’t be able to read your slides at all. Instead, use bullet points and lists, and provide well-placed, clear spaces between your main points throughout the presentation.

Make your slides readable, especially your data slides. Try to use only 10 to 15 slides for each 10 minutes of presentation time.

Your conclusion slide should revisit the main message of your presentation, and then you can finish with a final slide of acknowledgements. Your acknowledgements should include your lab members and the individuals who did most of the work you’re talking about, your collaborators, and your funding sources.

3. **Know your time limits.** Although a conference talk might last just 10 minutes, another presentation might last 30 minutes to one hour. Plan out your presentation so that it fits well in the set timeframe, and try to plan one slide per minute for your talk.

Also, allow sufficient time for audience questions if that’s part of the talk. If you’re giving a 60-minute presentation, you would typically allow 15 minutes for a Q&A session at the end. This means that you would plan a presentation that’s actually only 45 minutes.

4. **Know yourself.** Understand your own quirks, limitations, habits and fears. Does public speaking make you nervous? Are you easily distracted and flustered by an audience member interrupting to ask a question? Be
aware of any issues before the presentation so you can practice dealing with them before the talk.

5. Get used to using any presentation tools. Try to get comfortable with any presentation equipment that you’ll need to use during the talk. Practice connecting any technology or devices like projectors, laptops and other tools. Also practice using a laser pointer, if you plan to use one during your talk.

6. Practice, practice, practice. Practice your entire presentation several times during the week before the talk. Aim to perform at least three full “dress rehearsals” to reduce your anxiety, get rid of your public-speaking jitters and perfect your presentation, Duffy advises.

As part of your practicing, notice your own body language. Ensure that you have strong posture, because this tells your audience that you’re confident and the authority on the topic. Also, speak up and ensure that the entire audience can hear you clearly. If you have a quieter speaking voice, use a microphone. Face the audience at all times -- never turn your back on the audience. Make your body language “open.”

Additionally, practice your cadence and avoid using too many words. Don’t let your voice rise at the ends of your sentences, because this makes you sound tentative.

Wear proper attire, such as slacks, blouses, blazers, suits, skirts, ties and dress shoes -- never jeans or sneakers, no matter the setting or audience. And don’t wear anything sexy.

Tips to Survive the Q&A Session:

- Watch the audience to see who raises her hand first, second and so on, so you can call on the audience members in order.
- When you’re answering a question, look directly at the audience member who asked it and don’t gaze around the room or look at your feet.
- Allow yourself a few moments to formulate your answer.
- Try to provide concise, clear answers and avoid rambling or running off-topic.
- If you don’t understand, ask the audience member to rephrase or repeat the question.
- Admit that you don’t know the answer up-front, and don’t try to fudge the answer if you aren’t sure what it is.
Proper time-management and organization skills don’t come naturally to all professionals. In fact, many new PIs struggle with combating procrastination in the lab. Procrastination is a bad habit developed over time, often developing into a vicious cycle, according to Rita Emmett, author of The Procrastinator’s Handbook.

The feelings of guilt and anxiety that come from putting off important tasks can take an emotional toll. You end up expending more energy on the dread and anxiety of avoiding the task than you would spend on doing the task itself. And when you expend this energy fretting over the task you need to do, you’ll again put it off until you have more energy to do it.

**Key:** You must recognize and acknowledge that you’ve entered this procrastination cycle, and then break the cycle. Force yourself to begin working on the dreaded task, Emmett advises.

Moreover, forgive yourself for the procrastination, because doing so will help you to get back on track sooner. A study of undergraduate students by Canadian psychologists at Carleton University in Ottawa found that the students who forgave themselves for procrastinating over studying for a mid-term actually ended up preparing earlier and better for the next test than the students who still carried guilt.

**Try the ‘STING’ Strategy**

Forgiving yourself and letting go of the guilt won’t usually cure procrastination, however. Emmett suggests that you try the “STING” approach to break your bad procrastination habit:

- Select a time to start the task you’ve been putting off. Don’t wait for “the right moment,” but instead schedule a time. If you’re putting off a larger task, such as writing that important grant proposal, you can begin by scheduling one hour each week at first to get moving on it.

(CONTINUED...)
Identify the Psychological Sources of Procrastination

Sometimes, procrastination comes from psychological sources -- namely, fear and perfectionism. High achievers like PIs often have a fear of success, which can become a fertile breeding ground for procrastination, Emmett says. For example, you might fear that if you win the grant, you won’t be able to deliver on the project. So, you procrastinate over writing the grant proposal.

Likewise, perfectionism can be a powerful cause of procrastination. For example, you may put off reviewing your post-doc’s report because you know that the post-doc’s reports will require a lot of editing and re-writing.

**Strategy:** Identify and name your fears, and then discuss them with someone or yourself, Emmett recommends. Write up a list of skills or resources needed to dispel the fears. For instance, if you have a fear of giving feedback to your post-doc, write yourself a script of what to say. Or, if you’re fretting over delivering on that research project, make an outline of what kind of mentoring or help you’ll need to be successful.

Another strategy is to itemize your to-do list each day. Label each task for its priority level:
A - most crucial tasks (choose these tasks first)
B - important tasks (choose these second)
C - tasks with minimal value (do these only if you have enough time)
D - tasks with absolutely no value (try to get rid of all these tasks)

You can take all “quickie” items -- those that take less than one minute to do -- and do those first to pare down your to-do list. Also, assign deadlines to all tasks, because you’ll be more likely to get it done. If you schedule a task for “as soon as possible,” you’re more likely to procrastinate.

**Manage Interruptions & Distractions**

Continuous interruptions throughout your day can also inhibit your productivity in the lab. On average, PIs are distracted about every eight minutes, according to Don Wetmore of The Productivity Institute. These interruptions can not only take you off-task, but they also create unproductive lag-time while you’re trying to get back onto your task.

You may think that the phone ringing or a student peppering you with questions are the biggest types of interruptions, but consider both the external and internal interruptions that distract you from your work. External distractions are things like the phone ringing, e-mail pop-ups and visitors to your office or lab. Internal interruptions are usually your own thoughts, says Janice Russell, a professional organizer with Minding Your Matters in Cary, NC.

*Misconception:* Contrary to popular belief, internal interruptions are typically harder to deal with than external ones.

*Problem:* You’re working on a grant proposal, and you enable your e-mail pop-up windows just in case something important comes in. Within a few minutes, an e-mail pop-up displays a message from a colleague with a link to a news article. You click on the link, and then waste about 15 minutes reading the news clip and responding to your colleague.
**Solution:** Disable your e-mail pop-ups, and instead designate a set time after you’re finished working on the grant proposal to read your e-mails. While you’re at it, turn your cell phone to vibrate and set your desk phone directly to voicemail. Set a personal policy that you’ll answer your phone only when the caller ID displays certain callers.

**Problem:** Your highest priority for the day is to prepare for an important afternoon meeting, but you also need to write two letters of recommendation for students, work on an upcoming conference presentation and complete part of a grant proposal. As you work on your meeting preparations, you struggle with intrusive thoughts about these other tasks.

**Solution:** Schedule blocks of time to work on or complete each of these tasks. First, plan enough time for your highest-priority task of the day, and then plan precise set times to work on the other tasks. Scheduling specific time for each task will help you to focus better on each task at hand, because you won’t be interrupted by thoughts of when you’ll work on the other tasks.

Perfectionism can also cause distractions, Russell says. For example, you’re working on that grant proposal and struggle with finding the right words. You end up working on the proposal far longer than you’d planned to, pushing your other tasks for the day into tomorrow. The best way to combat this problem is to set an exact amount of time that you’ll work on the grant application, and stick to that timetable. Schedule in additional time later in the day if needed to accomplish what you need to.

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**Set Boundaries to Minimize Interruptions**

When you’re considering breaking a boundary and dealing with an interruption on the spot, ask yourself:

- Is this call or e-mail really so important that I cannot attend to it in an hour or two?
- How long will it take to answer the e-mail or phone call?
- How long will it take me to get back to what I was doing before?
Motivate Yourself to Get Started on Important -- But Not Urgent -- Projects

When a task or project is not urgent and won’t yield an immediate pay-off, many PIs tend to put off starting work on it. But when you continue to put off the task, over time it will become urgent, leading to unnecessary stress and often sloppier work.

Nobody but yourself can motivate you to work on important but not urgent tasks, says Valerie Grubb, operations consultant and principal of Val Grubb and Associates in New York. Here are some tips to get started:

1. **Block out the time and put it on your schedule.** Also, try to schedule the task during your peak hours -- usually between 9:00am and noon.

2. **Delegate a small piece of the task.** Delegating a part of the task to one of your staff members can help you to get the ball rolling.

3. **Begin with the smallest, easiest thing.** Starting with the hardest part of a project basically gives you more reason to put it off. Instead, try beginning with the shortest, easiest part to get started on the project and build some momentum, advises Joan Lloyd, an executive coach and management consultant at Joan Lloyd and Associates in Milwaukee.

4. **Break up the project into small, manageable segments.** Give yourself a reward for completing each part. For example, if you have a three-hour project, break it down into smaller “bites” over the course of four or five days.

Here are some other expert time-management tips to follow:

- **Set aside time each night to plan for the next day.** Knowing what you need to do tomorrow means you’ll sleep better tonight. Planning the night before will help you be more rested and focused the following day.

- **Work with a clean desk and a clean work environment.** Working in a messy environment causes
you to spend 60 to 90 minutes each day looking for things or being distracted. Schedule the time you will clean up your work area to enhance your focus.

• **Remove yourself from unneeded distribution, report and junk-mail lists to limit the constant flow of paper.** Then you won’t have to deal with that paper in the first place. Screen the paper so that only the important items end up on your desk.

• **Avoid crisis management mode.** If you wait until the deadline is near, you’ll just have to deal with added stress of rushing and cutting corners to get things done. And you’ll only have to go back and redo them. If you find yourself in that mode a lot, it probably has less to do with your day-to-day responsibilities and more to do with a lack of anticipation.

• **Delegate work.** If you want the task to get done, you don’t always have to do it yourself, especially if you’re pressed for time. Hand some things off to your staff members. Let go of a task you like to control. Give it to the right person, and give him the tools to do it as well as the support he needs. Allow him to make decisions and errors, offering feedback to maximize the results.

• **Create a meeting agenda.** For every meeting, create an agenda with times, and stick to it. Develop action items from the meeting, and determine who’s going to monitor their progress so you’re not rehashing things month after month. Assign time for each item on the agenda. For example: “2 - 2:20 New lab-task rotations: 2:20 - 2:45 Change in security procedures: 2:45 - 3:15.” This will tighten up the discussion and prevent the meeting from running over the allotted time.

• **Set up outside meetings at the appropriate locations.** If you have a meeting with a lab vendor but don’t want to spend a lot of time with them, for example, suggest meeting at a fast-food spot. But if you want the meeting to last some time, choose a nice cushy restaurant. Just by the choice of the venue, you can affect the time and quality of the meeting.

• **Identify how much of your time you spend on the things you do best.** And then, through adjustments, find more time in your day to do those things, which, in essence, significantly increases your results and personal productivity.
• Continue to search for better ways to do things. If you really want to use your time better and are aware of how you’re using it now, you’ll be able to recognize faster and more efficient ways of handling all your daily tasks.

• Create balance. Having too much to do and not enough time to do it leads to stress, frustration, and can put you in crisis-management mode. Learn to balance the seven areas of your life: health, family, finances, intellectual, social, research career and spiritual. If one is out of balance, it will upset the balance of the other areas. Don’t let your health or your family, or your research dominate your time.

• Use a calendar tool to prioritize your time. Take it with you everywhere, to the lab and to social and family engagements. The starting point of control is writing things down rather than trying to remember them. Keep all your appointments and scheduled events — work and personal — in one location. That way you won’t risk scheduling a work responsibility at the same time as a personal commitment.

• Chain yourself to the task. Perhaps it is 2 p.m., and you have to work on that long, tedious, tissue experiment. You want to leave at 5, but you waste nearly an hour and a half looking for some supplies, getting coffee, etc. Then you think, “Well, it’s too late to start on this.” Instead, chain yourself to the experiment area, and tell yourself you cannot move until the work is done. Give yourself a positive treat or reward at the end.

• Plan around interruptions. Maybe most of your interruptions occur early in the day and early in the week. That means if you plan to get a big crucial project done first thing Monday morning, you’re buying frustration because you no sooner get started and the phone rings or a lab tech comes in. Plan your major projects for later in the day and later in the week, when you likely have fewer interruptions.

• Get enough sleep. Studies show that about 75 percent of the population is tired almost any time of the day, mostly because of the way they run their days. Many people experience such highly stressful days because they don’t plan, and they are always reacting to the “stuff” thrown at them. Then they will not get quality sleep. Without a good night’s rest, you won’t be at your best.

• Get up an hour earlier. We all need a wake-up hour. Take advantage of this concept by getting up one hour earlier than usual each day to set the stage for the day. Focus on positive events in your life, do positive visualization. Block the negative messages. Read something positive or uplifting. Take a walk,
exercise, have breakfast, shower. Take control of your mind, body and environment.

- **Decide if you’re a racehorse or a tortoise.** A racehorse is someone who thrives on the overload. Having lots to do is what really gets a racehorse’s adrenaline pumping. A tortoise is someone who functions best at a more measured pace. Racehorses and tortoises accomplish just as much in this world. They just do it differently. If you’re a racehorse, bunch as many staff meetings together as possible. But if you’re a tortoise, you should spread them out.

- **Set a goal.** If you don’t know where you’re going, you’ll never know when you get there. Don’t get caught in the “have-tos,” doing the things you have to do. You won’t ever live a fully satisfying life unless you devote some time to the “want-tos.”

- **Write down the specific action steps to realize your dreams and goals.** Do it each night in your daily planning. For example, perhaps when you go to the lab each day you always park close to the door. So make a point to park on the other side of the parking lot and walk for a little extra exercise. Or maybe instead of taking the elevator to the third floor, you walk up the stairs.

Here are some time-management pitfalls to avoid:

- **Don’t shoot for perfection.** The 20/80 rule is where you put in 20 percent of your time and achieve 80 percent of your result, and then move on. If you suffer the curse of perfectionism, 80 percent isn’t enough; you want your result to be perfect. But it might cost another 80 percent of the time you have left to get that extra 20 percent of result, making it 16 times more expensive.

- **Don’t waste time on unnecessary meetings.** Ask yourself whether you’re needed at a particular meeting. What you’ll likely get out of it, and what you can contribute.

- **Don’t worry about recapturing all the lost interruption time.** Typically, people spend half their workdays getting interrupted. Recapturing just an hour and one-half per day, or seven and one-half hours per week, means you’ve recaptured nine work weeks in one year.
• **Don’t allocate your time based on who demands it most.** Rather, allocate based on who deserves it. But don’t be negative or arrogant as if to imply, “You don’t deserve my time.” Don’t let the demands for your time far outstrip your supply.

• **Don’t say, “I want to get it all done.”** Substitute, “I want to get the most important things done.” That will cause you to focus on quality rather than quantity.

• **Don’t fall victim to “stuff.”** Stuff is everything in that bottomless bucket of demands and responsibilities you can never complete. Throughout your day you didn’t get the important things done because you got caught up in “stuff.” The only way to get more time is to take it.

• **Don’t base your productivity on what you left on the table.** Base it on what you accomplished. As long as the items you did were more important than the ones you didn’t, you’ve had a productive day.

• **Don’t take all your unfinished items and just roll them over to the next day.** Instead, move them forward to the next appropriate day for completion — a day when you know you have time to get them done.

• **Don’t expect your creativity to ignite on-demand.** Despite all your best organizational efforts, remember that creativity is not time-driven.
## APPENDIX A: 
### Table: NIH Grants for New/Early Investigators

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<tr>
<th>Grant</th>
<th>Title</th>
<th>Description</th>
<th>Budget</th>
<th>Funding Period</th>
<th>Participating ICs</th>
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| K01   | Mentored Research Scientist Development Award | The K01 provides support and “protected time” of three to five years for an intensive, supervised career development experience in the biomedical, behavioral or clinical sciences leading to research independence. | Varies; awarded budgets composed of salary and other program-related expenses | 5 years maximum | • NHLBI  
• NHGRI  
• NIA  
• NIAAA  
• NIAID  
• NIAMS  
• NIBIB  
• NICHD  
• NIDCD  
• NIDA  
• NIMH  
• NINR  
• NCCAM  
• NCRR  
• ODS  
• ORIP |
| K08   | Mentored Clinical Scientist Research Career Development Award | The K08 aims to prepare qualified individuals for careers that have a significant impact on the health-related research needs of the Nation. The grant is specifically for individuals who have a clinical doctoral degree, providing support and “protected time” for an intensive, supervised research career development experience in the fields of biomedical, behavioral and translational research. | Varies; awarded budgets composed of salary and other program-related expenses | 5 years maximum | • NCI  
• NEI  
• NHLBI  
• NIA  
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• NIAID  
• NIAMS  
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• NIDCR  
• NIDDK  
• NIDA  
• NIEHS  
• NIGM  
• NIMH  
• NINDS  
• NCCAM  
• NLM |
| K22   | Transition Career Development Award | Provides support to an individual postdoctoral fellow in transition to a faculty position. | Varies, depending on IC. | Varies, depending on IC. | • NCI  
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| K23   | Mentored Patient-Oriented Research Career Development Award | Supports the career development of investigators who have made a commitment to focus their research endeavors on patient-oriented research. | Varies; Award budgets composed of salary and other program-related expenses | 5 years maximum | • NCI  
• NEI  
• NHLBI  
• NIA  
• NIAAA  
• NIAID  
• NIAMS  
• NIBIB  
• NICHD  
• NIDCD  
• NIDCR  
• NIDDK  
• NIDA  
• NIEHS  
• NIGMS  
• NIMH  
• NINDS  
• NINR  
• NCCAM  
• ODS |
| R03   | NIH Small Grant Program | Supports small research projects that can be carried out in a short time period with limited resources. | Up to $50,000 per year | Up to 2 years (not renewable) | Unsolicited:  
• NHGRI  
• NIA  
• NIAAA  
• NIAID  
• NIBIB  
• NICHD  
• NIDA  
• NIEHS  
• NIMH  
• NINDS  
• NINR  

Solicited Only:  
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• NCATS  
• NCCAM  
• NCI  
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<td>R15</td>
<td>Academic Research Enhancement Award</td>
<td>Supports small-scale research projects in the biomedical and behavioral sciences conducted by faculty and students at educational institutions that have not been major recipients of NIH grant funds. AREA aims to: support meritorious research; expose students to research; and strengthen the research environment of the institution.</td>
<td>Up to $300,000 in direct costs, total</td>
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<td>K99/R00</td>
<td>Pathway to Independence Award</td>
<td>Facilitates 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.</td>
<td>K99: Total yearly costs of $90,000 maximum</td>
<td>Up to 5 years: K99 mentored phase 2 years, R00 independent phase 3 years</td>
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<td>• NHLBI</td>
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<td>• NIAID</td>
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<td>• NIBIB</td>
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<td>• NIDCD</td>
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<td>• NIDCR</td>
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<td>• NIEHS</td>
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<td>• NIGMS</td>
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<td>• NIMH</td>
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<td>• NCCAM</td>
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<td>• NCRR</td>
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<td>• ORIP</td>
</tr>
</tbody>
</table>
## APPENDIX B:
### Table: NSF Grants for New/Early Investigators

<table>
<thead>
<tr>
<th>Grant</th>
<th>Title</th>
<th>Description</th>
<th>Budget</th>
<th>Funding Period</th>
<th>Participating ICs</th>
</tr>
</thead>
</table>
| CAREER     | Faculty Early Career Development Program | Supports junior faculty who exemplify the role of teacher-scholars through outstanding research, excellent education and the integration of education and research. | Up to $220,000 per year; Minimum total award $400,000 | 5 years        | • Biological Sciences  
|            |                                          |                                                                                                                                             |                             |                | • Computer & Information Science & Engineering  
|            |                                          |                                                                                                                                             |                             |                | • Education & Human Resources  
|            |                                          |                                                                                                                                             |                             |                | • Engineering  
|            |                                          |                                                                                                                                             |                             |                | • Geosciences  
|            |                                          |                                                                                                                                             |                             |                | • Mathematical & Physical Sciences  
|            |                                          |                                                                                                                                             |                             |                | • Social, Behavioral & Economic Sciences  
|            |                                          |                                                                                                                                             |                             |                | • Office of Cyberinfrastructure  
|            |                                          |                                                                                                                                             |                             |                | • Office of International Science and Engineering  
<p>|            |                                          |                                                                                                                                             |                             |                | • Office of Polar Programs                                                                 |
| EAGER      | EArly-concept Grants for Exploratory Research | Supports exploratory work in its early stages on untested, but potentially transformative, research ideas or approaches. This work may be considered especially “high risk – high payoff” in the sense that it, for example, involves radically different approaches, applies new expertise, or engages novel disciplinary or interdisciplinary perspectives. | Up to $300,000             | 2 years maximum | NSF-wide                                                                 |</p>
<table>
<thead>
<tr>
<th>Grant</th>
<th>Title</th>
<th>Description</th>
<th>Budget</th>
<th>Funding Period</th>
<th>Participating ICs</th>
</tr>
</thead>
<tbody>
<tr>
<td>RAPID</td>
<td>Grants for Rapid Response Research</td>
<td>For proposals with a severe urgency with regard to availability of, or access to data, facilities or specialized equipment, including quick-response research on natural or anthropogenic disasters and similar unanticipated events.</td>
<td>Up to $200,000</td>
<td>1 year</td>
<td>NSF-wide</td>
</tr>
</tbody>
</table>
| RUI   | Research in Undergraduate Institutions | Supports research by faculty members of predominantly undergraduate institutions through the funding of (1) individual and collaborative research projects, (2) the purchase of shared-use research instrumentation, and (3) Research Opportunity Awards for work with NSF-supported investigators at other institutions. | Varies | 1 to 3 years | • Office of Integrative Activities  
• Office of Polar Programs  
• Biological Sciences  
• Education & Human Resources  
• Engineering  
• Geosciences  
• Mathematical & Physical Sciences  
• Social, Behavioral & Economic Sciences  
• Computer & Information Science & Engineering |
APPENDIX C:
Key Resources for NIH & NSF Awards

NIH New & Early Stage Investigator Policies

NIH K Kiosk: Information about NIH Career Development Awards
http://grants.nih.gov/training/careerdevelopmentawards.htm

NIH Pathway to Independence Award (K99-R00)

NIH Small Grant Program (R03)
http://grants.nih.gov/grants/funding/r03.htm

NIH Academic Research Enhancement Award (AREA) Grants (R15)
http://grants.nih.gov/grants/funding/area.htm

NSF Faculty Early Career Development (CAREER) Program

NSF Early-concept Grants for Exploratory Research (EAGER)

NSF Grants for Rapid Response Research (RAPID)
http://www.nsf.gov/pubs/policydocs/pappguide/nsf09_1/gpg_2.jsp#IID1

NSF Research in Undergraduate Institutions (RUI)
### APPENDIX D: OLAW’s New Cage-Space Minimum Recommendations

<table>
<thead>
<tr>
<th>Animal</th>
<th>Cage Dimension</th>
<th>Body Weight</th>
<th>Minimum Size (per animal, squared)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mice in groups</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Height:</td>
<td>All weights</td>
<td>5 in. (12.7 cm)</td>
</tr>
<tr>
<td></td>
<td>Floor area:</td>
<td>Less than 10g</td>
<td>6 in. (38.7 cm)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10 – 15g</td>
<td>8 in. (51.6 cm)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>15 – 25g</td>
<td>12 in (77.4 cm)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>More than 25g</td>
<td>15 in. (96.7 cm)</td>
</tr>
<tr>
<td><strong>Female mouse &amp; litter</strong></td>
<td>Height:</td>
<td>N/A</td>
<td>5 in. (12.7 cm)</td>
</tr>
<tr>
<td></td>
<td>Floor area:</td>
<td>N/A</td>
<td>51 in. (330 cm)</td>
</tr>
<tr>
<td><strong>Rats in groups</strong></td>
<td>Height:</td>
<td>All weights</td>
<td>7 in. (17.8 cm)</td>
</tr>
<tr>
<td></td>
<td>Floor area:</td>
<td>Less than 100g</td>
<td>17 in. (109.6 cm)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>100 – 200g</td>
<td>23 in. (148.35 cm)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>201 – 300g</td>
<td>29 in. (187.05 cm)</td>
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<tr>
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<td></td>
<td>301 – 400g</td>
<td>40 in. (258.0 cm)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>401 – 500g</td>
<td>60 in. (387.0 cm)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>More than 500g</td>
<td>70 in. (451.5 cm)</td>
</tr>
<tr>
<td><strong>Female rat &amp; litter</strong></td>
<td>Height:</td>
<td>N/A</td>
<td>7 in. (17.8 cm)</td>
</tr>
<tr>
<td></td>
<td>Floor area:</td>
<td>N/A</td>
<td>124 in. (800.0 cm)</td>
</tr>
<tr>
<td><strong>Hamsters in groups</strong></td>
<td>Height:</td>
<td>All weights</td>
<td>6 in. (15.2 cm)</td>
</tr>
<tr>
<td></td>
<td>Floor area:</td>
<td>Less than 60g</td>
<td>10 in. (64.5 cm)</td>
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<tr>
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<td>60 – 80g</td>
<td>13 in. (83.8 cm)</td>
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<tr>
<td></td>
<td></td>
<td>81 – 100g</td>
<td>16 in. (103.2 cm)</td>
</tr>
<tr>
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<td></td>
<td>More than 100g</td>
<td>19 in. (122.5 cm)</td>
</tr>
<tr>
<td><strong>Guinea pigs in groups</strong></td>
<td>Height:</td>
<td>All weights</td>
<td>7 in. (17.8 cm)</td>
</tr>
<tr>
<td></td>
<td>Floor area:</td>
<td>Up to 350g</td>
<td>60 in. (387.0 cm)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>More than 350g</td>
<td>101 in. (651.5 cm)</td>
</tr>
<tr>
<td><strong>Rabbits in pairs or groups</strong></td>
<td>Height:</td>
<td>All weights</td>
<td>16 in. (40.5 cm)</td>
</tr>
<tr>
<td></td>
<td>Floor area:</td>
<td>Less than 2kg</td>
<td>1.5 ft. (0.14 m)</td>
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<tr>
<td></td>
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<td>2 – 4kg</td>
<td>3.0 ft. (0.28 m)</td>
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<td>4 – 5.4kg</td>
<td>4.0 ft. (0.37 m)</td>
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<tr>
<td></td>
<td></td>
<td>More than 5.4kg</td>
<td>5.0 ft. (0.46 m)</td>
</tr>
</tbody>
</table>
## APPENDIX E:
Table: Immigrant & Non-Immigrant Visas

<table>
<thead>
<tr>
<th>Visa</th>
<th>Description</th>
<th>Employment Eligibility</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>H-1B</strong> <strong>Temporary Worker in a Specialty Occupation</strong></td>
<td>Individuals in the U.S. to perform professional services for a sponsoring employer in a specific position for a fixed period of time. Employment authorization is granted for an initial period of up to 3 years. Extension for an additional 3 years is possible. Further extensions permitted under certain circumstances.</td>
<td>Employment permitted only with the sponsoring institution that obtained USCIS approval for the visa classification. Prohibited from receiving payments from other organizations. However, individuals may receive USCIS approval to work in H-1B status for more than one employer. Each employer must petition USCIS and receive approval for the employment. USCIS Form I-797A authorizes employment. EAD is not required.</td>
</tr>
<tr>
<td><strong>J-1</strong> <strong>Exchange Visitor (Student)</strong></td>
<td>Individuals in the U.S. as exchange visitors for the primary purpose of studying at an academic institution under the auspices of the U.S. Department of State and a Designated Program Sponsor.</td>
<td>May be employed on the campus of the school in which they are enrolled to a maximum of 20 hours per week with prior written authorization form the Responsible Officer of their Designated Program. May work off campus under limited circumstances provided they have obtained prior written authorization from the Responsible Officer. Employment does not require additional permission from USCIS or an EAD. Eligible for 18 months of academic training following completion of their program (36 months for postdoctoral training).</td>
</tr>
<tr>
<td><strong>J-1</strong> <strong>Exchange Visitor (Short-Term Scholar, Professor, Researcher, or Specialist)</strong></td>
<td>Individuals in the U.S. as visiting researchers or professors under the auspices of the U.S. Department of State and a Designated Program Sponsor.</td>
<td>Eligible to receive payment from the organization listed on SEVIS Form DS 2019 as the source of funds and/or the Designated Program Sponsor for the period of validity as stated on the DS 2019. Under limited circumstances, may receive compensation from other institutions provided prior written authorization from the Responsible Officer of their Designated Program has been secured. Form DS 2019 authorizes employment. EAD is not required.</td>
</tr>
<tr>
<td><strong>O-1</strong> <strong>Person of Extraordinary Ability</strong></td>
<td>Individuals of extraordinary ability in the sciences, arts, education, business or athletics who are in the U.S. to work for a sponsoring employer or organization (O-1), and their accompanying personnel (O-2).</td>
<td>May be employed and compensated only by the petitioning employer or agency through whom the status was obtained. USCIS Form I-797A authorizes employment. EAD card is not required.</td>
</tr>
<tr>
<td>Visa</td>
<td>Description</td>
<td>Employment Eligibility</td>
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<tr>
<td>TN</td>
<td>For citizens of Canada and Mexico. Individuals in the U.S. to perform professional services for a sponsoring employer in a specific position for a fixed period of time.</td>
<td>May be employed and compensated only by the sponsoring employer through whom the status was obtained. Require only an I-94 card as employment authorization or USCIS Form I-797. EAD is not required.</td>
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<tr>
<td>Trade NAFTA</td>
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<tr>
<td>EB-1</td>
<td>This preference is reserved for persons of extraordinary ability in the sciences, arts, education, business, or athletics; outstanding professors or researchers; and multinational executives and managers.</td>
<td>No labor certification required.</td>
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<tr>
<td>Immigrant Visa, First Preference</td>
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<tr>
<td>EB-2</td>
<td>This preference is reserved for persons who are members of the professions holding advanced degrees or for persons with exceptional ability in the arts, sciences or business.</td>
<td>Labor certification required, unless applicant can obtain a National Interest Waiver.</td>
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<tr>
<td>Immigrant Visa, Second Preference</td>
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<tr>
<td>EB-3</td>
<td>This preference is reserved for professionals, skilled workers and other workers.</td>
<td>Labor certification required.</td>
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<tr>
<td>Immigrant Visa, Third Preference</td>
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<tr>
<td>EB-4</td>
<td>This preference is reserved for “special immigrants,” which include certain religious workers, employees of U.S. foreign service posts, retired employees of international organizations, alien minors who are wards of courts in the United States, and other classes of aliens.</td>
<td>No labor certification required.</td>
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<tr>
<td>Immigrant Visa, Fourth Preference</td>
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<tr>
<td>EB-5</td>
<td>This preference is reserved for business investors who invest $1 million or $500,000 (if the investment is made in a targeted employment area) in a new commercial enterprise that employs at least 10 full-time U.S. workers.</td>
<td>No labor certification required.</td>
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<tr>
<td>Immigrant Visa, Fifth Preference</td>
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</tbody>
</table>

### APPENDIX F:
**Table: Immigrant & Non-Immigrant Visas**

Program Director/Principal Investigator (Last, First, Middle):

This report format should NOT be used for data collection from study participants.

**Study Title:**

**Total Planned Enrollment:**

<table>
<thead>
<tr>
<th>TARGETED/PLANNED ENROLLMENT: Number of Subjects</th>
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</thead>
<tbody>
<tr>
<td>Ethnic Category</td>
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<tr>
<td>-----------------</td>
</tr>
<tr>
<td>Hispanic or Latino</td>
</tr>
<tr>
<td>Not Hispanic or Latino</td>
</tr>
<tr>
<td><strong>Ethnic Category: Total of All Subjects</strong>*</td>
</tr>
<tr>
<td><strong>Racial Categories</strong></td>
</tr>
<tr>
<td>American Indian/Alaska Native</td>
</tr>
<tr>
<td>Asian</td>
</tr>
<tr>
<td>Native Hawaiian or Other Pacific Islander</td>
</tr>
<tr>
<td>Black or African American</td>
</tr>
<tr>
<td>White</td>
</tr>
<tr>
<td><strong>Racial Categories: Total of All Subjects</strong>*</td>
</tr>
</tbody>
</table>

*The “Ethnic Category: Total of All Subjects” must be equal to the “Racial Categories: Total of All Subjects.”*
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