

Making the Right Moves

A Practical Guide to Scientific Management for Postdocs and New Faculty

Burroughs Wellcome Fund
Howard Hughes Medical Institute



Second Edition

© 2006 by the Howard Hughes Medical Institute and Burroughs Wellcome Fund
All rights reserved.

09 08 07 06 1 2 3 4 5

Permission to use, copy, and distribute this manual or excerpts from this manual is granted provided that (1) the copyright notice above appears in all reproductions; (2) use is for noncommercial educational purposes only; (3) the manual or excerpts are not modified in any way; and (4) no figures or graphic images are used, copied, or distributed separate from accompanying text. Requests beyond that scope should be directed to labmgmt@hhmi.org.

The views expressed in this publication are those of its contributors and do not necessarily reflect the views of the Howard Hughes Medical Institute or the Burroughs Wellcome Fund.

This manual is also available online at <http://www.hhmi.org/labmanagement>.

Project Developers: Maryrose Franko, Ph.D., and Martin Ionescu-Pioggia, Ph.D.
Editor: Laura Bonetta, Ph.D.
Managing Editor: Patricia Davenport
Production Manager: Dean Trackman
Designer: Raw Sienna Digital
Writers: Joan Guberman, Judith Saks, Barbara Shapiro, and Marion Torchia
Copyeditors: Cay Butler and Kathleen Savory
Indexer: Mary E. Coe

Burroughs Wellcome Fund
21 T.W. Alexander Drive
P.O. Box 13901
Research Triangle Park, North Carolina
27709-3901
<http://www.bwfund.org>

Howard Hughes Medical Institute
4000 Jones Bridge Road
Chevy Chase, Maryland 20815-6789
<http://www.hhmi.org>

Chapter 4

STAFFING YOUR LABORATORY

Staffing your lab with the right people is one of the most important things you can do to ensure the success of your research. This chapter focuses on four laboratory positions—technician, postdoc, graduate student, and undergraduate—although much of the material would be relevant for anyone you bring on board. The chapter reviews issues to consider when determining your staffing needs and suggests strategies to help you manage the process for recruiting, interviewing, and evaluating applicants. The chapter also offers guidance on what to do if you have to ask someone to leave your lab.

For a discussion of the skills needed to manage the people in your lab day to day and get them to work productively, see chapter 3, “Laboratory Leadership in Science.” Also consult your institution’s human resources (HR) staff—they have expertise and resources to help you set performance expectations, maintain performance records, motivate staff and evaluate their performance, deal with behavior or performance problems, and manage issues related to staff promotion and job growth.

GETTING STARTED

The process for staffing your lab will vary depending on the position you are trying to fill and the extent to which your institution’s HR department is involved. Because the hiring process in an academic setting can be protracted and time-consuming, you should involve your department’s administrative staff or your institution’s HR department from the beginning.

Know the Difference Between Employees and Students

It is important to distinguish between employees and students. Generally, technicians and postdocs are considered to be employees of your university or research institution. They receive regular wages and have taxes withheld, and federal and state laws and your institution’s personnel policies apply to their employment. On the other hand, undergraduate and graduate students are just that—students. Although they may receive a stipend for work in your laboratory, their relationship to you in almost

all cases is that of learner to teacher, not employee to employer. For the most part, students work in your lab to gain experience and to learn how to do science, not because they receive monetary compensation.

In addition, employees are “hired” and “fired,” and students are “assigned” to a lab and “released” from it. Although this may seem like mere wordplay, the nuances of these relationships are important because of the legal implications.

Avoid Discrimination

In the United States, many laws—at the federal, state, and local levels—guide and control how you as the employer’s representative work with other employees, particularly those you supervise. These laws determine many aspects of the employer/employee relationship. One very important principle to follow is to avoid discrimination on the basis of an individual’s membership in a protected group or an individual’s protected characteristic. Generally, this means that you cannot discriminate in an employment-related decision (such as interviewing, recruiting, selecting, hiring, training, evaluating, promoting, disciplining, or terminating) on the basis of someone’s race, color, religion, age, sex, national origin, sexual orientation, marital status, mental or physical disability, or other protected status. Work with HR and with knowledgeable people in your department to ensure that you follow the law and your institution’s policies and procedures.

Determine Your Staffing Needs

Your decision to take on staff will depend on several factors, such as the provisions of your start-up package, the stability of your external funding sources, the progress of your research, and even your personal preferences about performing various laboratory tasks. Established scientists caution new principal investigators against rushing out and hiring people just to fill an empty lab. Before you bring on staff, think carefully about the consequences. Will you be able to recruit the caliber of people you need? Can you make the time to train and mentor others? Remember, you need to preserve sufficient time and space for your own work at the bench.

Often, the first person a new investigator hires is a lab technician. This versatile lab member can help you with time-consuming initial tasks, such as logging in and setting up equipment and handling routine tasks that keep your laboratory working. Although your budget may more easily accommodate a junior technician, you might

“

Early in my career, when I couldn't attract top postdocs, I put my energy into graduate students and technicians. The graduate students are like raw lumps of clay that have the opportunity to mold themselves into something really great.

—Thomas Cech, HHMI

”

benefit more by hiring an experienced technician who can help train other staff as they come on board. Some experienced technicians can also contribute in substantive ways to your research project. A technician who is familiar with the administrative processes of your institution can also be extremely valuable.

Consider bringing a graduate student on board once your lab is running and you have the time to invest in training. Working with your technician and graduate student can provide you with additional intellectual stimulation, and when each is able to work independently, you should have more time for grant writing and doing experiments. Hire a postdoc when your main project is well under way and you have enough other projects, so that you can turn one of them over to the postdoc and allow him or her to have a great deal of responsibility.

You may want to be cautious about taking on undergraduates because of the large time investment needed to make them fully a part of the lab. If you decide to take on an undergraduate, consider limiting the initial assignment to one semester. At the end of that time, determine whether the student should continue for a second semester. (Additional considerations for working with undergraduates and other lab members can be found in chapter 5, “Mentoring and Being Mentored.”)

Write the Job Description

The next step is developing a job description for the open position. First, identify and prioritize the initial and ongoing lab tasks for which you need support. Then determine the qualifications needed to best complete these tasks and develop a general plan for allocating the person’s time. Most HR departments have job descriptions that you can use as models. Bear in mind that the position will have to fit within your institution’s established compensation and classification system. The process may be more complicated if unions represent identified groups of employees at your institution.

RECRUITING APPLICANTS

Get the Word Out

Informal methods. Try to recruit by word of mouth. Ideally, you want people to seek you out. Meetings and seminars where you present your work are good venues to reach graduate students and postdocs, as well as lab technicians who are not employed by your institution. Another strategy is to include a statement on your Web site inviting people to contact you if they are interested in working with you. As you get to know students in your classes, you may find some who are interested in learning more about your work and carrying out a research project in your laboratory. In addition, you may be able to recruit graduate students from those who rotate through your lab as part of the curriculum.

Formal advertisements. To recruit postdocs, you may decide to place advertisements in journals such as *Science* (<http://recruit.sciencemag.org>), *Cell* (<http://www.cell.com>), and *Nature* (<http://www.nature.com>), both in hard copy and on the Web. Other resources for advertising are the Federation of American

Societies for Experimental Biology's Career Resources Web site (<http://www.faseb.org/careers/careerresources.htm>), your scientific society's Web site, *Science's* ScienceCareers.org (<http://sciencecareers.sciencemag.org>), and the mailing list servers maintained by professional associations, such as the Association for Women in Science. For any advertisements you place, make sure you follow your institution's policies.

What Do You Have to Offer?

As a beginning investigator, you may find it a challenge to recruit the people you want, especially postdocs and experienced lab technicians. Here are some things you can do to increase your chances:

- ◆ Promote your vision. When you talk to the applicant, take time to identify your vision for your lab. Your excitement about your work and your lab will excite and interest potential staff.
- ◆ Communicate your lab culture. Think about how to create a lab environment that allows you and your staff to work efficiently and harmoniously. If good communication, collaboration, and cooperation are valued concepts in your lab, they can be selling points in recruitment.
- ◆ Convey your commitment to mentoring. Let potential staff know that they will be working directly with you and that you have an interest in helping them in their careers.
- ◆ Offer flexibility where you can. Flexibility, especially about assignments or research avenues, is attractive to most job applicants.
- ◆ Provide a realistic level of reassurance regarding the stability of your funding. Potential staff are likely to be aware that the money to pay their salaries may be coming from your research grants.

What They Are Looking For

Lab technicians. Technicians may be attracted to a beginning laboratory because they are eager for the opportunity to work closely with the principal investigator and are interested in learning new techniques and being included on papers. Good salaries and status (related to publishing papers) may be of prime importance to career lab techs, whereas experience, especially experience that will help them decide whether to go to graduate school or medical school, may be more important to short-term lab technicians.

Graduate students. Graduate students are often attracted to new labs because, like lab technicians, they are eager for the opportunity to work directly with principal investigators. Mentoring graduate students can be time-consuming, especially for the first few months. Therefore, you may want to sign up your first graduate student when your lab is running well and you have time to work with each student properly. Thoughtful mentoring of graduate students early in your career will help you develop a positive reputation and will increase your ability to attract other grad-

uate students. On the other hand, if your first graduate students have negative experiences in your lab, they will quickly share this with their peers, and your ability to recruit students will suffer greatly.

“

When I talk to students about what kind of a lab they should join, I always tell them that it's a very special experience to go into the laboratory of someone who is just beginning an independent research career, because the principal investigator is in the lab all the time working shoulder to shoulder with them. There is a lot of excitement and anticipation about exactly which direction the laboratory will go.

—Thomas Cech, HHMI

”

Undergraduate students. Undergraduate students may want to work in your lab because they are curious about research, perhaps because they have talked with their peers who are having a good experience in a lab and want to find out whether they should consider graduate study. Or they may be looking for academic credit, funding, or recommendations for graduate or medical school. Try to select undergraduates who are motivated to contribute to the productivity of your lab.

Postdocs. It may take two to three years for you to recruit a postdoc with the desired qualifications. Most postdocs are attracted to more established labs because these usually are better launching pads for their careers. Nevertheless, some postdocs might be attracted by your research area, your concern for furthering their careers, or your institution's reputation and geographic location. If you have a good reputation from your own postdoctoral work, you may be able to recruit highly qualified postdocs right away. Having a policy that allows postdocs to take their projects, or some aspect of their projects, when they leave your lab is also a potent recruitment tool.

SCREENING APPLICANTS

Many principal investigators do all the screening for jobs for which scientific qualifications are important but may rely on HR to do the initial screening for administrative positions. However, as a beginning investigator, you probably will not be swamped with applicants, so you may want to screen all the applicants yourself.

When you review résumés, check skills against qualifications and look for transferable skills. Always review résumés carefully—some applicants may inflate their experience. Gaps in employment and job-hopping may be signs of problems.

Tips for Specific Positions

For an applicant to a postdoc position, consider publication *quality*—not just quantity—and the applicant’s contribution. A first-author citation indicates that the applicant probably spearheaded the project. A middle-author citation indicates that the applicant contributed experimental expertise but may have had less to do with the project’s intellectual construct. Although it may not be realistic for a beginning investigator, try to find a postdoc with a record of accomplishment—usually two first-author papers—that indicates he or she will be able to obtain independent funding.

If a technician has contributed to publications, you should evaluate them to determine whether the technician has the ability to contribute intellectually as well as technically to the lab. The résumés of less-experienced lab technicians may not show a record of contributions to published papers or other indicators of productivity. Carefully check references to find out about their capabilities.

For a graduate student, speak informally with other people who have worked with the student, including teaching assistants who may know how the student has performed in a laboratory course. Take the student to lunch and see how articulate, bright, and energized he or she is. When selecting graduate students and undergraduates, remember that a high grade-point average is no guarantee of success in your lab.

Check References Directly

For a variety of reasons, including fear of a lawsuit or hurt feelings and concerns about confidentiality, people rarely write negative letters of recommendation. Therefore, you need to contact applicants’ references by telephone. You may want to talk with HR in advance about your institution’s policies on conducting reference checks.

What to ask a reference. When discussing an applicant with someone who has provided a reference for him or her:

- ◆ Describe the job and the work atmosphere you want to create.
- ◆ Ask short, open-ended questions, and avoid asking questions to which the desired response is obvious.
- ◆ You might want to ask, Why is this person leaving? Is he or she reliable? Would you rehire this person? What are this person’s strengths and weaknesses? What are you most disappointed in with respect to this person?
- ◆ Probe for further information, and ask for examples. Do not settle for yes or no answers.
- ◆ Try to determine whether your lab values are similar to those of the reference, perhaps by asking about the reference’s lab and philosophy. This information should help you decide how much weight to give to the reference.

Types of Interview Questions

Open-ended questions cannot be answered yes or no; for example, “Tell me about yourself.” The applicant determines the direction of the answer.

Directive questions solicit information about a specific point; for example, “What skills do you have for this position?” The interviewer determines the focus of the answer.

Reflective questions solicit information about a past experience that might serve to predict the applicant’s future performance; for example, “Describe a time when you demonstrated initiative.”

Contact all references. You are trying to make a decision about someone with whom you will be spending many of your waking hours—make sure you get the information you need. To correct for bias in the responses of any one reference, make sure you call all of an applicant’s references, even those overseas. Don’t rely on e-mail to make the reference check—you’re unlikely to get the kind of information you’re looking for.

Sometimes, applicants won’t give the name of a current supervisor as a reference. If that is the case, you must respect their request for confidentiality. However, you should probably ask why the applicant doesn’t want you to call. You can also ask for additional references who can provide you with information about this person’s work habits, accomplishments, and history.

Further Screen Applicants by Telephone

You may want to screen promising applicants by telephone before inviting any of them for a formal interview. As with interviewing references, focus on asking open-ended questions. For foreign applicants, open-ended questions are particularly helpful in determining the person’s ability to communicate effectively in English. The appendix (page 96) shows a sample outline that can help you in your phone interviews with applicants. (Consider developing a similar form for talking to applicants’ references.)

INTERVIEWING APPLICANTS

Invite Applicants to Visit Your Lab

After you have completed the initial screening, narrow your list of potential applicants to a reasonable number of good prospects. Then, invite each person to visit your lab for a formal interview. Remember, the initial telephone screening interview is no substitute for this in-person interview. (Your institution may be willing to pay the travel costs of applicants for a postdoc position.) In addition to the interview with you, the applicant should meet informally with other members of your lab or, if this is your first hire, meet with your colleagues, perhaps over lunch or dinner. Also arrange for the applicant to spend some time with other lab members and colleagues without you. For a postdoc position, require that each applicant deliver a seminar to members of your lab or department, and then get their feedback.

Share your requirements and expectations for the successful applicant with the other people you have asked to help conduct interviews. This way everyone will be looking for the same attributes and skills.

“

The presentation [postdoc candidates] give to the lab is key. You can check out their ability in public speaking, which is important because in science a lot of times you are a salesperson. I usually try to ask them some decently tough questions—not to try to stump them, but just to make sure that they can think on their feet, because you have to do that a lot as a scientist.

—B. Brett Finlay, University of British Columbia

”

Conduct a Structured Interview

The goal of the structured interview is to use a standardized set of predetermined questions to gather key information in an efficient, equitable, and nondiscriminatory manner from all qualified applicants. You want to give each applicant a fair opportunity to compete for the position. Your questions should be

- ◆ Outlined ahead of time so that you ask basically the same questions of each applicant
- ◆ Job-related and legal (avoid asking personal questions)
- ◆ Short and open-ended, like those used when checking references
- ◆ Focused and designed to elicit information (avoid asking philosophical questions)

Tailor your follow-up questions to reflect each applicant's responses and to encourage each applicant to provide examples from his or her own experiences.

Topics to Avoid

Most illegal or ill-conceived questions deal with race, color, national origin, sex, religion, disability, or age. You should not ask about sexual orientation, marital status, marriage plans, pregnancy or plans for having children, the number and ages of dependent children, childcare arrangements, or other non-work-related matters. Remember that job-related questions are the only appropriate means by which to determine skills and qualifications. Your HR department can provide more guidance on topics to avoid during interviews.

Develop the Interview Questions

As you develop your questions, think about how to determine whether the applicant has the knowledge, technical skills, and personal qualities that you need. Review the job description you created earlier, the applicant's résumé, and your notes from your conversations with the references to identify any items or information gaps that need clarification in the interview.

“

I ask them, “Why do you want to come to this lab? What interests you? What areas do you want to work in?” I’m looking for people who say they want to broaden their horizons, not those who want to continue doing the same thing.

—B. Brett Finlay, University of British Columbia

”

Sample interview questions. *At the Helm: A Laboratory Navigator* by Kathy Barker (see “Resources,” page 95) contains a list of general questions as well as those geared for specific laboratory positions and for determining specific personal characteristics. In addition, you may want to tailor the following questions to the position for which you are interviewing.

Experience and Skills

- ◆ Tell me about your most significant accomplishments.
- ◆ Tell me the part you played in conducting a specific project or implementing a new approach or technology in your lab.
- ◆ I see you have worked with [insert specific technology or technique]. Tell me about its features and benefits.

Commitment and Initiative

- ◆ Why do you want to work in my lab?
- ◆ Where do you see yourself in five years?
- ◆ What kinds of projects do you want to do? Why?
- ◆ Tell me how you stay current in your field.
- ◆ Describe a time when you were in charge of a project and what you feel you accomplished.
- ◆ Tell me about a project or situation that required you to take initiative.

Working and Learning Styles

- ◆ What motivates you at work?
- ◆ Would you rather work on several projects at a time or on one project?
- ◆ Do you learn better from books, hands-on experience, or other people?
- ◆ Tell me about a project that required you to work as part of a team. What was the outcome of the team’s efforts?
- ◆ How would you feel about leaving a project for a few hours to help someone else?

- ◆ If you encountered a problem in the lab, would you ask someone for help or would you try to deal with it yourself?
- ◆ You may be asked to work after hours or on a weekend. Would this be a problem?

Time Management

- ◆ How do you prioritize your work?
- ◆ What happens when you have two priorities competing for your time?

Decision Making and Problem Solving

- ◆ What is your biggest challenge in your current job? How are you dealing with it?
- ◆ Tell me about a time when you made a decision that resulted in unintended (or unexpected) consequences (either good or bad).
- ◆ Give me an example of a situation where you found it necessary to gather other opinions before you made a decision.

Interpersonal Skills

- ◆ How important is it to you to be liked by your colleagues and why?
- ◆ If you heard through the grapevine that someone didn't care for you, what would you do, if anything?
- ◆ Tell me about a situation in which your work was criticized. How did you rectify the situation?
- ◆ Describe a scientist whom you like and respect. What do you like about this person?

Cultural differences. You may find yourself considering applicants from different cultures whose beliefs, such as those about self-promotion, collaboration, and deference, may differ from the beliefs commonly held in the United States. To learn more about cultural factors, see chapter 5, "Mentoring and Being Mentored." To ensure you are considering all candidates fairly, refer to Kathy Barker's *At the Helm: A Laboratory Navigator*; in that book the author provides a list of useful questions you might ask a candidate, including the following:

- ◆ How do you feel about getting in front of a group and describing your personal accomplishments?
- ◆ How would you respond if a more senior lab colleague took credit for your project?
- ◆ If you did not understand something, would you persist in asking for help even if the principal investigator got annoyed?

“

My favorite questions are, “What do you want to be doing five years from now? Ten years from now? What area do you want to be working in?” These give me an idea of just how mature [applicants] are in terms of how much they have thought about what they want to do and how committed they are.

—Gail Cassell, Eli Lilly and Company

”

Tips for Conducting an Interview

- ◆ Before you begin, try to make the applicant feel comfortable. Make appropriate small talk, offer a beverage, and compliment the applicant on making it thus far in the selection process. Remember that the applicant is also deciding whether he or she wants to work for you.
- ◆ Develop professional rapport, but avoid a social atmosphere:
 - Explain how the interview will be structured.
 - Briefly describe the selection process.
 - Outline the responsibilities for the open position.
 - Convey your expectations about the job. Include values that may seem obvious to you, such as your commitment to lab safety and scientific rigor.
 - Keep in mind the topics to avoid.
- ◆ Take brief notes. Record actual answers to questions, not evaluative or conclusive comments.
- ◆ Listen carefully. Let the applicant do most of the talking.
- ◆ Develop a high tolerance for silence. Give the applicant a chance to think and develop thoughtful answers to your questions.
- ◆ Give the applicant many chances to ask questions. This will give you some insight into what is important to him or her.
- ◆ Never make promises or give commitments, even those that seem innocent to you.
- ◆ Ask the applicant about his or her timetable for leaving the current job, even if you asked it during the telephone interview.

◆ Before ending the interview, do the following:

Give the applicant a chance to add anything else he or she thinks may be important for you to know in making your decision.

Make the applicant aware of the next steps, such as additional interviews and the time frame for hiring.

Thank the applicant for his or her time.

Special Considerations

This section is especially relevant for interviewing technicians, postdocs, and other professional laboratory staff.

Pregnancy. If, during the interview, a well-qualified applicant tells you she is pregnant, remember it is illegal to discriminate against someone because she is pregnant. Familiarize yourself with your institution's policies on maternity leave before making any statements to the applicant about what length of maternity leave would be permitted and whether the leave would be paid or unpaid. Similarly, your institution may have a policy on paternity leave that may apply to an applicant.

Visas. If you are filling a postdoc position and are dealing with foreign applicants, remember that visa rules and requirements are complex and change frequently. Some visa types are more desirable from the perspective of the applicant (e.g., because they allow for concurrent application for permanent residence in the United States). Other visa types are more desirable from the perspective of the employer (e.g., because they are easier to administer). Special concerns for any type of visa may include visa arrangements for a spouse and other family members, requirements to return to the home country, and employment implications. Keep in mind that obtaining a visa can be a very slow and lengthy process. (Obtaining visas to travel to the United States has become even more time-consuming given increased U.S. security concerns and clearance.)

Consult HR, your institution's international office, and your department's administrative staff about visa rules and requirements. They can also help you determine which visa is most appropriate for a given applicant. You can also check the latest information from the State Department (http://travel.state.gov/visa/visa_1750.html) and the U. S. Citizenship and Immigration Services (formerly the Immigration and Naturalization Service, <http://www.uscis.gov/graphics/index.htm>). The site <http://www.visalaw.com> may be helpful. A brief visa primer also is available in *At the Helm: A Laboratory Navigator* by Kathy Barker.

In addition, try to determine the consequences (for you as well as the applicant) if poor performance forces you to ask the postdoc to leave your laboratory. Because this is an extremely complex area of immigration law, it is important that you consult your institution's HR or legal department and follow their advice.

EVALUATING APPLICANTS

Before you begin evaluating an applicant, make sure that you have all the necessary information. Conduct any reference interviews that you were unable to complete before the interview. Gather opinions from others who have met with the applicant. As needed, seek guidance from your department and HR.

Maintaining Objectivity

As in any situation that involves interpreting interpersonal behavior, objectivity in evaluation may be difficult. Nevertheless, try to avoid the following:

- ◆ Relying too heavily on first impressions.
- ◆ Making a decision too early in the interview, before asking all questions.
- ◆ Downgrading an applicant because of a negative characteristic that is not relevant to the job itself.
- ◆ Allowing a positive characteristic to overshadow your perception of all other traits, sometimes called the “halo effect.”
- ◆ Judging the applicant in comparison with yourself.
- ◆ Comparing applicants with one another rather than with the selection criteria (e.g., if you have been interviewing poorly qualified applicants, you may rate average applicants highly).
- ◆ Allowing factors not directly related to the interview to influence your estimation of the applicant (e.g., interviewing during times of the day when you may be tired).

What to Look For

In addition to determining whether the applicant has the qualifications required to perform well in your lab, you should also keep the following points in mind:

- ◆ Consider the “chemistry.” First and foremost, pay attention to your intuitive reaction to the person. Look for a person who is interested in, and able to get along with, others.
- ◆ Ascertain whether the applicant is a good fit. Keep in mind that you are building your team and need people with the skills and personalities to get things done. Look for people who have a track record of productivity and have demonstrated an ability to learn new skills.
- ◆ Seek someone who has a passion for science and a strong work ethic. Enthusiasm, a can-do attitude, and the willingness to go the extra mile are critical attributes.
- ◆ Check the applicant’s career plans. Knowing what the applicant wants to be doing in 5 or 10 years can give you insight into his or her scientific maturity and creativity, as well as his or her commitment to a specific research area.

- ◆ Be certain the applicant is committed to good research practices. Record keeping and reporting results are even more important now than in the past because of patent and other legal issues. Insist on the highest level of scientific integrity from anyone you are considering.

“

If people in the lab had reservations about whether they would get along with someone, I probably wouldn't bring that person in.

—Tamara Doering, Washington University School of Medicine

If people don't seem like they would be fun to work with, I would use that as a reason to turn them down. Even if they have a lot of papers and seem to be very smart, I think you might want to think twice about hiring them.

—Thomas Cech, HHMI

”

Red Flags

Warning signs during an interview that should alert you to potential problems include:

- ◆ Unwillingness to take responsibility for something that has gone wrong.
- ◆ Complaining about an adviser and coworkers.
- ◆ Demanding privileges not given to others.
- ◆ Delaying answering questions, challenging your questions, or avoiding answering them all together. (Humor and sarcasm can be tools to avoid answering questions.)
- ◆ Unless you have been rude, responding to an interview question with anger is never appropriate.
- ◆ Incongruence between what you hear and what you see (e.g., downcast eyes and slouching are not signs of an eager, assertive candidate).
- ◆ Trying to control the interview and otherwise behaving inappropriately.

MAKING THE OFFER

This section is especially relevant for hiring technicians, postdocs, and other professional laboratory staff.

Before you make an offer, check with your department to learn which items of the job are negotiable and whether you are responsible for negotiating them. HR or your department should provide you with institutional salary ranges for the position. In some institutions, HR will determine the initial salary that you can offer. In other institutions, you may be given some leeway within a predetermined range that is appropriate for the job description.

Once you have identified the person you wish to hire, contact him or her by telephone to extend the offer and to discuss start date, salary, and other conditions of employment. (Be sure to check with HR first to determine whether you or they will make this contact and cover these issues.)

Inform All the Applicants

First, inform the person you have selected. If he or she turns down the offer, you can move to your second choice.

Once you have filled the position, let the other applicants know. You do not need to give a specific reason for your decision not to hire an applicant. However, you may state that the selected candidate had better qualifications or more relevant experience or that it is your policy not to disclose this information. Check with HR and your department's administrative staff about policy in this area.

The Offer Letter

After you and the selected candidate have confirmed the job details via telephone, your institution will send the formal offer letter. Usually, it confirms the offer terms, including start date and salary. Coordinate with HR and your department's administrative staff to determine what information to include.

An offer letter to a foreign national may need to include more information. For example, it may need to spell out that employment is contingent on the ability to obtain authorization for the individual to work in the United States and to keep the work authorization in effect. HR or your department's administrative staff will help you follow policies correctly in this type of situation.

ASKING STAFF TO LEAVE

Despite all your best efforts, you may need to ask someone to leave your lab. Before considering dismissal, be sure that you have tried various avenues to help this person be successful in your lab. This may include assistance with scientific techniques and counseling for behavioral issues. Also, be certain that your dissatisfaction is based on objective observations, not your personal biases.

Try to determine whether you think the person would be better off in another lab or should consider another career. For students and postdocs, this usually means talking with that person and his or her faculty adviser or the graduate student committee. It may be best to suggest to someone that research is not for them if you truly believe the profession is not suited to his or her talents or personality. You can provide that person with encouragement and options. For example, *Science's* ScienceCareers.org Web site provides a range of career options for people with bio-science backgrounds (<http://sciencecareers.sciencemag.org>).

There are no hard and fast rules about how a manager should address performance or behavior problems in the lab. However, keep in mind the following, especially if you're thinking about letting someone go:

- ◆ Be fair.
- ◆ Let there be no surprises.

Fairness dictates that lab members receive some type of notice about unsatisfactory performance. Make sure the person knows your concerns and is given a reasonable opportunity to respond and turn things around.

Keep a Record

You should outline and set expectations for the performance and conduct of everyone in your lab. The process is more formal for employees than it is for students.

For technicians, postdocs, and other professionals, job expectations should be made clear. Don't expect your employees to read your mind about what you want them to accomplish and how you want them to accomplish it. Keep good records of your conversations with everyone so that you can track your own efforts and determine whether your staff has met expectations. If a lab member is not meeting expectations, make sure you document your attempts to help the person improve his or her performance or prepare for a new career. Should you ultimately have to terminate this person, these records can help avert external challenges to your decision.

“

When postdocs don't fit in, I try to help them find other positions. Sometimes they realize that this isn't where they belong and they do it themselves. I say, "What do you want to work on? Let's see what we can do." People are different, sometimes things don't work out, and this is not a reason to be defensive. The focus is to help people do what they value.

—Suzanne Pfeffer, Stanford University School of Medicine

Deliver a Warning

Warnings should be delivered by you, calmly and in private. Listen to the employee's point of view and explanation. Develop a plan for addressing the problem with benchmarks and timelines. You may want to commit your action plan to writing. If you provide advance notice, employees will not be surprised when you take forceful action concerning unsatisfactory performance or behavior.

If You Decide to Terminate

An employee with serious work-related problems is a disruptive force and, especially in a small lab, can significantly retard research progress. Although it is not easy to decide to terminate someone, those investigators who have had to release staff say that in retrospect their biggest mistake was not doing it sooner.

To be fair to yourself and your staff and to avoid lawsuits, an involuntary termination should never happen out of the blue unless it is the result of substantial misconduct, such as clear fraud or violence in the workplace. Always avoid firing on the spot. You should find a way to calm the situation so that you don't take precipitous action. A suspension with or without pay may be a good option for the short term while you consider the situation. If you have decided that termination is your only solution, consult with HR as soon as possible to ensure that you are complying with institutional and legal requirements relating to termination and correctly documenting your actions.

Questions to ask yourself before letting someone go. HR professionals recommend that, if circumstances permit, you ask yourself the following questions and document each of the actions before proceeding:

- ◆ Have you given the person at least some type of notice or warning?
- ◆ Have you made it clear to the person what he or she is doing wrong?
- ◆ Has the person received counseling or assistance in learning new or difficult tasks? If so, how much?
- ◆ Are you treating (or have you treated) the person differently from other staff in your lab?
- ◆ Are you following written procedures and institutional policies?
- ◆ Does the documentation in the personnel file support the reason for discharge?

Ideally, you have conducted regular and candid performance reviews with all your laboratory staff and now can use this documentation to help support your decision. (For a discussion of conducting performance reviews, see chapter 3, "Laboratory Leadership in Science.")

How to terminate. Terminating anyone from your lab is a confidential matter and should not be discussed, before or after the fact, with others in the lab. A termination meeting should be conducted by you, the investigator, in your office, in a way that is private and respectful. (You can always ask HR for assistance if you are unsure how to proceed or if you suspect that your employee may act inappropriately.)

Prepare for the meeting. Develop a script and practice it until you can convey the information confidently. Keep in mind that what is said during the termination meeting can become part of the basis for a subsequent challenge. Remember to

- ◆ Be polite.
- ◆ Stay focused on the issue at hand. Get to the point quickly. Explain the decision briefly and clearly. Don't apologize or argue with the employee in an effort to justify your decision.
- ◆ Avoid laying blame.
- ◆ Arrange to have scientific materials and equipment and supplies returned to you, including lab notebooks; protocol books (unless it is a personal copy); lists of clones, cells, and experiments in progress; and keys.
- ◆ Let the employee have an opportunity to have his or her say, and pay close attention to what is being said.
- ◆ Refer the employee to HR or to the office responsible for discussing benefit eligibility.
- ◆ Take notes that document this meeting and convert them into an informal or formal memo to file.
- ◆ Try to part on cordial terms. Science is a small community, and your paths may cross again.

Termination letters and references. As part of final documentation, a termination letter may be required by your institution or by state law. In addition, you may be asked for, or may wish to offer, a reference. Check with HR about proper procedures.

Visa considerations. Consult with HR or your department's administrative staff about visa issues before terminating a foreign national employee. Be certain that you are not legally responsible for continuing to pay the salary of someone no longer working in your lab. Again, it's better to understand these requirements before you hire someone with a visa.

RESOURCES

Austin, Robert D. “Managing Knowledge Workers.” ScienceCareers.org (April 26, 2002), http://sciencecareers.sciencemag.org/career_development/previous_issues/articles/1470/managing_knowledge_workers.

Barker, Kathy. *At the Helm: A Laboratory Navigator*. Cold Spring Harbor, NY: Cold Spring Harbor Laboratory Press, 2002.

Federation of American Societies for Experimental Biology. Career pages, <http://www.faseb.org/careers/careerresources.htm>.

Harmening, Denise M. *Laboratory Management: Principles and Processes*. Upper Saddle River, NJ: Prentice Hall, 2003.

HRhero. “The Art of Firing,” parts 1, 2, and 3, <http://www.hrhero.com/topics/fire/fire-art1.shtml>.

Rehrig, Norita H. *Six Steps to Successful Interviewing: How to Build Your Reputation by Picking the Winners*. Bethlehem, PA: College Placement Council, 1990.

Siering, Marlene. “Hire the Best.” *Denver Business Journal* (November 17, 1997), <http://www.bizjournals.com/denver/stories/1997/11/17/smallb2.html>.

University of Michigan Employment and Executive Services. “Conducting a Successful Employee Selection Process,” <http://www.umich.edu/~hrra/empserv/deptinfo/empsel.htm>.

University of Michigan Employment and Executive Services. “Electronic Recruitment Resources,” <http://www.umich.edu/~hrra/empserv/deptinfo/electronic.htm>.

Varnadoe, Lionel A. *Medical Laboratory Management and Supervision: Operations, Review, and Study Guide*. Philadelphia, PA: F.A. Davis Company, 1996.

APPENDIX: TELEPHONE INTERVIEW OUTLINE

Date: _____

Candidate: _____

Investigator's Questions (Use open-ended questions, and ask for examples.)

To see if we might fit, give me an idea of what you are looking for.

What are your goals for this position? (short-term expectations, long-term plans)

Tell me about yourself as a scientist:

- ◆ What are your strengths?
- ◆ What are your weaknesses?
- ◆ What do you want to learn?
- ◆ What are you looking for in a supervisor?

What is your preferred interaction style? (with me, with others, on joint projects)

Timing, current job

Visa status

Investigator's Comments

Background, interests, goals

The projects we are working on

What I am looking for

What I expect (enthusiastic, interested, communicative, a hard worker, responsible)

What I will offer (be there, help, communicate, support career with communication about goals, funding for x amount of time)

The university, department, town

Timing, constraints

Source: This interview form is adapted from one developed by Tamara L. Doering, Washington University School of Medicine.

Chapter 9

GETTING FUNDED

You've begun your career as an academic scientist. Your lab is up and running, and your research program is under way. But the pressure is on—soon you will have to find financial support for your research from sources other than your institution. It's time to learn the art of getting funded.

Numerous public and private sources support scientific studies, but the National Institutes of Health (NIH), a component of the Public Health Service under the U.S. Department of Health and Human Services, is by far the nation's largest funder of academic research. For that reason, this chapter focuses primarily on NIH and emphasizes the R01 grant, an investigator-initiated research project grant for which most beginning academic investigators will have to apply.

This chapter provides an overview of the NIH funding process and the two-level review system that is used by NIH for most R01 grant applications. It also details the steps involved in preparing a strong R01 grant application, including turning your concept into a solid research plan and making sure that individuals with the appropriate expertise review your application. In addition, the chapter discusses what to do if your application is not funded. The chapter also provides some information about another major funder of basic science research, the National Science Foundation (NSF).

“

There is no grantsmanship that will turn a bad idea into a good one, but there are many ways to disguise a good one.

—William Raub, former deputy director, NIH

”

UNDERSTANDING THE NIH FUNDING PROCESS

NIH Institutes and Centers

An important part of writing a successful grant application is having a good understanding of the mission of the funding organization and the type of projects it supports. At this point in your career, you are probably already familiar with NIH and may have even applied for NIH postdoctoral funding. However, it's still useful to remember that NIH is composed of institutes and centers (I/Cs) whose numbers increase and whose structures are reorganized periodically. (From a grant applicant's perspective, the only relevant distinction between institutes and centers is that an institute can make awards of less than \$50,000 without approval from its national advisory council, but a center cannot.) As of May 2006, NIH had 20 institutes and 7 centers. Each I/C has its own mission and research agenda, and 24 of the current 27 I/Cs have funding programs for extramural awards (research conducted outside their own facilities and staff), including those that fund R01 grants. Although not essential, it will be useful for you to identify an I/C that is likely to be interested in your research (see "Find a Home for Your Application at NIH," page 164).

Question: At what stage in my career should I apply for my first R01 grant?

Answer: After you have accepted a position at a university or medical center, you may be encouraged by your department chair to apply for your first NIH grant, even before you move into your new lab. Some experts warn, however, that it might be better to wait until the second year of your appointment, because it will help your application considerably if you have generated some preliminary data in your new lab. Whenever you decide to apply, remember that you are in that special position of "new NIH investigator" only once; make the most of it.

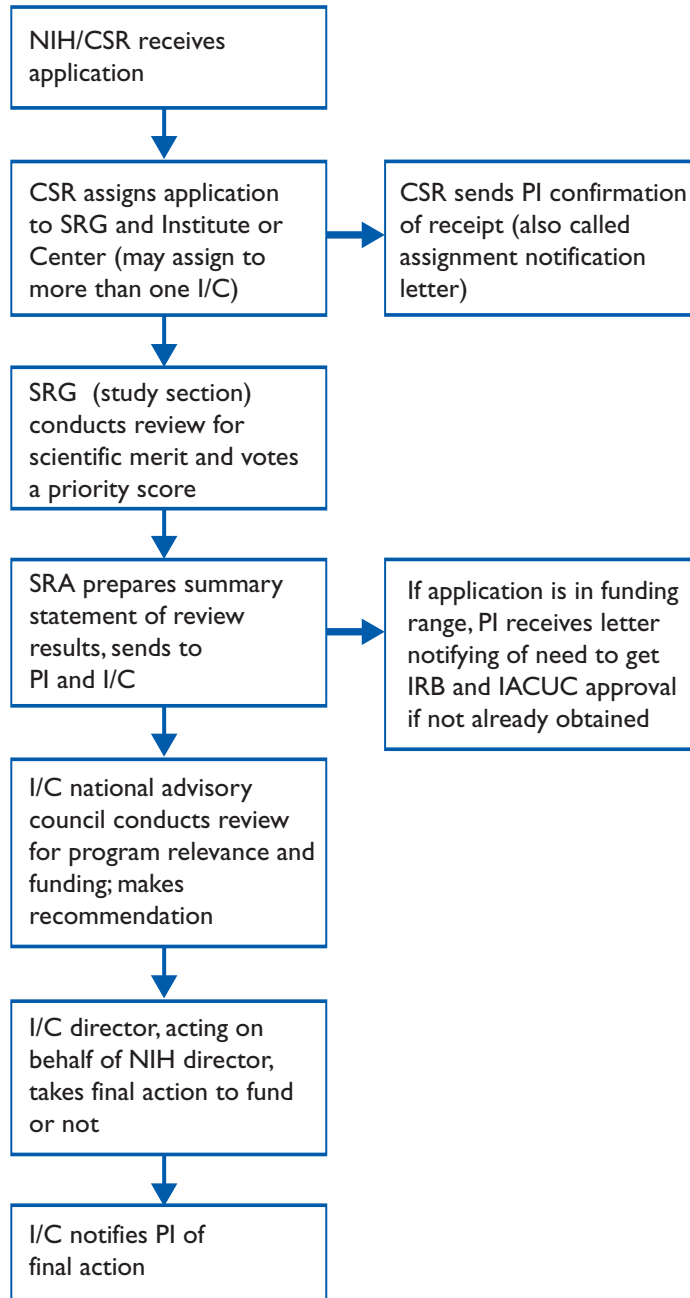
Question: What's the difference between an RFA and a PA?

Answer: An RFA invites grant applications in a well-defined scientific area for which an I/C has determined a specific research need (e.g., to study West Nile virus). This is usually a one-time competition and funds are set aside for a certain number of awards. A PA invites grant applications for a scientific area for which an extramural research program within an I/C has new or expanded interest or continuing interest (e.g., to study drug addiction). These applications are accepted on standard receipt dates on an ongoing basis.

The R01 Review: An Overview

R01 grant applications are usually investigator-initiated. Applications can also be submitted in response to a Request for Applications (RFA) or a Program Announcement (PA), both of which are announced in the NIH Guide for Grants and Contracts (<http://grants.nih.gov/grants/guide/index.html>). R01 applications submitted in response to an RFA are generally reviewed by the issuing I/C. R01 applications submitted in response to a PA are reviewed by the Center for Scientific Review (CSR). Regardless, all applications are sent to the CSR and then follow a two-level review process: CSR 1) assigns the application to a Scientific Review Group (SRG) for evaluation of scientific and technical merit and 2) assigns it to one or more I/Cs to review for programmatic relevance and funding recommendations. (Figure 9.1 provides an overview of this two-level review process.) CSR conducts scientific peer review of approximately 70 percent of the applications sent to NIH; I/Cs evaluate the others. Of the more than 68,000 applications received annually by NIH, perhaps only 20 to 25 percent are funded. The funding range can vary from year to year and from one I/C to another.

Figure 9.1.
Overview of
the NIH R01
grant review
process



CSR: Center for Scientific Review
 IACUC: Institutional Animal Care and Use Committee
 I/C: NIH Institute or Center
 IRB: Institutional Review Board
 PI: Principal Investigator
 SRA: Scientific Review Administrator
 SRG: Scientific Review Group

Common Abbreviations

AREA: Academic Research Enhancement Award
 CRISP: Computer Retrieval of Information on Scientific Projects
 CSR: Center for Scientific Review
 IACUC: Institutional Animal Care and Use Committee
 I/C: NIH Institute or Center (also written IC)
 IRB: Institutional Review Board
 IRG: Integrated Review Group
 OER: Office of Extramural Research
 OHRP: Office for Human Research Protections (formerly OPRR, Office of Protection from Research Risks)
 OLAW: Office of Laboratory Animal Welfare (formerly Division of Animal Welfare within OPRR)
 PA: Program Announcement
 RFA: Request for Applications
 RFP: Request for Proposals
 SEP: Special Emphasis Panel
 SRA: Scientific Review Administrator
 SRG: Scientific Review Group

First-Level Review: Scientific Review Group

One type of SRG, the study section, is used by CSR to review R01 grant applications. Study sections are clustered into Integrated Review Groups (IRGs), organized around a general scientific area. Each study section has a specific scientific focus. (For simplicity, the terms study section and SRG are used interchangeably in this chapter.)

R01 applications are usually assigned first to an IRG and then to a study section within that IRG. The study section reviews the grant application for scientific merit, rates it with a numerical priority score from which a percentile ranking is derived, and recommends an appropriate level of support and duration of award.

Scores, ranks, and percentiles. Every member of a study section gives each application a rating, or priority score. Those scores are averaged to create a three-digit number, which is that application's final score in the NIH computer system. A 100 is the best possible score, and a 500 is the worst possible score. Some applications are not dis-

cussed at the review meeting and thus do not receive a score (see "Streamlining and Deferrals," page 158).

Percentiling is a reflection of the rank of a particular score in the pool of all scores given by a study section in its current meeting plus the two previous meetings. For example, an application whose score ranked number 50 out of 100 applications would receive a percentile of 49.5, according to the following formula:

$$P = 100 \times (R - \frac{1}{2}) / N$$

In the formula, P is the percentile, R is the ranking (in this case, 50), and N is the total number of applications.

The percentiling process is specific to each study section and is the way that NIH I/Cs can account for different scoring behavior in the various study sections. Thus, if the 20th percentile is a 150 priority score in Study Section A and a 190 priority score in Study Section B, both applications are considered in the 20th percentile and treated as such when funding decisions are made by the I/Cs.

Behind Closed Doors: Demystifying the Study Section

Chartered study sections

- ◆ Are managed by a scientific review administrator (SRA), a professional at the M.D. or Ph.D. level with a scientific background close to the study section's area of expertise.
- ◆ Have 12 to 24 members recruited by the SRA, most of whom are from academia—some have long-term appointments and others are temporary members.
- ◆ Review as many as 60 to 100 applications per meeting.
- ◆ Usually assign three reviewers to each application.
- ◆ Are supported by a grants technical assistant, who reports to the SRA.

Under the terms of the Federal Advisory Committee Act, study section meetings are closed. Meetings include

- ◆ Orientation (discussion of general business)
- ◆ Provisional approval of list of streamlined applications
- ◆ Discussion of remaining applications

The discussion of applications includes the following:

- ◆ Reviewers with a conflict of interest are excused.
- ◆ Assigned reviewers present strengths, weaknesses, and their preliminary scores.
- ◆ Other members discuss scientific and technical merit.
- ◆ Range of scores is expressed (every member scores every application).
- ◆ Codes for gender, minority, and children and human subjects are assigned (NIH has requirements for inclusion of women, minorities, and children in clinical research and strict criteria for research involving human subjects and animals).
- ◆ Recommended budget changes are discussed.

After each meeting, the SRA documents the results in a summary statement, which is forwarded to both the I/C and the principal investigator.

Summary statements may vary somewhat depending on the SRA, but all of them contain

- ◆ Overall résumé and summary of review discussion (for applications that were discussed and scored)
- ◆ Essentially unedited critiques by the assigned reviewers
- ◆ Priority score and percentile ranking
- ◆ Budget recommendations
- ◆ Administrative notes (e.g., comments on human subjects or animal welfare)

For more information about what happens in a study section, see the CSR Web site (<http://www.csr.nih.gov>). Also, professional societies, such as the American Society for Cell Biology, often conduct mock study sections at their meetings using already-funded applications.

Poor priority scores. Applications can receive poor priority scores for any number of reasons, including the following:

- ◆ Lack of original ideas
- ◆ Absence of an acceptable scientific rationale
- ◆ Lack of experience in the essential methodology
- ◆ Questionable reasoning in experimental approach
- ◆ Diffuse, superficial, or unfocused research plan
- ◆ Lack of sufficient experimental detail
- ◆ Lack of knowledge of published relevant work
- ◆ Unrealistically large amount of work for the given time frame or funding level
- ◆ Uncertainty about future directions

Question: What should I do if an SRA asks me to be a reviewer for a study section?

Answer: Views differ on this question. Service on a study section can provide valuable insights for grant writing and open professional doors in other ways. However, many senior scientists counsel that junior faculty should wait until they have obtained tenure before accepting an invitation to be appointed to a term on a study section, because they should be devoting their energies to their research, which is the primary basis for the tenure decision. However, agreeing to serve as a temporary member might be appropriate at this stage in your career.

Streamlining and deferrals. A study section gives a score to only about half the applications assigned to it every review cycle. Through a process called “streamlining,” applications that are deemed by reviewers to be in the lower half of those assigned for review are read by the assigned reviewers and receive written critiques, but they are not scored or discussed at the review meeting. Any member can object to the streamlining of any application, thereby bringing it to full discussion at the meeting. Streamlining was instituted to allow more time for discussion of applications near the fundable range and to shorten the meetings. This more efficient process also helps attract more reviewers.

A study section can also defer an application if, for example, more information is needed before the reviewers can adequately consider the application. Deferred applications require a majority vote by the study section and are rated “DF.” Deferrals are rare.

Second-Level Review: I/C National Advisory Council or Board

After an R01 application has undergone study section review, it undergoes a second-level review by the national advisory council or board of an I/C. The advisory council is composed of people outside the I/C. Approximately two-thirds are scientific members who are generally established in their fields, such as deans or department chairs. Others are advocates for specific health issues and patient populations, ethicists, and laypersons. The secretary of Health and Human Services has ultimate authority to make these appointments.

The advisory council assesses the quality of the study section's scientific review, makes recommendations to I/C staff on funding, and evaluates the application's relevance to program priorities. For every scored application, the advisory council will do one of the following:

- ◆ Concur with the study section's action.
- ◆ Modify the study section's action (but it cannot change the priority score).
- ◆ Defer the study section's action for another review, with no changes allowed (e.g., if the principal investigator has appealed, the council may recommend a re-review because it considers the first review flawed).

The I/C director, acting on behalf of the NIH director, takes final action. Awards are made on the basis of scientific merit, program considerations, and available funds. The director usually (but not always) follows the advisory council's recommendations.

Roughly half of the funding I/Cs post their funding plans on their Web sites. The funding plan is the percentile to which the I/C anticipates being able to fund applications on the basis of its budget, recent funding history, and program priorities. If that information is posted, you can check the Web site after you receive the summary statement that shows your application's percentile. Regardless of whether the I/C to which your application was assigned posts its funding plan, you may want to ask the I/C program official responsible for the administrative management of pending applications/revisions and funded grants about the likelihood of your obtaining funding.

Review and Funding Cycles

The meetings of the national advisory councils form the basis for NIH's three overlapping review and funding cycles (see figure 9.2). However, NIH is trying to expedite the funding process by making some awards before the council meeting. For example, a candidate for expedited funding might be an R01 application that has a high score, is in an area of strong interest, and does not involve human subjects.

Figure 9.2.
Typical
timeline for a
new R01
application

	Cycle 1	Cycle 2	Cycle 3
Application Submitted	February	June	October
SRG (Study Section) Review	June	October	February
Advisory Council Review	September	January	May
Earliest Award	December	April	July

Note: This timeline is specific to R01 research grants. Always check with the I/C to verify due dates for specific types of applications. RFA due dates are stated in the solicitations.

Depending on the I/C, approximately 30 percent of funds are allocated at each of the first two meetings; more is spent at the third meeting. Some I/Cs may be a bit more conservative in funding (e.g., to the 25th percentile) in the first two cycles to hold funds in reserve in case strong applications are submitted during the final funding cycle. In addition, every advisory council and I/C staff have “select pay” for which they can nominate applications that have poorer scores but are of high interest for funding.

As much as possible, consider the timing of your application in terms of the career track at your institution. You want to be funded when decisions about tenure are made.

Opportunities for Beginning Investigators

NIH actively seeks to support beginning investigators. When you apply for your first NIH grant, check the box on the form that signals to reviewers that you’re a new investigator (meaning you haven’t been principal investigator on an NIH research grant before). The reviewers are often more forgiving of applications from novices.

Other, non-R01 research awards available specifically to beginning investigators include

- ◆ Mentored Research Scientist Development Award (K01)
- ◆ Independent Scientist Award (K02)
- ◆ Mentored Clinical Scientist Development Award (K08)
- ◆ Small Grant (R03)
- ◆ Academic Research Enhancement Award (R15)
- ◆ Exploratory/Developmental Grant (R21)
- ◆ Career Transition Award (K22)

Many of these programs are announced periodically in the NIH Guide to Grants and Contracts (<http://grants.nih.gov/grants/guide/index.html>). Each has its own criteria for eligibility and submission of applications. Information on these and other NIH extramural funding opportunities can be found at <http://grants.nih.gov/oer.htm>.

In addition to NIH, other federal agencies and private sector organizations solicit and fund research grants, and each has its own application and review system (see “Resources,” page 173). You can send the same application to multiple funding sources in the public and private sectors, but you must disclose your multiple applications to each potential funder to avoid “double dipping” when awards are made.

PREPARING A STRONG GRANT APPLICATION

Getting Started

Successful grant applications begin with a good idea. Figures 9.3 and 9.4 (pages 162 and 163) show the sequence of steps that can carry you from a good idea through the submission of an application to the final decision about funding.

Once you have a good idea, you can get started in two realms: your own institution and an appropriate NIH I/C. These activities overlap to some extent, but they are presented sequentially below.

Seek input at your own institution. An experienced scientific reviewer and NIH grantee recommends seeking peer review of your research proposal at your own institution according to a plan devised by Keith Yamamoto, University of California–San Francisco. The process, which begins at least two months before the application deadline of your grant, involves the following steps:

1. Choose three senior colleagues as your “grant committee.” Ideally, these would be successful grantees and would include someone who has experience on a study section.
2. Discuss research goals, aims, and ideas with the committee (1.5 hours).

Components of the NIH R01 Grant Application

- ◆ **Research Plan:** Abstract, Specific Aims, Background (like a review article), and Significance
- ◆ **Progress Report** (preliminary results and demonstration of relevant expertise)
- ◆ **Research Design and Methods**
- ◆ **Resources and Facilities**
- ◆ **Budget**
- ◆ **Budget Justification**

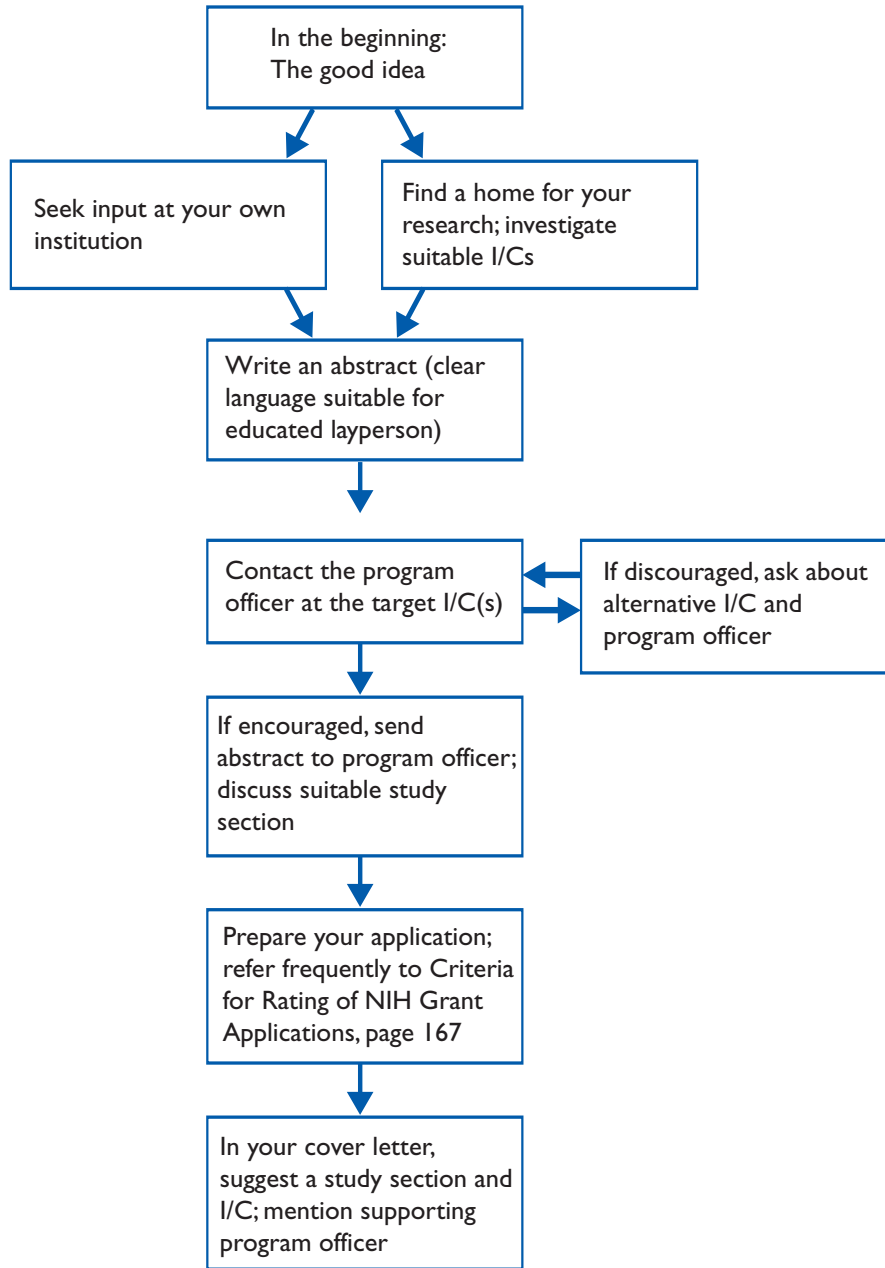
Tip: Conclude each section in the research plan with a few sentences stating what you will learn and why that information is important—for example, “These experiments are important because nothing is known about X, and they will enable us to distinguish between two controversial models that are widely discussed in the field.”

For information about how to prepare a grant application form, visit http://grants.nih.gov/grants/grant_tips.htm.

3. Draft one page listing three to five specific aims, and explain why each aim is important.
4. Discuss your aims and rationales with the committee (1.5 hours).
5. Refine your aims according to committee comments.
6. Draft the abstract and the research design and methods sections. Then draft the progress report and the background and significance sections. (See box “Components of the NIH R01 Grant Application” and “Preparing Your Application,” page 166.)
7. Read “Criteria for Rating of NIH Grant Applications” (page 167), and revise your drafts as appropriate.
8. Seek feedback on the drafts from your committee.

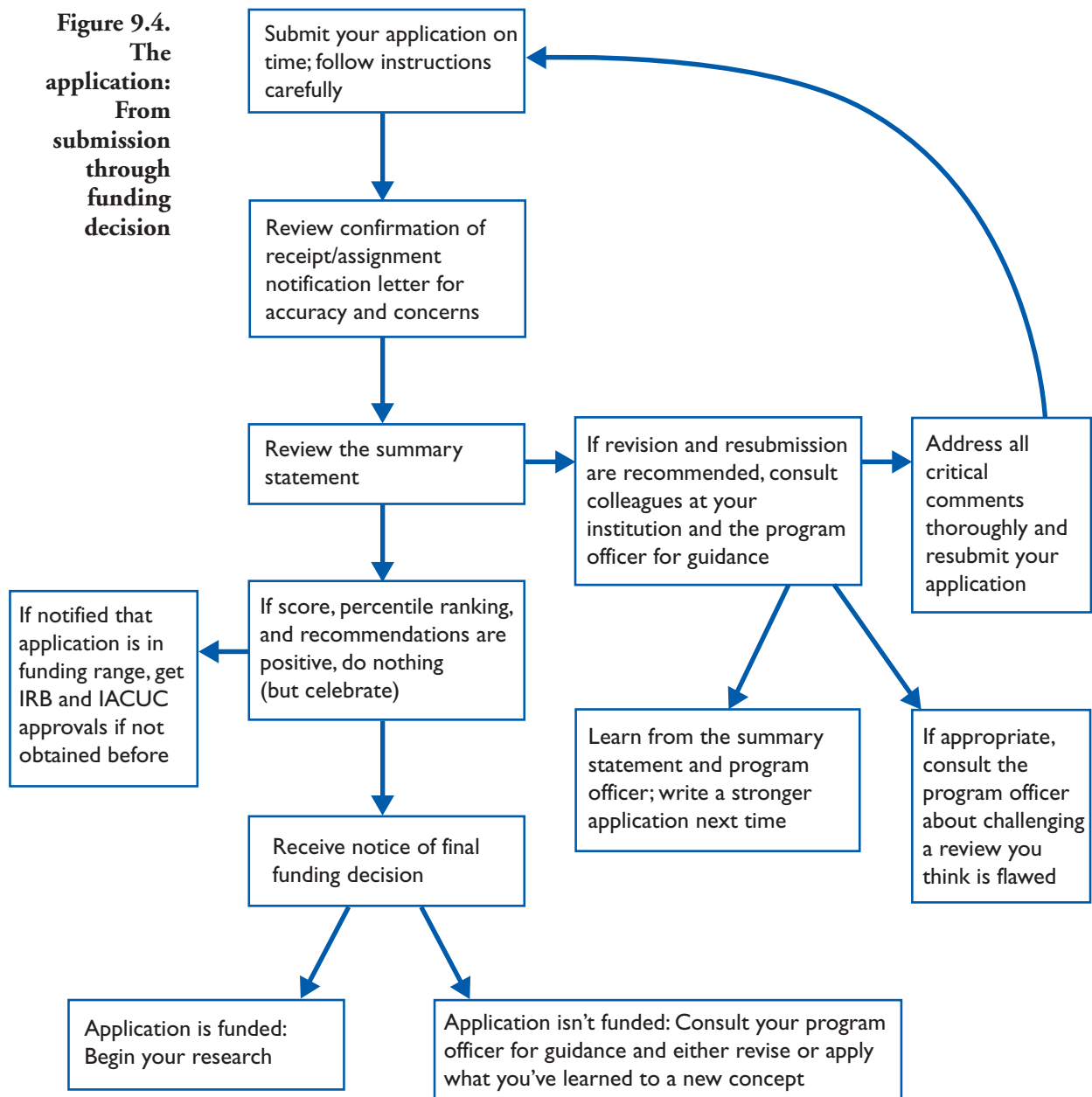
In addition to seeking advice from other scientists, seek administrative advice from appropriate review bodies, such as your local Institutional Review Board and Institutional Animal Care and Use Committee.

Figure 9.3.
The
application:
From concept
to submission



I/Cs: NIH Institutes and Centers

Figure 9.4.
The application:
From submission through funding decision



IACUC: Institutional Animal Care and Use Committee
IRB: Institutional Review Board

“

Your NIH R01 history is a form of peer review at the national level and is weighed heavily in decisions about promotion and tenure.

—Suzanne Pfeffer, Stanford University School of Medicine

”

Reviewers will look for your track record in the field, so, if necessary, create one by conducting some preliminary work and presenting the results in your grant application.

Find a home for your application at NIH. In many cases the appropriate I/C and program officer for your research might be your mentor's. On the other hand, it may take legwork to find the I/C most likely to be interested in your idea. An experienced NIH program officer suggests that beginning scientists should

- ◆ Check the NIH Guide to Grants and Contracts (<http://grants.nih.gov/grants/guide/index.html>) for relevant and recent PAs and RFAs.
- ◆ Check the NIH CRISP (Computer Retrieval of Information on Scientific Projects) database (<http://crisp.cit.nih.gov>) for projects like yours that have been funded. The two letters in the grant number tell you which I/C funded the project.
- ◆ Conduct a literature search to see what has already been done in your area. (This can help you address the innovation aspect of evaluation criteria and, if appropriate, revise your study design or methods accordingly.)

Once you've narrowed the list of potential I/Cs, go to the Web site of each I/C to learn what areas they are currently interested in and are funding. (The NIH Web site lists all its I/Cs and offices at <http://www.nih.gov/icd>.) I/C Web sites commonly describe scientific areas of interest as well as identify the staff members who are responsible for each program area and maintain a portfolio of grants in that area.

The I/C program officer is the best person to help you decide what type of grant to apply for and which study section may be most appropriate. The program officer whose area of responsibility is most appropriate to your research also can be your best advocate and adviser at NIH throughout the application process. The program officer will not evaluate the quality of the research idea or the science. That job is left to your institutional colleagues and the study section.

Before you call this key person, be sure to have an abstract of your research project ready (see box “Tips on Writing an Abstract” on page 165). The program officer will probably ask for a copy; if not, you can offer to send one.

Review by more than one I/C. Remember, you can ask for assignment to a second I/C if you've had encouragement from another program officer or think that your application fits within another I/C's scientific areas of interest. Your application can be funded by only one I/C, but more than one advisory council can

Tips on Writing an Abstract

The abstract should convey the big picture—the general hypothesis and aims, the methodological approach, and the significance of the research. It should also include key words, which the referral officer at NIH will use to assign your application to the right study section, whether or not you request a particular review group. Try to avoid technical jargon, and write the abstract in language an educated layperson can understand.

review it to broaden your chance of funding. In such cases, the application will be assigned a primary and a secondary I/C. The secondary I/C can consider it for funding only if the primary I/C opts to relinquish first right of funding.

Despite your homework on finding the appropriate I/C, the first program officer you contact may not consider your proposal appropriate for funding by that I/C. In such cases, the program officer will likely suggest a more suitable I/C and program officer.

Getting Assigned to the Right Study Section

The most important thing you can do to bolster your chance of funding is to have your application assigned to the right study section. Read the study section descriptions and rosters before finishing and submitting your application. Remember that key words in the title, the abstract, and the specific aims will be used to direct your application to a suitable study section.

If you submit a cover letter, it should contain an informed request for assignment to a specific study section and a brief explanation of why you think it's best suited for your application as you have determined through your own research and your discussion with the program officer. Include the name of the program officer who supports this request. CSR staff members will consider your suggestion for a study section; if your suggestion is logical, it is likely they will honor it. You can also recommend the type of expertise needed to evaluate your application, but you should not provide specific names of potential reviewers.

After you have been notified about the study section to which your application has been assigned, check the roster to make sure the expertise you consider essential to a fair and thorough evaluation of your application is still represented. If someone who you regard as an important interpreter of your research plan has dropped off the roster, you can request that expertise be added. These requests are generally taken seriously and responded to, and appropriate expertise is provided onsite or through an outside review by phone or mail. Similarly, if someone has joined the study section and you think for some reason that this person will not provide a fair review, you can request that this person not review your grant. Be aware, however, that during the study section meeting, the person you are excluding will be informed that you made this request.

Preparing Your Application

First, be sure you're using the most current application form. (The Web site <http://grants.nih.gov/grants/forms.htm> has the most current version of the PHS 398 Grant Application Kit.) Second, follow a simple mantra: Start early, write, read, rest, re-read, revise.

In your application, you should address the following questions, keeping in mind the information given under "Criteria for Rating of NIH Grant Applications," page 167):

- ◆ What do you want to do?
- ◆ Why is it important?
- ◆ Why do you think you can do it?
- ◆ Has this area been studied before (and if so, what has been done)?
- ◆ What approaches will you use, and why?
- ◆ Why do you think it's feasible?
- ◆ What will you do if your initial approach doesn't work as planned?
- ◆ What resources and expertise are available to you from your institution?

You should keep the following suggestions in mind as you prepare your application:

- ◆ Read and follow instructions, paying close attention to budget requirements and eligibility criteria (see "A Bit About Budgets," page 168).
- ◆ Prepare your application with care, and use spell check. No matter how strong the science, typos and grammatical errors leave a poor impression.
- ◆ Don't try to evade the page limit by using small type or narrow margins. You could delay your application if you disregard NIH's formatting requirements. Don't feel you must write up to the full page limit; you get points for strength, not length.
- ◆ Quantify whenever possible.
- ◆ Edit. Try to keep your specific aims to two or three sentences each. Remember that reviewers have dozens of applications to evaluate.
- ◆ Use language and formatting to create signposts for overworked reviewers, for example:

The *long-term* objectives of this project are...

The *general strategy* of the proposed research is to...

The *specific aims* of the present study are to...

Four goals are envisioned: ...

In these experiments, molecular genetic, biochemical, and structural approaches will be used to...

Reviewers Focus on the Four Cs

Clarity. Cross-reference current literature in laying out your premises.

Content. Organize your ideas around associated aims linked to your central hypothesis. (The mission statement of each I/C sets forth its areas of emphasis.)

Coherence of concepts. Present a coherent set of ideas predicated on previous work.

Cutting edge. Be ready to take legitimate risks, preferably based on preliminary data, to move the science forward. NIH rates grant applications on innovation (see “Criteria for Rating of NIH Grant Applications” on this page).

- ◆ Don't put anything that is critical for reviewers to read, such as key graphics, in an appendix because reviewers are not required to read appendixes.
- ◆ Include clear tables, figures, and diagrams (along with legends) in the text.
- ◆ Conduct a thorough literature search and cite all relevant literature (omissions here are often a source of criticism). Be sure to discuss your work in the context of these published results.
- ◆ Provide preliminary data whenever they exist.

Preliminary data. NIH understands that beginning investigators may not have much opportunity to acquire preliminary data. The NIH Guide to Grants and Contracts (<http://grants.nih.gov/grants/guide/index.html>)

often announces programs (e.g., R03 and R21) that are specifically designed to allow new investigators to obtain preliminary data.

Criteria for rating of NIH grant applications. Here are some questions that reviewers will ask about your proposal:

- ◆ *Significance:* Does it address an important problem? Will it advance scientific knowledge? Will it affect concepts or methods in this field?
- ◆ *Approach:* Are the experimental design and methods appropriate to the aims? Does it acknowledge problem areas and consider alternative tactics (in other words, is there a thoughtful backup plan)?
- ◆ *Innovation:* Does it employ novel concepts, approaches, or methods? Does it challenge existing paradigms or develop new methodologies?

Question: How do I distinguish myself from my mentor if I want to continue in the same research area?

Answer: Get a letter from your mentor explaining that he or she is pleased to know that you will be continuing to work on project X, which he or she will not pursue. Have this discussion with your mentor before you start to write the grant application.

- ◆ *Investigator:* Is the investigator appropriately trained to carry out the proposed work? Is the work appropriate to the experience of the principal investigator and collaborators?
- ◆ *Environment:* Does the institutional environment contribute to the probability of success? Is there evidence of institutional support?

Remember, every yes answer strengthens your application. Every no answer represents an area of potential vulnerability during scientific review. For a detailed description of these criteria, see the PHS 398 application instructions at http://grants.nih.gov/grants/grants_tips.htm. In addition, guidelines for reviewers for grants from new investigators can be found at <http://www.csr.nih.gov/guidelines/newinvestigator.htm>.

A BIT ABOUT BUDGETS

This section does not discuss how to draw up a budget for your grant application. Most institutions have a central grants office with experienced staff who can devise budgets suitable to the scope of the research proposed and in keeping with your institution's policies. Take advantage of that expertise.

However, this section does provide an overview of six budget-related topics. The first, direct costs versus indirect costs, can be the source of misunderstanding between faculty and administration at academic institutions. The next, modular grants, concerns the initial budget request that is now part of many NIH grant applications. Budget justification, administrative budget supplement, and competing budget supplement are relevant to later requests to supplement the initial award amount. The last topic concerns equipment costs.

Direct Costs Versus Indirect Costs

Direct costs comprise those expenses that are directly related to conducting a research project. They include salaries, employee benefits, equipment and scientific instruments, consumable supplies such as printer paper and pipettes, reagents, laboratory computers, and postage. Indirect costs (informally termed “overhead”) comprise the expenses that are paid to your institution by the funding organization to support your research but that can't easily be charged directly to a specific grant. These include administration, utilities, computer infrastructure, building maintenance, security, and custodial services. These costs can be from 10 percent to 80 percent of the total direct costs of a research grant. Generally, an institution's administrators negotiate indirect costs, on behalf of the investigator, with the funding organizations (such as NIH or the National Science Foundation) that allow these costs. The organization then provides funds for indirect costs to the institution, along with funds to cover direct costs charged to the research grants. In general, beginning investigators need not be concerned about indirect costs. However, you should be aware that a significant part of the budget for a large funding agency may include indirect costs; the more paid to institutions for indirect costs, the less available for direct costs for investigators and their research projects.

Modular Grants

To simplify the budgeting process, research budgets are now requested in units, or “modules,” of \$25,000. This applies to all investigator-initiated grants (R01, R03, R15, and R21) with direct costs of up to \$250,000 per year over the period of the award. All salary, fringe benefits, and inflation increases must be built into the modular framework. The number of modules can differ from year to year. For example, acquisition of equipment can make first-year costs higher than those for subsequent years. Request what you need, but be sure to justify that amount. Budget cuts are also modular. R01s over \$250,000 per year and P01 grants are nonmodular.

Budget Justification

The budget justification is a categorical description of the proposed costs. Generally, it explains staffing and supply/service consumption patterns, the methods used to estimate/calculate these items, and other details such as lists of items that make up the total costs for a category. The budget justification should address each of the major cost categories, such as

- ◆ Personnel
 - Number of positions and level of expertise for each position
 - Percent effort for each position
 - What will each member of the proposed research team be doing?
- ◆ Equipment
 - Why do you need this piece of equipment?
 - What equipment did you use to get preliminary data?
 - Why is the above equipment not sufficient to support R01-level effort? (Cost sharing for new equipment is advisable.)
- ◆ Supplies
 - Categorize
- ◆ Explain large expenses
- ◆ Travel
 - Describe proposed meetings, travelers, and estimated cost/trip
 - Justify any foreign travel
- ◆ Other
 - Detailed description of animal per diem costs
 - Categorize other expenses

Administrative Budget Supplement

This budget request covers unforeseen expenses that arise, generally because initial budget assumptions have changed. Examples are increases in the cost of isotopes or animal care. Administrative supplements are also offered occasionally for special purposes. For example, you may be able to get an administrative supplement to pay for a minority student to work in your lab. These requests are submitted to the I/C program staff rather than to the CSR for peer review. If you have questions about the appropriateness of this type of request, ask your program officer.

Competing Budget Supplement

Competing continuation applications are designed for the principal investigator who wants to modify the scope of approved work (e.g., by adding an aim or following an exciting lead). These requests are subject to the competitive peer-review process, usually through the same study section that reviewed the initial application. If you're considering this mechanism, ask your program officer about the feasibility of getting those funds from the sponsoring I/C.

More advice on laboratory budgets can be found in the resources listed at the end of this chapter.

Equipment: What You Should Know

When planning to buy equipment, keep in mind the following:

- ◆ Cost sharing has many benefits. Consider arranging for your department or institution to share equipment costs.
- ◆ If you need new equipment to pursue your research, ask for it on your renewal application. Never request major equipment funds in the last year of the grant.

Office of Extramural Research Salary Cap Summary

October 1, 2004, through December 31, 2004:
\$175,700

January 1, 2005, through December 31, 2005:
\$180,100

January 1, 2006, through December 31, 2006:
\$183,500

- ◆ Your institution owns equipment funded by your grant only after the award period ends. If you're the principal investigator and you relocate, the equipment generally goes with you.
- ◆ If you're in doubt about anything related to equipment, ask a grants management specialist at your institution.

You may find help with equipment costs through the Shared Instrumentation Grant Program (S10) or the Small Instrumentation Grants Program (S15) run by NIH's National Center for Research Resources. For more information about these programs, visit <http://www.ncrr.nih.gov>.

SUBMITTING YOUR APPLICATION

Follow instructions for mailing. Applications must be received by or mailed on or before the published receipt date. It's appropriate to send a courtesy copy of your application to the I/C's program officer.

Confirmation Letter

NIH will send you a confirmation of receipt, which is also called an assignment notification letter. Review it carefully to make sure all information is correct and you have no concerns (e.g., about assignment to a study section other than the one you requested). The letter will include the following items:

- ◆ An application number with codes for the type of grant (such as R01), the assigned I/C, and an identifying application ID number. The two letters in the ID number denote the primary I/C to which the application has been assigned.
- ◆ The assigned SRG (or study section)
- ◆ The name of the SRA and contact information

The letter will also outline the expected timetable for review and funding decisions and explain who to contact if you have questions.

New Data

If new data become available after you have submitted the application, contact the SRA of your assigned study section. You may be allowed to submit this additional information. The SRA can tell you how much to send, what format to use, and when and where to send it.

Interpreting the Summary Statement

After the study section meeting, the SRA will draft a summary statement (see “Behind Closed Doors: Demystifying the Study Section,” page 157). Usually, the summary statement is straightforward and will tell you whether your grant is likely to get funded or not, but in some cases, you may need help interpreting it. For example, if your summary statement recommends revision and resubmission, do the reviewers really want to see it again? Or have they politely refrained from stating plainly that they consider your hypothesis untenable, your expectations excessive, or your approach extremely flawed?

The program officer, who usually attends the study section meetings or enlists a colleague to do so, can help you interpret the results of the scientific review. If the program officer wasn't present, he or she can call the SRA for guidance. Your institutional mentor or grant committee can also help you evaluate the summary statement. After the national advisory council meeting, you can discuss the potential for funding or revisions with the program officer.

Occasionally, mistakes are made during the review process. If you believe that the reviewers criticized you for information that they overlooked in your application or think the review was flawed for other reasons, consult the program officer about the possibility of appealing the study section's decision. Although this action is sometimes appropriate, it's usually better to address review comments and resubmit your application. Follow the program officer's guidance on this matter.

If the reviewers thought your starting hypothesis was seriously flawed, don't waste your time revising and resubmitting the application. Instead, learn as much as you can from the summary statement and discussion with the program officer and your colleagues, reconsider your project and approach, and write a stronger application the next time.

Resubmitting Your Application

If your application is not immediately funded, remember that with an NIH funding average of 20 to 25 percent, many applications aren't funded the first time. If the program officer thinks it's worthwhile for you to revise the application, keep the following points in mind:

- ◆ Reviewers of amended applications get to see the summary statement from the previous reviews.
- ◆ Always treat review comments respectfully.
- ◆ Respond to all suggestions and comments, even if you don't agree with them.

- ◆ Be explicit about changes: Mark each section of the revised application where you have addressed reviewer critiques.
- ◆ Provide any additional data that are now available and update your publication list, if necessary.
- ◆ Resubmit the revised application by the due date. Your revised application now begins its journey through the review process all over again, along with the next batch of new submissions from other applicants.

Although your first instinct may be to request that your revised application be assigned to a different study section, you would need a compelling scientific reason for that request to be honored. Further, there's always the possibility that a different study section might find additional reasons to criticize your application.

A revised application supersedes the previous version, erasing the earlier score and pushing you back farther in line in the funding decision-making process. However, as the funding cycles progress and I/C staff have a clearer idea of what remains in their award budget for that fiscal year, they can reactivate the previous version if they find that the score on your initial application looks promising for funding (see "Review and Funding Cycles," page 159). If you submit a revised application and the program officer later tells you to withdraw it because your funding chances now look good, do so.

How many times can, or should, you revise and resubmit the same application? NIH policy is that after a second revision, you must reconsider your project and approach and submit a new application.

THE NATIONAL SCIENCE FOUNDATION

The National Science Foundation (NSF) is an independent federal agency with an annual budget of about \$5.5 billion. It is the funding source for approximately 20 percent of all federally supported basic research conducted by U.S. colleges and universities. It provides funding only for nonmedical biological research: According to NSF, "...Research with disease-related goals, including work on the etiology, diagnosis or treatment of physical or mental disease, abnormality, or malfunction in human beings or animals, is normally not supported. Animal models of such conditions or the development or testing of drugs or other procedures for their treatment also are not eligible for support." Complete information may be found at <http://www.nsf.gov>. Information on funding opportunities in biology may be found at <http://www.nsf.gov/dir/index.jsp?org=BIO>.

RESOURCES

Example of a Funded R01

Annotated R01 grant application (NIAID), <http://www.niaid.nih.gov/ncn/grants/app/app.pdf>.

NIH I/Cs and Offices

General information, <http://www.nih.gov/icd>.

NIH Peer Review: Process, Forms, Guidelines

CRISP, a searchable database of federally funded biomedical research projects conducted at universities, hospitals, and other research institutions, <http://crisp.cit.nih.gov>.

Overview of peer-review process, <http://www.csr.nih.gov/review/policy.asp>.

Study section rosters, <http://www.csr.nih.gov/Committees/rosterindex.asp>.

Grant application forms, <http://grants.nih.gov/grants/forms.htm>.

Preparation instructions, <http://grants.nih.gov/grants/funding/phs398/phs398.html>.

Office of Laboratory Animal Welfare, <http://grants.nih.gov/grants/olaw/olaw.htm>.

NIH Funding Opportunities

Grants and funding opportunities, <http://grants.nih.gov/grants/index.cfm>.

Guide to grants and contracts, <http://grants.nih.gov/grants/guide/index.html>.

Grants site map, with links to other relevant sites, <http://grants.nih.gov/grants/sitemap.htm>.

Office of Extramural Research, <http://grants.nih.gov/grants/oer.htm>.

Other Sources of Funding Information

FedBizOpps, an evolving database of all federal government granting programs of more than \$25,000, <http://www.fedbizopps.gov>.

GrantsNet, maintained by the American Association for the Advancement of Science, <http://www.grantsnet.org>.

Laboratory Budgets

Brown, Megan T. "Preparing and Managing Your First Lab Budget: Finance 101 for New Investigators." ScienceCareers.org (October 22, 1999), [http://sciencecareers.sciencemag.org/career_development/previous_issues/articles/0210/preparing_and_managing_your_first_lab_budget_finance_101_for_new_investigators/\(parent\)/158](http://sciencecareers.sciencemag.org/career_development/previous_issues/articles/0210/preparing_and_managing_your_first_lab_budget_finance_101_for_new_investigators/(parent)/158).

Chapter 7

PROJECT MANAGEMENT

To increase the output of your laboratory, you can either increase resources—by getting another grant and recruiting more people to work with you—or make better use of what you already have. One tool for achieving the latter is project management. Put simply, project management means allocating, using, and tracking resources to achieve a goal in a desired time frame. In a scientific setting, goals may include publishing a paper, obtaining a research grant, completing a set of experiments, or even achieving tenure. While keeping creativity intact, project management can help reduce wasted effort, track progress (or lack of it), and respond quickly to deviations from important aims. This chapter highlights some of the techniques of project management and how you can use them. The appendix at the end of the chapter shows a real-life example of project management applied to a project to determine the role of a gene in prostate cancer.

“

Project management helps you efficiently use your research funds, personnel, and time to publish research papers, obtain funding, and be promoted.

—Milton Datta, Emory University School of Medicine

”

WHAT IS PROJECT MANAGEMENT?

Project management is a series of flexible and iterative steps through which you identify where you want to go and a reasonable way to get there, with specifics of who will do what and when. The steps of project management are similar to the components of a grant proposal (see chapter 9, “Getting Funded”). With a grant proposal, the probability of success is proportional to the thought that has gone into each part of the proposal. The reviewers as well as the funding agency staff want to see that you have thought things through. The same process also applies to other aspects of running your laboratory and planning your career.

“

A detailed, well-designed project plan is one of the sharpest tools available for convincing a funder, such as NSF or NIH, to give you the resources you require.

—Stanley Portny, Stanley E. Portny and Associates

”

Deciding on a Project

You may have an endless number of ideas for projects, but your resources (e.g., research funds, number of students and postdocs, time, and so on) are limited. The first thing you will have to do is decide which projects to pursue within the limits of your resources and considering your laboratory’s mission (see chapter 3, “Laboratory Leadership in Science”).

For, example, you may want to obtain a second R01 grant because it will allow you to pursue another line of research and increase your chances of obtaining tenure. The grant deadline is in nine months. You should ask yourself the following:

- ◆ What experiments do I need to conduct to write a research paper and submit it for publication before the grant deadline?
- ◆ Do I have enough time to obtain the necessary data?
- ◆ Which students and postdocs could generate these data?

Once you have defined your overall objectives, how to get there, and from whom you need buy-in and participation, you can start the process of planning your project, working backwards from your stated objective:

*My project is to get an R01 funded within one and a half years.
I will need to*

- ◆ *Obtain final data for the grant proposal (12 months)*
- ◆ *Submit the grant with preliminary data (9 months)*
- ◆ *Submit a paper for publication (6 months)*
- ◆ *Integrate data and start writing a manuscript (5 months)*
- ◆ *Complete the initial set of experiments (1 to 5 months)*

Project management consists of planning each part of your project using the tools outlined in the sections below. One of the most important benefits of project management is that it helps you accurately anticipate how much time a project will take and what resources you will need. Even if some back-of-the-envelope thinking convinces you that a project is worth pursuing and that you can generate an initial set of publishable results for your grant in five months, you will need to plan each

step more carefully to answer the following questions:

- ◆ How long will the project really take?
- ◆ Do we really have the people to do this?
- ◆ Do we really have the funds to do it?
- ◆ Can we get it done in time?

GETTING STARTED

The Statement of Work

The statement of work is a written document that clearly explains what the project is. It should include the following sections:

Purpose. This section should include

- ◆ *Background:* Why was the project initiated and by whom, what happens if it's not done, and what else relates to it?
- ◆ *Scope of work:* What will you do?—a brief statement describing the major work to be performed.

Question: Don't the strict definitions you impose when you set up a project management plan limit scientific creativity?

Answer: Not at all. All projects, including highly innovative ones, rely on defined resources. Regardless of the scientific goals of a project, project management helps you determine whether your ideas can be implemented with the resources at hand and how best to approach these ideas. If you realize ahead of time that you don't have the resources you need, you'll know you need to get them.

Question: Does project management discourage us from trying high-risk projects?

Answer: Scientists must work within the limits of their resources. This does not mean high-risk projects should not be done; it just means that one should know the risks involved before starting the project. Project management helps define what the risks will be; for example, you may use up your start-up funds before you get an NIH grant or you may produce one paper, rather than three, in one year. Once you know the risks involved, you can plan for them. Project management can also help you conserve some of your resources to use for high-risk projects. The more information you have at the outset of a project, the better you will be at allocating resources. The better you are at allocating resources for the work that has to get done (e.g., the experiments proposed in your funded grant), the more likely you will be able to save some funds for more speculative projects.

Question: Given the uncertainties in science, is project management feasible?

Answer: Project management isn't meant to be rigid or blindly restrictive. Indeed, by reexamining goals and circumstances in a systemized way, project management encourages you to reconsider which path is best many times during the course of a given project.

- ◆ *Strategy:* How will you perform the work, who will do it, and what funds are available for the work?

Objectives. Objectives are the end results achieved by the project. Each objective should include

- ◆ *Statement:* A description of the desired outcome when the project is completed.
- ◆ *Measures:* Indicators to assess how well you have achieved the desired outcome.
- ◆ *Specifications:* Target values of the measures that define successful results.

Constraints. These are the restrictions on the project, which fall into two categories:

- ◆ *Limitations:* Constraints set by others (such as limited start-up funds for your laboratory, or teaching responsibilities that will limit your research time).
- ◆ *Needs:* Constraints set by the project team (such as wanting to complete a project three weeks early because one of the key people will be leaving the lab).

Assumptions. These are the unknowns you posit in developing the plan—statements about uncertain information you will take as fact as you conceive, plan, and perform the project (e.g., you may assume that your clinical or teaching loads will not increase in the next year or that no one will leave the project before a certain milestone is reached).

Be aware that as your project progresses, your goals may change. Build in periodic reviews of results against objectives and revise the objectives if necessary. No matter how much you've invested in a project, it's never too late to redirect or stop work altogether if you discover, for example, that another route is more promising than the main avenue of research, or a key premise was off base, or that someone publishes the work before you do.

The appendix at the end of this chapter shows a real-life example of a statement of work.

Defining the Audience

Any of your audiences—the people and groups that have an interest in your project, are affected by it, or are needed to support it—can sink the entire enterprise if their needs are not considered. Early on, you should make a list of the project's audiences, both within your institution and outside it. Although you can do this in your head, a written list serves as a reminder throughout the project to touch base with these stakeholders as you proceed. A project can succeed only if everyone involved does his or her part.

Divide your audience list into three categories:

- ◆ *Drivers:* People who tell you what to do, defining to some degree what your project will produce and what constitutes success. As a principle investigator, you are the main driver for your research. Additional drivers might include competitors and collaborators in your field, the editors of scientific journals (if they are advising you on what experiments should be done in order to get a manuscript published), and the study section reviewers of the research grants (if their feedback is shaping the course of your research project). If possible, keep these people abreast of how the project is going or consult with them before changing direction or branching out in a different area. For example, if an editor at *Nature* has requested specific experiments in a revised manuscript but you decide to do different ones that you think are more appropriate or easier to do given the expertise in your lab, you can contact the editor to make sure that the proposed experiments will satisfy his or her requirements.
- ◆ *Supporters:* People who will perform the work or make the work possible (e.g., the students and postdocs in your lab as well as the program director for the organization that is funding the project). Make sure that these people are motivated to do the work and understand how what they are doing relates to achieving the overall scientific goal. (See chapter 3, “Laboratory Leadership in Science.”)
- ◆ *Observers:* People who have an interest in your project but are neither drivers nor supporters. They are interested in what you’re doing, but they’re not telling you what to do or how to do it (e.g., other scientists working in your field, mentors, and potential supporters). It can be helpful to your career to let as many scientists as possible know what you have accomplished. This can be done by giving presentations at meetings and conferences, by asking colleagues to review a manuscript that you are preparing to submit for publication, or by sending scientists in your field copies of a paper you have published. Keep in mind that people who are familiar with your work, but who are not direct collaborators, will have to submit letters for your tenure. These people might also invite you to give talks or suggest that you participate in study sections or become part of a meeting planning team.

As you work on the project, revise the list as necessary. Categorizing audiences is less difficult than it may look, and you don’t have to start from scratch for every activity. Many of the same people are likely to be on your audience list over time for different activities.

Defining Who Does What and When

The work breakdown structure (WBS) is an outline of all the work that will have to be performed for your project. To develop a WBS, start with broad work assignments, break them down into activities, and divide these into discrete steps (see the appendix for a real-life example). In the jargon of the project management field, an

activity is a task that must be performed for your project and an event is a milestone marking the completion of one or more activities. You will want to list on your timeline resources and the people that will carry out the activities, so that you can successfully complete some milestone event—for example, getting a paper accepted, a grant funded, or a difficult technique reduced to practice.

The WBS is one of the most important elements of project management as it will help you schedule the project and its parts, estimate resources, assign tasks and responsibilities, and control the project. (For more information about developing this kind of outline, see http://www.4pm.com/articles/work_breakdown_structure.htm).

When you develop a WBS, think in one- to two-week increments. You probably wouldn't want to include detailed plans for activities that take less time (e.g., experiments to be done each day). However, the level of detail you include in your WBS depends, in part, on who is doing the work. Most undergraduates will need more detail than an experienced postdoc or technician. It may be useful to teach your trainees to think in this time- and resource-aware way, perhaps by, early in their stay in your lab, having them write out detailed weekly plans or design flow charts for how they intend to work through a difficult technical issue at the bench.

To decide whether a particular part of the project is detailed enough, ask yourself these three questions. Based on the WBS can

- ◆ You determine a reasonable estimate of the resources (including people) required for this work?
- ◆ You determine a reasonable estimate of the time required to do this work?
- ◆ Anyone charged with one of these activities understand it well enough to do it to your satisfaction?

Question: Is project management a top-down or a mutual process?

Answer: It must be mutual. For the best possible outcome, you need both staff insights and “buy-in.” Project management does not say, “Forget thinking and just do what I say.” It’s a process for identifying what to think about, not how to think about it.

Question: If I have experiments A, B, C, and D, is it reasonable to do detailed planning only for A first and deal with the others later?

Answer: That may be reasonable, but what if B isn't entirely dependent on A, and you could have done some work for B or any of the other experiments without waiting until A was done? Project management tools and software can help you see where timelines may overlap, so that you can use your time most productively.

If the answer to any of these questions is “no,” more detail is necessary.

In science, it's unlikely that you'll be able to make a detailed plan very far in advance. Much of the detailed planning will be done “on the fly” as the project proceeds. Try a rolling approach, in which you revise estimates in more detail as you progress through the project.

In addition to planning experiments, you can use the WBS to set up the lab and divide big tasks into smaller ones—for example, ordering equipment; hiring staff; and dealing with institutional review boards (IRBs), radiation safety, and other issues.

TRACKING THE WORK AND THE RESOURCES

Complex projects require a series of activities, some of which will have to be performed in sequence and others in parallel. Project schedules outline the order in which activities are to be performed and estimates of how long each will take. In addition, for each step of the schedule, you will need to assign the necessary resources, including people, funds, equipment, supplies, facilities, and information. To schedule your activities and resources, you will need to follow these steps:

1. Identify activities and events (from the WBS).
2. Identify constraints (from the statement of work).
3. Determine the durations of different activities and, if more than one person will be involved, who will be doing them.
4. Decide on the order of performance.
5. Develop an initial schedule.
6. Revise your schedule as necessary.

Tools for Developing Schedules

You have probably seen some of the tools for developing schedules, timelines, flow charts, and so on, before. Here are some popular ones:

- ◆ *Key events schedule*: A table showing events and target dates for reaching them (remember that events are milestones signaling the completion of one or more activities).
- ◆ *Activities plan*: A table showing activities and their planned start and end dates (see appendix, page 141).
- ◆ *Gantt chart*: A graph consisting of horizontal bars that depict the start date and duration for each activity (see appendix, page 142).
- ◆ *PERT chart*: A diagram in which activities are represented by lines and events on the nodes (typically depicted as circles or bubbles).

The key events schedule and the activities plan display dates better; the Gantt and PERT charts give a better overview of how long activities take and where they coincide. Regardless of which format you use, take the time to develop a schedule you have a reasonable chance of meeting. Think realistically and estimate how long each step will take, how many uninterrupted hours you have available during the day, and how other demands on your time will affect what you or your lab can get done.

To determine how long a very complex process may take, think about similar things you've done before. Flip through your notebook or calendar and try to remember—how many hours did it really take you to write, edit, get feedback on, make figures for, revise, revise again, and submit that last paper or grant? Try to be conservative in your estimates. When it comes to planning benchwork, an accurate assessment of the skills, experience, and limitations of your staff will help

you match the right people to each task. Stretching is good, but failing because of overreaching is not. If your team lacks the expertise required for completing a specific goal you may need to find a suitable and willing collaborator. Collectively these scheduling tools will

- ◆ Provide ways of tracking the work.
- ◆ Identify the order of experiments, which will define how long it will take to get the job done.
- ◆ Show the relationship of experiments to each other (e.g., do they need to be done sequentially or can they be done in parallel?)
- ◆ Identify bottlenecks.

As the work progresses, make adjustments to your schedule or the resources needed. For example, the estimates of times can be replaced with actual times. In cases

where there are delays in the schedule, additional resources may be needed to make up for time and the diagram may be modified to reflect the new situation.

Question: It sometimes takes longer than I think it will to complete new experiments. How do I plan accordingly?

Answer: The work breakdown structure will help you see where inherent difficulties in experiments or bottlenecks in the procedures are, and you can then add time and resources to address these. For example, you may pair an experienced postdoc with a new student who is responsible for a step in the protocol, or give a technician who has to establish a new technique in the lab time for several trials and revisions of the procedure.

Do I Have the Resources?

Once you have made an outline of the activities to do in a given timeframe and who will perform the work, you may want to more precisely determine how much of a given resource the project will use up—e.g., how many hours a postdoc will have to work each week to complete his or her activities (see appendix, page 142) or how much money will be spent. This will help you identify potential bottlenecks—even the best postdoc cannot work 37 hours a day!

PROJECT MANAGEMENT SOFTWARE

If you are keeping track of a simple project involving only one or two individuals, you can probably use a network diagram drawn on a board or in an electronic document. But as the number of projects and responsibilities you juggle grows, you may want to make use of one of the many software packages available. They can help you spot, for example, resource conflicts (such as one person assigned to three overlapping activities) and identify which activities can be delayed to accommodate that problem without jeopardizing the schedule. Good software helps you brainstorm the organization of activities on screen, create a WBS, link activities, develop a schedule, identify resources, maintain information on progress, and generate reports. When you make a change, the software reflects the impact of that change throughout the project.

Microsoft Project, a program that seamlessly integrates with Microsoft Office, is a popular choice. The software package lets you enter any number of tasks and schedule them. You can then view the data using multiple formats (e.g., Gantt charts or PERT diagrams). You can also enter cost for each resource and the software will automatically track the spending of the project. Other popular choices are the packages Act! (Symantec Corp.) and Now Up-to-Date (Qualcomm, Inc.). For information about others, see <http://www.project-management-software.org>. Like other software, project management programs come with bells and whistles you may never need or use. Remember that software is merely a tool to help you plan and organize your work. It should not become your work, bogging you down in complex manipulations or fancy graphs and charts that look impressive but don't improve on simpler presentations of the information.

After some short training on these software packages, it is straightforward to build new plans. Several fields, including construction and some areas of business management, make extensive use of this kind of software. You may be able to find undergraduates, especially in engineering or business schools, who would be eager to polish their skills (and get a line for their résumé) by doing the grunt work needed to move your established pencil-and-paper plans onto the computer.

Question: I've done some experiments so many times that I already know how long it will take and the resources I need. Should I add these experiments to my plan?

Answer: Not for your benefit, but you have to consider whether others need to know what you're doing—the sequence of steps as well as the materials and time required. If they do, a written work plan can also be a useful part of the record. Project management isn't just a planning tool, it's also a training and communication tool.

Question: Despite the best explanations, inexperienced students may focus only on their part of the work. Are there devices to help them get the big picture?

Answer: It's important that they do get the big picture, and project management may be part of the solution. Although it's true that project management encourages a focus on details, it also encourages you to consider the big picture. Think of a project's detailed plan as being like a metabolic map: If students can see how their work connects to a greater whole, they may be more motivated to think about their own small projects and to ask bigger questions about the lab's work and the broader field. Young students may be reluctant to admit what they don't know. By walking them through the field's complicated issues and ongoing controversies, you can convey to them that it's alright not to know and customary to ask others to explain things. Get them to talk about what they're doing, and paraphrase what they say, highlighting the places where their work intersects with other work in the lab, or ask them to write a statement of work for their part of the project, which requires knowing the background on the project as a whole.

CONTROLLING THE PROJECT

Effective project management demands that the components of a project be constantly monitored and revised with new information. The principle investigator typically plays this role in addition to the following tasks:

- ◆ Championing the project for the project audience (e.g., through seminars and informal updates to supporters).
- ◆ Clearing away obstacles for the project team (such as minimizing other responsibilities for the team members and providing a supportive and comfortable work environment).
- ◆ Providing resources, by way of funds, access to essential equipment, and technical skills.
- ◆ Communicating the project vision to keep the team motivated and focused.
- ◆ Communicating with the department chair, NIH, journal editors, and the external collaborators.

“

The greatest chances for success are achieved when project information is used to align, guide, and motivate team members, and when these team members, in turn, use this information to guide their work.

—Stanley Portny and Jim Austin, “Project Management for Scientists,” ScienceCareers.org, 2002

”

Keeping Your Work on Track

It is hard to predict how the course of a project will run. Flexible planning is needed to help you deal with the unexpected and still keep your many projects moving. The following is a list to help you stay on track:

- ◆ As you would do in a good R01 or other grant application, consider different scenarios to identify what may not unfold as you anticipate, and identify the range of ramifications and how you would address them.
- ◆ Select aspects of your project that are most likely to slow things down (e.g., a graduate student who is not familiar with interpreting experimental results and thus may slow progress or a technician who does not aggressively follow up on orders from a slow vendor and thus may not receive needed reagents on time), and monitor them closely.

- ◆ Develop strategies to reduce the likelihood of deviations, as well as contingency plans for any that occur.
- ◆ Create indicators or defined results (such as a completed Western blot or a clearly interpretable experimental finding) that will help you evaluate the project against your stated objectives. The indicators should be clear and directly relate to your objectives. Poorly chosen indicators are worse than none at all and may cause you to abandon a project when in fact the objective may be sound.
- ◆ Monitor the project carefully and consistently to promptly identify detours from course.
- ◆ Implement contingency plans, and revise your master plan as necessary.

Question: How do I finish projects while allowing key people to leave when they're ready?

Answer: Project management can help you anticipate and plan for their departure. Identify who's most likely to leave and the places in the project where that's most likely to happen. When it does happen, stop and assess the impact on your project and determine steps you can take to minimize the effects.

As a scientist, you want your work to be worthwhile, even if it doesn't proceed the way you planned or produce the expected outcome. To get the most out of your investment of project resources, learn to work through the "what ifs" by positing multiple possible outcomes and timelines, and planning ways to deal with each one.

RESOURCES

Austin, Jim. "Management in the Lab." ScienceCareers.org (September 13, 2002), http://sciencecareers.sciencemag.org/career_development/previous_issues/articles/1890__1/management_in_the_lab.

Austin, Rob. "Project Management and Discovery." ScienceCareers.org (September 13, 2002), http://sciencecareers.sciencemag.org/career_development/previous_issues/articles/1890__1/project_management_and_discovery.

Barker, Kathy. *At The Helm: A Laboratory Navigator*. Cold Spring Harbor, NY: Cold Spring Harbor Laboratory Press, 2002.

Harmening, Denise M. *Laboratory Management: Principles and Processes*. Upper Saddle River, NJ: Prentice Hall, 2002.

Heldman, Kim. *Project Management JumpStart*. Alameda, CA: Sybex, 2003.

Henry, John B., ed. *Clinical Diagnosis and Management by Laboratory Methods*. Philadelphia, PA: W.B. Saunders, 2001.

Hudson, Jane, ed. *Principles of Clinical Laboratory Management: A Study Guide and Workbook*. Upper Saddle River, NJ: Prentice Hall, 2003.

- Kemp, Sid. *Project Management Demystified*. New York, NY: McGraw-Hill, 2004.
- Lewis, James P. *Fundamentals of Project Management: Developing Core Competencies to Help Outperform the Competition*. New York, NY: American Management Association, 2002.
- Luecke, Richard. *Managing Projects Large and Small: The Fundamental Skills to Deliver on Cost and on Time*. Cambridge, MA: Harvard Business School Press, 2003.
- Martin, Vivien. *Managing Projects in Health and Social Care*. London: Routledge, 2002.
- Portny, Stanley E. *Project Management for Dummies*. Hoboken, NJ: Wiley Publishing, 2000.
- Portny, Stanley E., and Jim Austin. "Project Management for Scientists." ScienceCareers.org (July 12, 2002), http://sciencecareers.sciencemag.org/career_development/previous_issues/articles/1750/project_management_for_scientists.
- Portny, Stanley E. "Project Management in an Uncertain Environment." ScienceCareers.org (August 23, 2002), http://sciencecareers.sciencemag.org/career_development/previous_issues/articles/1820/project_management_in_an_uncertain_environment.
- Project Management Institute. *Guide to the Project Management Body of Knowledge*. Newtown Square, PA: Project Management Institute, 2000.
- Sindermann, Carl J. *Winning the Games Scientists Play*. Cambridge, MA: Perseus Book Group, 2001.
- Usherwood, Tim. *Introduction to Project Management in Health Research: A Guide for New Researchers*. Bristol, PA: Open University Press, 1996.

APPENDIX: PROJECT MANAGEMENT— A REAL-LIFE EXAMPLE

The Statement of Work

Section 1: Purpose

Background. Theresa, a postdoc in the laboratory, wants to examine the possible role for alterations in the gene *Sumacan* in prostate cancer. She noted that *Sumacan*, which encodes a growth factor receptor, maps to a genetic region involved in human prostate cancer. Current studies in the lab focus on the role of *Sumacan* in brain tumors. Bob, a postdoc, is screening drugs that block *Sumacan* function; Ming Li, a graduate student, is elucidating the functional pathways *Sumacan* is involved in; and Steve, a graduate student, is performing a mutational analysis of the *Sumacan* gene. These same studies can be applied to prostate cancer, thereby opening up potential avenues for funding through prostate cancer foundations.

Scope of work.

- ◆ Examine whether the functional pathway for *Sumacan* is present in human prostate cancer cells.
- ◆ Compare the expression of *Sumacan* in normal human prostate tissues and prostate cancers, and correlate expression levels with clinical outcome in prostate cancer.
- ◆ Identify mutations in *Sumacan* in patients with prostate cancer.

Strategy. Each person in the lab is already working on different aspects of *Sumacan* biology in brain tumors. In each case, the work will be applied to prostate cancer cell lines that we will obtain from Mike, a colleague in our department. We have identified two additional potential collaborators—Rajiv, a pathologist who studies human prostate tissues and cancers, and Kathy, a geneticist who studies human prostate cancer families. We will use funds from our current R01 grant to obtain preliminary findings. We plan to use these findings to obtain a second R01 grant to the laboratory.

Section 2: Objective

Statement. Investigate the possible role of *Sumacan* in prostate cancer.

Measure #1. Our experiments will provide preliminary evidence to either support or deny a role for *Sumacan* in prostate cancer.

Specification. The experiments we carry out will answer the following questions:

- ◆ Is *Sumacan* expressed in the prostate?
- ◆ Is *Sumacan* expressed in prostate cancer?
- ◆ Is there a difference between the expression of *Sumacan* in the prostate and in prostate cancer?

Measure #2. The results obtained by these experiments will generate publications and grants.

Specifications.

- ◆ At least two (one for each postdoc working on the project) research articles will be accepted for publication in a top-tier research journal in the field.
- ◆ A request to NIH for funds to continue the research begun receives a percentile score on first-round submission of at least 25 percent and subsequent funding on the resubmission.

Measure #3. People in the field are aware of our research.

Specifications.

- ◆ We will receive several requests for information about the research.
- ◆ We will publish at least two research articles in the scientific literature.
- ◆ We will present the research results at at least two conferences in one year.

Section 3: Constraints

Limitations.

- ◆ The NIH proposal is due June 1, 2007. This means that the first research manuscript must be submitted for publication by approximately January 1, 2007, and accepted by mid-April 2007.
- ◆ Our lab has limited funds to cover the generation of preliminary data, which means that productivity has to be reviewed monthly.

Needs.

- ◆ Our lab needs to be able to grow prostate cancer cells.
- ◆ Our lab needs to be able to handle human prostate cancer specimens.

Section 4: Assumptions

- ◆ The current research team will be willing and able to perform prostate cancer studies in addition to their brain tumor studies.
- ◆ The collaborators we have identified will be willing and able to work with our group or will provide the name of another person who wants to collaborate.

The Work Breakdown Structure

Activity 1: Determine whether *Sumacan* is expressed in the prostate.

1. Determine where to obtain human prostate cells.
2. Determine how to grow human prostate cells.
 - ◆ The type of medium and serum they require
 - ◆ The optimal conditions for growth
3. Determine whether we can isolate RNA and protein from human prostate cells.
 - ◆ Try the same technique we use to isolate RNA from brain cells.
 - ◆ Develop a different technique.
4. Determine whether we can perform quantitative RT-PCR for *Sumacan* expression.
 - ◆ Primers and positive and negative controls
5. Determine whether we can perform a Western blot for *Sumacan* expression.
 - ◆ Test whether the antibody we use in the brain works in the prostate and determine what size protein band(s) is identified.
 - ◆ Identify positive or negative controls for protein quality and *Sumacan* identification.

Note: Steps 1 to 3 must be done sequentially, but once step 3 is completed, steps 4 and 5 can be done at the same time.

Activity 2: Determine whether *Sumacan* is expressed in prostate cancer cells.

1. Determine where to obtain human prostate cancer cells.
2. Determine how to grow human prostate cancer cells.
 - ◆ Type of medium and serum they require
 - ◆ Optimal conditions for growth
3. Determine whether we can isolate RNA and protein from human prostate cancer cells.
 - ◆ Try the same technique we use to isolate RNA from brain cells.
 - ◆ Develop a different technique.

4. Determine whether we can perform quantitative RT-PCR for *Sumacan* expression.
 - ◆ Primers and positive and negative controls

5. Determine whether we can perform a Western blot for *Sumacan* expression.
 - ◆ Test whether the antibody we use in the brain works in prostate cancer cells and determine what size protein band(s) is identified.
 - ◆ Identify positive or negative controls for protein quality and *Sumacan* identification.

Note: Steps 1 to 3 must be done sequentially, but once step 3 is completed, steps 4 and 5 can be done at the same time. In addition, activities 1 and 2 can be done at the same time, although this may result in higher resource costs if both tasks fail.

Activity 3: Determine whether there is a difference in *Sumacan* expression between normal and cancer cells.

1. Determine the difference in RNA expression.
2. Determine the difference in protein expression.
3. Determine the relationship between RNA and protein expression.

Note: Activity 3 involves analysis of the data collected in activities 1 and 2 and thus cannot be performed until these two activities are completed.

An Activities Plan

Activity	Person Responsible	Start Date	End Date	Notes
Identify sources of prostate cells	Theresa	Aug. 1	Aug. 5	
Identify sources of prostate cancer cells	Bob	Aug. 1	Aug. 5	
Grow prostate cells	Theresa	Aug. 5	Aug. 26	
Grow prostate cancer cells	Bob	Aug. 5	Aug. 26	
Isolate RNA and protein from prostate cells	Theresa	Aug. 26	Sept. 26	
Isolate RNA and protein from prostate cancer cells	Bob	Aug. 26	Sept. 26	
Perform RT-PCR on prostate cells	Theresa	Sept. 26	Oct. 26	
Perform RT-PCR on prostate cancer cells	Theresa	Sept. 26	Oct. 26	
Perform Western blots on prostate cells	Bob	Sept. 26	Oct. 26	
Perform Western blots on prostate cancer cells	Bob	Sept. 26	Oct. 26	
Compare the levels of <i>Sumacan</i> RNA in the prostate and prostate cancer cells	Theresa and Bob	Oct. 26	Nov. 5	
Compare the levels of <i>Sumacan</i> protein in the prostate and prostate cancer cells	Theresa and Bob	Oct. 26	Nov. 5	
Compare the levels of <i>Sumacan</i> RNA and protein with each other	Theresa and Bob	Oct. 26	Nov. 5	

Note: Each of these activities can be broken down further if more detail is needed. For example, if the activities are being performed by a new graduate student, you may want to explain the different protocols to use to perform RT-PCR from prostate cancer cells and what controls should be used as well as alternative protocols to use in case the first ones do not work.

A Gantt Chart

Activity	August	September	October	November	Person responsible
SUMACAN EXPRESSION IN PROSTATE CELLS					
Find cells	█				Theresa
Grow cells		█ █ █			Theresa
Isolate RNA and protein			█ █ █ █ █		Theresa
RT-PCR and Western blots				█ █ █ █ █	Theresa and Bob
SUMACAN EXPRESSION IN PROSTATE CANCER					
Find cells	█				Bob
Grow cells		█ █ █ █ █			Bob
Isolate RNA and protein			█ █ █ █ █ █ █		Bob
RT-PCR and Western blots				█ █ █ █ █ █ █	Theresa and Bob
COMPARE RESULTS					
Data Analysis					Theresa, Bob and PI

A Loading Chart

This chart displays Theresa's workload. She is responsible for the first three steps in determining *Sumacan* expression in prostate cells. Step 1 (looking for prostate cells) is done in week 1, step 2 (trying to grow the cells) in weeks 2 to 4, step 3 (isolating RNA and protein) in weeks 5 to 8, and step 4 (doing RT-PCR on normal and cancer cells) in weeks 9 to 13. In addition, during the time the project is being run, she will be teaching a microbiology lab course (5 hours/day with monthly exams).

Weeks	1	2	3	4	5	6	7	8	9	10	11	12	13
Research Hours	7	10	10	10	8	8	8	10	25	25	25	25	25
Microbiology Lab Hours	25	25	25	35	25	25	25	35	25	25	25	35	25
Total Time	32	35	35	45	33	33	33	45	50	50	50	60	50

Source: The examples in this appendix were provided by Milton W. Datta, Emory University School of Medicine.

Chapter 12

SETTING UP COLLABORATIONS

Twenty-first century science is often a collaborative effort. As a beginning investigator, you may want or need to work with scientists in other labs who can offer resources or technical expertise to complement your own. Because a scientific collaboration is a complex exchange, you will need to sharpen your managerial and political skills to be a successful collaborator. This chapter summarizes some of the questions you should ask yourself before embarking on a collaborative project and provides some guidelines to help ensure that the project and your interactions with colleagues proceed smoothly.

THE VARIETIES OF COLLABORATION

Collaborators are researchers who share an interest in the outcome of a project, not service providers or customers. Sharing reagents or materials described in a publication does not in itself constitute a collaboration; scientists are expected to make published materials available to others. Similarly, a service rendered by a scientist in a core service facility within his or her own institution is usually not considered a collaboration. The core service facility exists to perform specific tasks for other laboratories.

Collaborations can vary greatly in scope, duration, and degree of formality. A limited collaboration might entail only a series of consultations about a technique or the provision of samples to be tested. At the other extreme, several scientists or laboratories might join together to establish a permanent consortium or center for the pursuit of a particular line of research. Depending on its complexity, a collaboration can be launched by an informal agreement that is sealed with a handshake or an e-mail or by a legally binding document.

SHOULD YOU COLLABORATE?

Collaboration is a major responsibility—one that is not to be entered into lightly. It will take time, effort, and the nurturing of relationships. Before you start a collaboration, you should know for sure that you can see it through. The larger the collaboration, the more complicated fulfilling your obligations may be. Be sure that you are ready to collaborate and that a given opportunity is right for you. Once you've signed on, you will be expected to follow through on your commitments, and your scientific reputation will be at stake.

Assessing a Collaborative Opportunity

Regardless of whether you are approached by another scientist to collaborate or you are thinking of approaching someone to collaborate with you, here are some questions you should ask yourself before embarking on the project:

- ◆ Do I need this collaboration in order to move my own work forward? Is there a missing piece—a technique or resource—that I must have?
- ◆ Even if collaboration is not strictly necessary to my current work, will interacting with the proposed collaborators enable me to contribute something significant to science?
- ◆ Do I really have the expertise or other resources that are sought by the other collaborator?
- ◆ Can this collaboration be conducted efficiently, given such factors as distance, restrictions imposed by my institution, and, in the case of international collaborations, cultural differences or legal and political complications?
- ◆ Is there funding for the work envisioned? If not, can it be obtained?
- ◆ Can I afford the time? How much will it take away from my other responsibilities? Is the project close enough to my central interests to warrant the necessary time expenditure?
- ◆ Is this person someone with whom I want to collaborate? What is his or her track record? Can someone I trust tell me whether this potential collaborator is honest and reliable?
- ◆ Are our professional and scientific interests compatible? Does what each of us has to gain or lose by collaborating seem comparable?
- ◆ Will this person be accessible to me and consistently interested in the project? (There is no point in collaborating if interaction will be difficult. An investigator at a small lab may be a better match than the director of a large operation because a more established scientist is likely to be busier and less in need of the collaboration.)

Question: If I am not interested in a collaborative project with my department chair or someone else who can influence my tenure appointment, how do I decline politely?

Answer: Explain to your chair that you don't have the resources at the moment to enter a collaborative project or that it would not be beneficial to your grad student, who needs to work on a project that is all his or her own. Offer instead to provide input and suggestions into the research and, if possible, suggest other people with similar expertise who may be good collaborators.

- ◆ In a larger group, will there be a reliable “point person” who is responsible for handling day-to-day issues and small matters?
- ◆ What exactly is being asked of me? (For example, if someone simply wants your technical expertise or the opportunity to run his or her experiments on your equipment, he or she may not consider you a collaborator at all. The essential ingredient of collaboration is mutual interest in the research outcome. If you have this interest, but the other party assumes that you do not, you may not be treated as a collaborator. This may be acceptable, as long as you understand what you are getting into.)
- ◆ Can I rule out potential conflicts, either personal or institutional? (For example, you do not want to collaborate with a competitor of your department chair or someone with whom your chair is already collaborating.)

Before making a decision about a collaboration, consider all factors. A good collaboration can take your research in a completely unexpected course; a bad one can siphon off energy and demoralize you.

SETTING UP A COLLABORATION

Someone may eventually ask you to collaborate, but if you are a beginning investigator, it is more likely that you will need to approach a potential collaborator yourself. A collaboration, like many relationships, has no fixed rules; however, there are some guidelines you can follow to ensure that the collaboration starts off on the right foot and proceeds smoothly (also see box “Personal Qualities of a Good Collaborator,” page 207).

Approaching a Potential Collaborator

Once you have identified a potential collaborator and decided that you want to go forward, develop an outline of your proposal for the joint project. Define in detail how you think each of you can complement the other's efforts.

Send an e-mail. Make your initial contact with an inquiry designed to whet the other person's appetite. Send a short e-mail describing your research in general terms and asking for the opportunity for a conversation. Do not call on the telephone first—you do not want to put the person on the spot, and you do want to give him or her a chance to find out more about you through personal contacts or your scientific publications.

“

In your initial e-mail, say up front that you are interested in a collaboration. Don't pretend to be asking for expert advice.

—Tom Misteli, National Cancer Institute

”

In your e-mail, focus on the big picture and on conveying your enthusiasm. You must convince your potential collaborator of the following:

- ◆ You have the expertise you claim.
- ◆ You believe that he or she is the best-possible collaborator for the project at hand.
- ◆ Both of you stand to benefit.
- ◆ The whole is indeed greater than the sum of the parts.

Be informed. To make your pitch effective, you need to be familiar with your potential collaborator's work. Be sure to read the lab's published papers. You will also need to have a clear idea of what you want to do and of the respective role each of you will play.

Your e-mail should lead to telephone conversations. After that, a trip to your collaborator's lab for a face-to-face meeting is often worthwhile.

The Collaboration Agreement

Using an informal agreement. An exchange of e-mails is usually sufficient to get a project under way. Before you actually start the work, however, it's best to develop and agree on a detailed written summary of your joint research plan. The plan should spell out the following:

- ◆ The purpose of the collaboration
- ◆ The scope of work
- ◆ The expected contribution of each collaborator
- ◆ Financial responsibilities of each collaborator
- ◆ Milestones
- ◆ Reporting obligations
- ◆ Expectations about authorship

An explicit plan offers several advantages. It prevents misunderstandings, and it helps keep the project on track. Furthermore, if you expect to apply for funding for the project, this information can function as a grant proposal. In a collaboration between two academic labs, the collaboration agreement can simply be e-mailed

back and forth until both parties are satisfied; obtaining signatures could seem overly formal, but it is very important that you conclude these negotiations and reach a clear agreement.

Using a formal agreement. A formal, legally binding written agreement is probably necessary if the collaboration involves a commercial entity such as a pharmaceutical company or a commercial application in which a patent is an expected outcome. You and your collaborator will want to consult with appropriate offices at your respective institutions to help you draft this agreement. This will typically be the technology transfer office or the grants and contracts office; their staff may also arrange for legal review by the institution's attorneys. Make sure to spell out the time period of the collaboration or provide a mechanism by which you can terminate your involvement.

Be aware that if your academic collaborator has financial support from a company for his or her share of the work, the funding agreement may contain restrictions that apply to the collaborative project. For example, the company may have the right to delay publication and to license the results of the collaboration. If the collaboration is an important one for your laboratory, be sure to ask in advance whether your collaborator will use company funding for his or her work on your joint project. If so, you can ask your institution's technology transfer office to help you determine whether there are restrictions that apply to your share of the work. It may be possible to negotiate an agreement that limits the effect your collaborator's funding arrangements have on you. (See chapter 11, "Understanding Technology Transfer," for more information about company-sponsored research.)

THE INGREDIENTS OF A SUCCESSFUL COLLABORATION

Once your agreement is in place and your expectations of one another are clear, you and your collaborator can focus on keeping your lines of communication open and maintaining attitudes of mutual consideration and respect.

Keeping the Lines of Communication Open

An open, trusting relationship is essential if you want to be able to discuss problems candidly and to give and receive critical feedback. In a good collaboration, participants stay in close touch and are accessible to one another. Make it a practice to return your collaborator's calls right away. Make fulfilling your promises to collaborators a significant priority. Don't postpone collaborative commitment for local urgencies that may not have significant impact on your career and scientific reputation.

Meetings. Set up systems to ensure that regular communication takes place. A fixed schedule of face-to-face meetings or conference calls is a must. Also consider setting up occasional videoconferences if your institution and your collaborator's have such facilities. No matter what type of meeting you choose, send out agendas by e-mail, take notes during the discussions, and send out e-mail summaries of the meetings. Include in the summaries "action items" for each collaborator.

Keeping up. Once the project is under way, stay with it. Do not be the “rate-limiting step” that holds things up. When unavoidable conflicts emerge and you can’t meet a deadline, let that fact be known right away, so that the deadline can be reset.

Dealing with Authorship and Intellectual Property Issues

Expectations for authorship. Because credit for your work, expressed as authorship of publications, is crucial to your scientific career, you need to pay attention to how credit will be distributed in a collaboration. It’s best to discuss expectations for authorship, including who will be first author, before a collaboration begins. This is especially important for trainees in your laboratory whose career progress depends on producing work that gives them clear high priority among a paper’s authors. However, agree to revisit authorship as publication nears; the relative contributions of different participants often changes from what was originally envisioned. Once you have a sense of whether the data from your experiments can be published, discuss plans for publication immediately; don’t wait until a manuscript draft is prepared.

Pursuing patents. If patents are sought, applications should be filed before the work is presented publicly or is published; otherwise, rights will be lost. Do not jeopardize your own or the other party’s intellectual property rights by disclosing your results prematurely.

If your collaboration produces patentable discoveries, you will undoubtedly need to deal with the legal concept of “joint intellectual property.” Generally, you will have to assign your ownership in intellectual property to your institution or employer, and your collaborator must do the same to his or her institution. Each party to a collaboration will retain its own “background” intellectual property—that is, the intellectual property it owned before undertaking the project. Each party will also retain the intellectual property rights to discoveries created solely by its own researchers in the course of the project. Joint intellectual property is that created jointly by collaborating researchers. The collaborators’ institutions may file a joint patent application that names inventors from both institutions, and the institutions will hold the patent jointly. Often, the institutions will need to reach an agreement on management and licensing of the intellectual property so that any royalties can be shared according to an agreed-upon formula.

If you think a joint patent application is a likely outcome of your collaboration, ask yourself these questions before you begin the collaboration:

- ◆ What aspects of the proposed project are so interactive that any potential discoveries will be owned jointly?
- ◆ What aspects of shared work are the property of one laboratory?
- ◆ When and how will you discuss patents and publications with workers in your laboratories?
- ◆ Who will take responsibility for, and incur the expense of, filing joint patent applications?
- ◆ Who will maintain the patents once received?

See chapter 11, “Understanding Technology Transfer,” for more information about the patent process, including the effect disclosures can have on the ability to obtain patent rights.

SPECIAL CHALLENGES FOR THE BEGINNING INVESTIGATOR

In the early stages of your career, collaboration can present particular challenges. You are under pressure to get your own research program up and running. You can't afford to let your progress toward tenure be impeded by collaborations that do not yield good results and appropriate credit. You need to keep the following facts of scientific life firmly in mind as you decide about specific collaborations:

Personal Qualities of a Good Collaborator

Honesty

- ◆ Disclose anything that might affect someone's decision to collaborate.
- ◆ Once the collaboration is under way, be willing to “cut through the nonsense” and offer constructive criticism.

Openness

- ◆ Stay in touch with your collaborator throughout the project, especially when there are problems or delays.
- ◆ Try to resolve problems with your collaborator directly.

Fairness

- ◆ Be sure to give credit where it is due.

Industry

- ◆ Put your full effort into the project.
- ◆ Carry your fair share of the labor and financial outlays.

Respect

- ◆ Appreciate your collaborator's contributions.
- ◆ Never assume that your contributions are more important than those of your collaborator.

Reliability

- ◆ Deliver what you have promised, on time.

- ◆ If you collaborate with established, well-known scientists, your tenure committee may undervalue your role in the effort. People may assume that you played a minor role, even if you are first author on a paper. For the same reason, collaborating with your postdoctoral mentor may not enhance your reputation as an independent investigator. If you do collaborate with established scientists or your previous mentor, make sure you arrange the collaboration so that the relative contributions of each scientist are made clear in publications and other communications.
- ◆ The larger the collaborator's lab and the more complex the collaboration, the harder it will be to negotiate first or last authorship. Smaller projects may offer a better chance of getting credit.
- ◆ If you have special technical expertise that is in demand, you may be inundated by numerous requests to collaborate, even within your own department. Do not allow your time to become so fragmented that your central research projects are neglected. Learn to say no gracefully and, if needed, ask your department chair to offer some protection.

- ◆ If you engage in multiple collaborations, the probability increases that you will find yourself with a conflict of interest. Especially in these early years, it is better to keep things simple so that you know all the actors and can identify potential conflicts.

When Your Students and Postdocs Collaborate

Your graduate students and postdocs need to learn to collaborate. You can start them off by assigning them joint projects and by guiding them in establishing their expectations of each other and in monitoring the fulfillment of promises. However, you should be prepared to referee, especially when it's necessary to contain inappropriately aggressive members of your group.

It is quite another matter when your students and postdocs approach scientists outside your lab or are themselves approached as potential collaborators. They may have no idea of the politics involved or of the extent of the commitments they are making. Encourage your trainees to look broadly for help and resources, but insist on your prerogative to approve all outside commitments in advance.

INTERNATIONAL COLLABORATIONS

The practical difficulties of international collaboration can be daunting. They include geographic distance, as well as cultural, linguistic, and political barriers. You must be realistic in judging whether you have the energy and resources to make a long-distance project worthwhile. Ask yourself these questions:

- ◆ How much travel will be required? What will be the costs of each trip in terms of airfare, hotel accommodations, and time away from the lab?
- ◆ Is travel to this country safe?
- ◆ How good are the channels of long-distance communication? (E-mail is virtually universal and certainly will help, but if the other lab is on the other side of the world, long-distance telephone conversations will be inconvenient because of the time difference.)
- ◆ Do I understand the other culture—especially its etiquette of information sharing—well enough to communicate about scientific matters?
- ◆ Do I know the language of my potential collaborators? Do they have a good command of oral and written English? Will scientific papers be published in another language? If so, how can I vouch for the translation?
- ◆ What are the country's customs regarding publishing and authorship?
- ◆ Is the other lab adequately equipped and supported by the country's infrastructure (e.g., electricity, telecommunications)?

Although physical and technical factors are important, it is the human dimension that most often makes or breaks an international collaboration. Be especially sensitive to emotions that may be in play under the surface, especially if your collaborator's lab is less well funded than your own. For example, your collaborators may have concerns about being exploited or disparaged.

Considering these special challenges, international collaboration requires extra dedication. Two key ingredients should be in place at the outset: a stable funding source and at least one individual in the other lab who is as committed to the project as you are and is willing to help push past roadblocks that may arise.

WHEN A COLLABORATION IS NOT WORKING

Collaborations can fail for various reasons. Here are some possible scenarios:

- ◆ One party loses interest or develops other priorities and intentionally or inadvertently puts the project on the back burner. There's no intent to renege, but deadlines are allowed to slip.
- ◆ Illness or family problems hinder someone's progress.
- ◆ Key personnel move on or become uninvolved.
- ◆ Scientific results are not forthcoming, and the project simply stalls.
- ◆ Honest disagreements arise about the plan, finances, or authorship.
- ◆ One or both parties behave badly (e.g., they do not honor some aspect of the agreement, steal credit, or disparage the other collaborator to others).

When such situations arise, you will have to decide how to protect yourself. The worst thing you can do is to allow a bad situation to fester. If you decide your colleague is failing to fulfill the original agreements, get on the phone, or on a plane if need be, and have a straightforward discussion. It is worth your while to try to fix a situation, especially if you have invested significant time and resources in the project. If, however, the other party has lost all interest or you really don't get along, the best thing might be to back out. Although you may be tempted to let your colleagues know about the failure, remember that such a retaliation can harm your reputation as much as that of your collaborator.

If a collaboration doesn't succeed, it's important not to become discouraged. Although collaborations can be a lot of work and, at times, challenging, you will gain much from working with other scientists. Your research can take unexpected turns and expand into new and exciting areas. You will form professional relationships with scientists outside your department who may be willing to write letters of recommendation when it is time to apply for tenure. Your collaborators can help increase your visibility by inviting you to give seminars at their institutes, and they might send graduate students or postdocs to work in your lab.

RESOURCES

Adams, Michael J. “Mutual Benefit: Building a Successful Collaboration.” ScienceCareers.org (October 6, 2000), http://sciencecareers.sciencemag.org/career_development/previous_issues/articles/0630/mutual_benefit_building_a_successful_collaboration.

Dee, Phil. “Yours Transferably: Going Global 2—Making Contact.” ScienceCareers.org (February 16, 2000), http://sciencecareers.sciencemag.org/career_development/previous_issues/articles/0840/yours_transferably_going_global_2_making_contact.

DePass, Anthony. “Collaborations: Critical to Research Success at Minority Institutions.” ScienceCareers.org (March 2, 2001), http://sciencecareers.sciencemag.org/career_development/previous_issues/articles/0840/underrepresented_minorities_in_science_collaborations_critical_to_research_success_at_minority_institutions.

Chapter 11

UNDERSTANDING TECHNOLOGY TRANSFER

Two decades of explosive growth in biomedical science have quietly revolutionized the role of academic investigators in the commercialization of research results. Patent applications for promising discoveries, once the near-exclusive domain of industry, are now filed routinely by research universities. Through the process known as technology transfer, these patents are licensed to companies for development into marketable products or services.

The technology transfer guidelines at your institution will be based, at least in part, on federal and state laws, regulations, and guidance. This chapter provides an overview of the technology transfer information most important to academic scientists. The information should be viewed as a supplement to the information in your institution's faculty handbook and its intellectual property policies.

The chapter reviews the role of the university's technology transfer office (TTO) and covers the ways in which a university's intellectual property (IP) is protected, the process for bringing an invention to market, and diverse types of legal agreements. Conflicts of commitment and interest are also discussed.

UNIVERSITY TECHNOLOGY TRANSFER OFFICES

In 1980, the U.S. Congress passed the Bayh-Dole Act to jump-start the transfer of inventions from federally funded academic laboratories to the public. As a result, today most academic research institutions have TTOs that, with the help of the inventor, evaluate an invention for potential use and marketability and handle the forms, filings, negotiations, and follow-up of technology transfer. Most universities' TTOs follow the provisions of the Bayh-Dole Act, regardless of whether the research is federally funded. This means that if you make a discovery with potential commercial value, your university will own and control the IP, but you will get a percentage of any resulting licensing income, including royalties.

Soon after taking your post at your new institution, you should meet with the TTO staff. They can tell you about what they do and how they can help you.

THE TECHNOLOGY TRANSFER PROCESS

It Starts with an Invention

For a scientist, most technology transfer begins with an invention: a new and useful process, a machine, an article of manufacture, composition of matter, or any related improvement to these. The invention itself has two steps: conception and reduction to practice. Reduction to practice is further subclassified into two types:

- ◆ Constructive reduction to practice involves filing a patent application even though an invention isn't yet physically reduced to practice or "made." The information in the application should make it possible for a person of ordinary skill in the art to make and use the invention without undue research or experimentation.
- ◆ Actual reduction to practice requires a working model demonstrating that the invention will work as intended.

Moving from Invention to License

The journey from invention to license can be frustratingly long and very expensive. The following are typical steps:

- ◆ *Discussion:* The inventor informally discusses the invention with the institution's TTO. These discussions may help the inventor decide whether to proceed with filing an invention disclosure. In some cases, further work on the invention may be advisable before proceeding.
- ◆ *Disclosure:* The inventor reports the invention to the TTO using the institution's standard disclosure form.
- ◆ *Evaluation:* The TTO assesses the invention for patentability and commercial potential.
- ◆ *Filing and commercialization decisions:* The TTO may ask the inventor to do further work on the invention before proceeding, may file a patent application if the invention has commercial potential and appears to be patentable, or may decide to market the invention without filing for patent protection. If the TTO is not excited by commercialization prospects, it may "waive title," in which case ownership rights may be released to the inventor. Some universities waive title only on certain conditions—for example, an inventor may be asked to reimburse patent costs or pay a percentage of any income from the invention or both.
- ◆ *Marketing:* The TTO will contact potential licensees.
- ◆ *Licensing:* The TTO will negotiate and manage licenses to companies.

At the end of this process, approximately 30 percent of inventions reported to the TTO (disclosure) will be licensed.

Should I File an Invention Disclosure?

Deciding whether to file a disclosure with the TTO to report a discovery made in your lab may not be a clear-cut matter. You may wish to discuss it with TTO staff before making a decision. Some of the factors that might encourage you to file include the following:

- ◆ The invention could lead to a useful diagnostic or pharmaceutical, and patent protection would be necessary to convince a company to incur the costs of development and clinical trials.
- ◆ You and your university, department, and colleagues could profit from a patent both financially and in terms of enhanced reputation.
- ◆ If you pass on the opportunity to file a disclosure, and go ahead with public disclosure of your work, it may not be possible to obtain patent protection later on.

Before filing a disclosure, you should also be aware of the following considerations:

- ◆ Dealing with the TTO, patent attorneys, and eventually, licensees, can be very time-consuming.
- ◆ Filing for patent protection can delay publication; you will want assurances from the TTO that the delay will be minimal (often 30–60 days is reasonable).
- ◆ If you can't identify a specific use and potential licensees, it may be unrealistic to expect that the TTO will be able to solve this problem.
- ◆ Be careful with patents on research tools; you will want your invention to be made broadly available, not restricted for the use of a few.

THE LEGAL TERMS AND AGREEMENTS

This discussion is an overview of some of the common terms and legal agreements used in connection with technology transfer. For more information and project-specific assistance, consult your institution's TTO.

Patents

The U.S. Patent and Trademark Office (USPTO) grants three types of patents:

- ◆ Utility patents (20 years) may be granted to anyone who invents or discovers any new and useful process, machine, article of manufacture, composition of matter, or any new and useful improvement to these.
- ◆ Design patents (14 years) may be granted to anyone who invents a new, original, and ornamental design for an article of manufacture.
- ◆ Plant patents (17 years) may be granted to anyone who invents or discovers and asexually reproduces any distinct and new variety of plant.

Most patents produced by academic researchers fall into the utility category.

“

Educate yourself about what constitutes public disclosure. Talking to a grad student doesn't, a faculty lecture comes close, and a presentation in a public forum may cost you the patent rights.

—Martha Connolly, Maryland Technology Enterprise Institute

”

What does a patent do? A patent gives the owner or an exclusive licensee the right to exclude others from making, using, or selling the patented invention for a specific period that begins with issuance of the patent. The patent provides protection within the country where the patent is granted. For U.S. patent protection, an

application may be filed up to one year after public disclosure of the invention, but patent rights outside the United States can't be obtained if public disclosure occurs before a patent application is filed.

Question: Are the public disclosure rules the same for foreign patent rights?

Answer: No. If your invention is publicly disclosed before you file a patent application, you lose foreign rights. If you file a U.S. application before the first public disclosure, you have one year from that filing date to file foreign patent applications. A Patent Cooperation Treaty application preserves the right to file in selected foreign countries for 18 months after the one-year period.

Researchers must have a clear understanding of what constitutes public disclosure. If something you say or write allows someone else to practice your invention before a patent application is filed, you may have created a bar to filing patents on your invention outside of the United States. Before discussing your discovery in any forum that could be considered public, you may wish to consult your TTO about the proposed disclosure.

What is—and is not—patentable? To be patentable, an invention must be useful, novel, and “nonobvious” to someone of ordinary skill in the art. If you think you have a discovery that meets these criteria, the best approach may be to go directly to your TTO and let the experts take charge from there.

You may want to conduct a “patentability search” of key words at <http://www.uspto.gov> to screen for similar inventions in the files of patent applications. You can do this yourself, without the aid of a patent professional.

Certain forms of unpatented IP may be licensed to companies by the TTO for commercial use. These kinds of IP include the following:

- ◆ *Tangible property:* This can be licensed for compensation but without patent protection; others are not precluded from independently developing the same materials. Examples are cloned DNA, viral vectors, cell lines, seeds, tissues, and organisms.

- ◆ *Know-how*: This can be licensed in some circumstances, usually nonexclusively in conjunction with a patent license. Examples are techniques, experimental systems, and special knowledge.
- ◆ *Copyrighted works*: Although copyright in scholarly works normally rests with the authors, copyright in other written works may be claimed by the university. Examples are formulas, algorithms, and software, including source code.

In contrast to industry, universities almost never maintain trade secrets, which are antithetical to the knowledge-expanding culture of an educational institution.

Who Owns Inventions at a University?

As a condition of employment, U.S. universities require faculty and staff to assign invention rights to the university. A common key phrase in university IP policies is “use of university funds or facilities” in conception or reduction to practice of inventions or development of materials, which extends the institution’s ownership to IP of graduate students and guest researchers. In other words, the university owns inventions made by university personnel and may have rights in inventions made by others using university funds or resources.

The patent application. When the TTO is confident that your invention meets the criteria for being patented and has commercial potential, it’s time to prepare a patent application. Like most legal documents, a patent application is best prepared by a specialist—a patent attorney or agent. Universities normally hire patent law firms to prosecute patent applications.

The patent attorney is likely to need input both from the inventor(s) and the TTO in order to prepare a patent application. You can expect to speak with the patent attorney several times over the course of the patent process. You will probably also be asked to review draft documents. The major elements

of a patent application are the abstract, background/introduction, specification (how to practice), and claims.

In preparing the patent application, the patent attorney will need to make a determination of who should be named as inventors. It is important that this determination

be accurate, because a patent may be invalid if the named inventors are not correct (either because an individual who did not make an inventive contribution is named or because an individual who made an inventive contribution is not named). The inventors may differ from the authors of the paper that describes the invention. For example, a postdoc who joined the project after the inventive steps had occurred and then provided supporting data might be a coauthor but not an inventor. Normally, only the named inventors share royalties under institutional policies.

Question: How much does it cost to get a patent?

Answer: Costs vary widely depending on factors such as the patent attorney’s time spent and hourly rate, what is being patented, the number of claims in the application, the number of (and reasons for) USPTO rejections, and whether foreign filings are pursued. Preparation costs can run between \$5,000 and \$20,000 and up, and filing fees and possible prosecution cost between \$3,000 and \$5,000 and up (sometimes much more). The university pays the fees, but in almost all cases, the first income from the invention is earmarked for reimbursement of these costs. Only then does the income-sharing formula for the inventors kick in.

What happens to the patent application? From the time the application is filed, the USPTO usually takes 12 to 18 months to complete its examination and issue an “Office Action.”

The first Office Action is generally a rejection. The applicant is then required to narrow patent claims and justify the novelty or nonobviousness of the invention in the light of prior art identified by the USPTO. Subsequent Office Actions often result in issuance of a patent, but this process takes an average of about three years.

An alternative is a provisional patent application, a streamlined version that can be filed without some of the time-consuming formalities of the standard form. The USPTO doesn’t examine this type of application, a patent can’t be issued directly from it, and it expires automatically one year after its filing. During that year, the university can file a regular patent application. So what’s the point? This option has at least three benefits:

- ◆ Temporary filing protection can be secured for your invention for less money (less time for an attorney and a filing fee of only \$100 for a small entity or a university).
- ◆ If filed before a public disclosure, a provisional application preserves the right to file for foreign patent protection.
- ◆ The one-year term of a provisional application doesn’t count toward the 20-year (or other) patent term.

Many applications filed by universities are provisional, even if the application is extremely thorough. The reason: This option buys valuable time. The technology is usually at an early stage of development. A year later, the TTO can file a regular application that includes not only the invention described in the provisional patent application but additional results developed in the interim, which may result in approval of broader claims.

Technology Transfer and Faculty Recruitment

Increasingly, TTO staff are part of the university recruiting team. When faculty candidates compare employment offers, many often consider the university’s commercialization record and policies regarding income sharing.

Commercialization record. Licensing and commercialization success can be strong selling points, along with the TTO’s track record in crafting advantageous terms.

Income sharing. Formulas differ for distributing IP-related royalty and equity income, but a common distribution is 40 percent as taxable income to the inventors (split if there are multiple inventors), 40 percent to the inventors’ departments for education and research, and 20 percent to the university for management of the invention and support of technology transfer efforts. However, some universities give the inventors as much as 50 percent of net licensing income, and others give the inventors as little as 20 percent.

Despite its conditional nature, a provisional application shouldn't be a sloppy filing that the TTO plans to fix during the following year. It should be prepared by a patent attorney or agent and held to the same standards as the work that led you to this point. In addition, be aware that in some cases in which a provisional patent is filed, TTO staff may not yet have done a thorough search for competing or similar patents. You should find out whether such searches have been conducted and make sure a patent attorney examines the results.

Licensing Agreements

In technology transfer terms, a license is a legal contract that allows a company to make, use, and/or sell a university's invention. Through a licensing agreement, someone agrees to pay for the use of IP that someone else (in this case, the university) owns—under strictly defined terms and conditions that are specific to each license—but the university maintains its ownership rights to the IP. In other words, a license allows people (or entities) to make, use, or sell something they don't own without being prosecuted. If special know-how developed by the inventors is needed to “practice” the invention, it's often included as part of the licensing agreement.

Licenses can be exclusive or nonexclusive. An exclusive license grants the right to use the invention to only one licensee. Exclusive licenses usually allow the license holder to sublicense the invention to others for a fee. These sublicenses generate “pass-through royalties” as an additional source of income to the university. A license also can be granted exclusively to one licensee for a specific application, or “field of use,” maintaining the university's option to issue licenses for other fields of use.

A nonexclusive license can be granted to multiple companies. The TTO, with the inventor, will decide whether an invention is best licensed exclusively or nonexclusively. Know-how is usually licensed nonexclusively in order to preserve the inventor's right to share the know-how with other scientists informally.

Question: Do I have any say in where my invention is licensed?

Answer: Although your university has ultimate authority regarding the choice of licensee and the license terms, you will probably have some control over where your invention goes. In the licensing process, a full faculty member's preferences will likely carry more weight than a postdoc's. In some cases, a company will already have licensing rights because it provided research funding or materials. If it exercises those rights, the university may not be able to license the invention to any other company, regardless of the university's or inventor's preferences.

Your TTO will probably handle licensing arrangements for your institution, but keep in mind one point: Many companies often want all future improvements to an invention to be licensed to them. However, universities generally do not license inventions or improvements (unless very narrowly defined) that have not been made. This policy serves as a protection to you, the inventor, to keep from encumbering your future research results. You need to be aware of the tension between the interests of the university and the companies to whom inventions may be licensed.

Negotiating the Agreement

The TTO has responsibility for protecting the university's and the inventor's interests. If the inventor insists on unreasonable terms, some TTOs may be obliged to present them, damaging the negotiating process and the relationship in which all of you will be tied. So, try to refrain from inserting yourself into the negotiating process in this way. During the negotiation, however, it is necessary for you to understand what restrictions an exclusive license may impose on your ability to share data or materials with others.

Option Agreements

An option agreement is a right to negotiate a license—a document that says, “I want to and I hope I can, but I’m not ready yet.” It’s less complex than a license, relatively easy to negotiate, and may or may not include the financial terms of the expected future license.

Because it’s of limited duration (usually 6 to 12 months), an option agreement is a useful mechanism in dealing with start-up companies and their inherent uncertainties. It gives the hopeful licensee an opportunity to secure funds and attract other resources needed for commercial development, and it gives all parties time to evaluate the technology and what each brings to the table and to establish trust.

Material Transfer Agreements

Often as a result of a publication or presentation, other researchers may request materials from your lab—generally a cell line, animal model, research reagent, genetic construct such as a plasmid or phage, or purified proteins. Some institutions require that a material transfer agreement (MTA) be signed and returned before material is sent out. Some send the MTA form with the shipment and consider delivery of the material to be implied consent, whether or not a signed MTA is ever returned. Others may be unconcerned about keeping records for outgoing material (at least when the recipient is another nonprofit institution).

Almost all MTAs for incoming materials require the signature of an authorized representative from the university. Even if an institutional signature is not required by the materials provider, university policy may call for institutional review of the terms anyway. Check with your university’s TTO about who needs to approve the terms for and signs MTAs for incoming materials for your lab.

MTAs have distinct uses and caveats according to the entities involved. The following lists address three MTA scenarios: transfer of materials between academic labs, from academia to industry, and from industry to academia.

MTAs covering transfers between academic labs. These MTAs usually have relatively benign provisions. An exception is when the materials have been exclusively licensed to a company that successfully negotiated for restrictions on distribution. Work to avoid this situation because it puts your responsibilities as an author to share reagents at odds with your contractual responsibilities to a licensee. MTAs used for transfers to an academic lab typically and reasonably require that recipients of the materials do the following:

- ◆ Use the materials for noncommercial research purposes only.
- ◆ Acknowledge the providing scientist in publications.

- ◆ Not send materials to third parties without the provider's consent.
- ◆ Assume responsibility for damages caused by use of the materials by the recipient.
- ◆ Not use the materials in human subjects.

MTAs used for transfers from academia to industry. These MTAs usually do not permit use of the materials commercially (e.g., for sale or to make a commercial product) or in human subjects but allow use for defined internal research purposes. They may also require that recipients do the following:

- ◆ Share manuscripts before publication, in addition to providing proper acknowledgment in publications.
- ◆ Indemnify the provider for damages caused by use of the materials by the recipient.
- ◆ Not send the materials to third parties.
- ◆ Pay a fee.

MTAs used for transfers from industry to academia. These MTAs tend to be the most restrictive and difficult to negotiate. They may include the following terms:

- ◆ *Ownership:* Beware if the definition of materials specifies that the company will own all derivatives and modifications made by the recipient or if the MTA requires assignment of inventions to the company or provides the company with an automatic nonexclusive license to all inventions. Many institutions try to avoid granting broad “reach-through” rights in new materials or inventions developed by their faculty.
- ◆ *Publications:* Beware if the MTA reserves to the company the right to approve or deny publications. More reasonably, the company may require review of manuscripts 60 days or more before submission for publication, and delay of publications for 60 days or more after manuscript submission. At a minimum, most companies want a 30-day prepublication review to protect confidentiality and their investment and to consider filing for patent protection.
- ◆ *Reporting:* The MTA may require extensive reporting and sharing of data from the recipient.

The university's TTO will scrutinize the language of an MTA for incoming materials for restrictions like these and weigh the costs and benefits. If negotiations can't alter unacceptable MTA terms, the university may refuse to proceed. Under these circumstances, the requesting university scientist will not be able to get the materials from that provider.

SPONSORSHIP AND CONSULTATION

Through publications, presentations, and personal contacts, the work of an academic investigator might pique the interest of industry. If there's a good fit between the avenue of research and the company's strategic interests, the company may want to buy an option to commercialize the lab's research results or support some of the investigator's research. Or the company may invite the investigator to become an adviser or consultant. The typical mechanisms for doing so are described next.

Sponsored Research Agreements

When a company funds a university laboratory's research, the terms are spelled out in yet another form of legal agreement, called a sponsored research agreement, negotiated by the TTO or the university's grants and contracts office. Most sponsored research agreements will take into account the following guidelines:

- ◆ *Project control:* The work should be entirely under the control of the university, not directed in any way by the sponsor.
- ◆ *Technical representatives:* A person from the institution and the sponsoring company should be identified to serve in this capacity, establishing a researcher-to-researcher relationship. These are usually the scientists leading the research at both places.
- ◆ *Reporting:* Reporting requirements should be limited, and oral reporting allowed as much as possible, to minimize what can otherwise be a time-consuming burden. Sponsors usually require quarterly or semiannual reports or meetings for periodic updates on the research.
- ◆ *Publishing rights:* The university should ensure that the laboratory has the right to publish and present all findings. The sponsor may have the right of advance review but not the power to veto proposed publications and not the right of editorial control.
- ◆ *Invention rights:* The university owns inventions that arise from the sponsored research but will tell the sponsor about the inventions in confidence.
- ◆ *Licensing rights:* The sponsor is usually given a time-limited right to negotiate for an exclusive or nonexclusive license to inventions that arise from the research.

Question: How do I find the right sponsor for my research?

Answer: Look for a strategic as well as a scientific fit, an alignment of business objectives, and a supportive alliance with management. Heed your instincts: If it doesn't feel right, chances are that it's not right.

- ◆ *Discussion and collaboration:* The university researchers should have the right to discuss their work on the sponsored project with other academic scientists and to collaborate with them (as long as the other scientists are not funded by a different company).

Consulting Agreements

Faculty members are usually allowed to spend a limited amount of time on consulting outside their institutions. If you have a manual that outlines the university's consulting policies, make sure you read it and understand the policies.

Review the agreement. If your institution chooses to review consulting agreements involving employees, the appropriate office will examine your proposed agreements for conflicts of interest and other problems. If your institution does not review these agreements, consider hiring a qualified person (e.g., a contract law specialist) at your own expense to conduct a contract review because consulting may subject you to personal liability. The TTO can probably give you a referral for this purpose.

Best practices. Consulting agreements vary widely to suit the particulars of a given situation, but they should abide by some general best practices as outlined below.

Companies should engage consultants for the exchange of ideas only, not to direct or conduct research on behalf of the company. They should not use the name of a consultant or university in promotional materials unless they have written consent.

Consultants should have a limited and reasonable time commitment (e.g., a maximum number of days per year for a specific number of years). There should be a provision allowing the consultant to terminate the agreement by giving reasonable notice, and it is fair for the company to have the same right. Consultants should

Protecting the Rights of Graduate Students

Typically, industry-funded research agreements provide the industrial partner with an interest (normally licensing rights) in intellectual property that results from the funded research and include confidentiality obligations restricting the dissemination of the results.

Such provisions may raise issues when students are involved in the research. For example, a graduate student has to be able to communicate his or her thesis work in order to graduate. It is important that students are fully informed by their existing or potential supervisors of any existing or potential contractual agreements between an industry sponsor and the university or academic center that may affect their projects. It is also important that university policies relating to student participation in industry-funded projects are followed. The supervisor should have a clear understanding of what the agreements entail and how they might affect a student's ability to communicate his or her work as well as inform students of any restrictions that may affect them. During the course of the industry-funded project, graduate students working on the project must be free to present and discuss their research in university forums, such as lab meetings or graduate student seminars, and meetings of the thesis advisory committee. This may be directly in conflict with confidentiality obligations in the agreement. In some cases, it may be possible to arrange for confidentiality agreements to be signed (e.g., by the thesis advisory committee); in other cases, it may be neither possible nor consistent with university policy. As to final publication, many universities have guidelines stipulating that publication of thesis-related research may be delayed no longer than 90 days from the time a manuscript is submitted to the sponsor for review. This delay should be sufficient for the filing of a patent application and allow the industry sponsor an opportunity to request deletion of any of its proprietary information from the manuscript.

not disclose information about their laboratory research that they wouldn't normally disclose to members of the scientific community. In addition, they may assign to the company rights in inventions arising from consulting activities if such rights haven't arisen from their own research undertaken as a university employee.

Consulting agreements should acknowledge that the consultant is an employee of the university and is subject to all of its policies, including those related to IP and conflict of interest (COI). If the company requires a noncompetition clause, the consulting agreement should state that this provision doesn't apply to the consultant's relationship with the university.

CONFLICTS OF COMMITMENT AND INTEREST

Whether the lure is simply scientific inquiry or economic rewards, a career can easily run aground on conflict of commitment or interest.

Conflict of Commitment

Is your time really your own? Yes and no. As an employee, your first professional obligation is to fulfill your agreed-upon duties to your employer—the university or research institution. Faculty members should give priority to their time and goals accordingly. The “20 percent rule” is a good guideline (if consistent with your university's policies): You may take up to 20 percent of your time for outside activities that are in the interest of you and the university.

Conflict of Interest

When dealing with technology transfer, a COI can lurk anywhere from the sponsorship of research to the nature and timing of published research results. One of the most common scenarios for COI is when the content or timing of published research findings affects license income, funding, or stock value for the financial gain of the investigator or the institution. The following definition, from Francis Meyer of A. M. Pappas & Associates, can help you recognize a potential COI:

“A conflict of interest is a situation in which financial or other personal and institutional considerations may directly or significantly affect, or have the appearance of directly and significantly affecting, a faculty or staff member's professional judgment in exercising any university duty or responsibility or in conducting or reporting of research.”

Here are some tips to help you avoid COIs:

- ◆ Remember that industry is interested in science to increase sales and profits. Altruism and enlightenment are not corporate incentives.
- ◆ Be careful about your involvement with start-up companies. With a start-up, you're more likely to have significant equity in the company, and if the company was founded on your technology, the possibility of a COI increases.

- ◆ Be careful of what you say during press interviews. It may be better to let the university do the public speaking about your research. Off-the-cuff remarks can present an opportunity for a COI to be perceived where none exists, and the perception can be as damaging to a scientist's credibility and career as the reality.

At some point in your research career you may make a discovery in your lab that has potential commercial application. By having a better understanding of the concepts, processes, and potential pitfalls of technology transfer, you will be better prepared to work with your university's TTO and with industry to bring your discovery to market.

RESOURCES

Association of American Medical Colleges. Reports from Task Force on Financial Conflicts of Interest in Clinical Research, <http://www.aamc.org/research/coi/start.htm>.

Association of American Universities. Information on intellectual property issues, <http://www.aau.edu/intellect/ipissues.cfm>

Association of University Technology Managers. http://www.autm.net/index_ie.html.

Cech, Thomas R., and Joan S. Leonard. "Conflicts of Interest—Moving Beyond Disclosure." *Science* 291(5506): 989, 2001.

Council on Governmental Relations. Information on intellectual property, http://www.cogr.edu/files/publications_intellectual.cfm.

Field, Thomas G. "Intellectual Property: The Practical and Legal Fundamentals." Franklin Pierce Law Center, <http://www.fplc.edu/tfield/plfip.htm>.

Howard Hughes Medical Institute. "What You Should Know About Intellectual Property, Research Collaborations, Materials Transfers, Consulting, and Confidential Disclosure Agreements," <http://www.hhmi.org/about/ogc/downloads/investigator-guide.pdf>.

Legal Information Institute, Cornell Law School. "Patent Law: An Overview." <http://www.law.cornell.edu/topics/patent.html>.

National Institutes of Health. Information on conflict of interest, <http://grants.nih.gov/grants/policy/coi/resources.htm>.

U.S. Patent and Trademark Office, <http://www.uspto.gov>.