THE REPRODUCTIVE
SCIENTIST DEVELOPMENT
PROGRAM

Lab Management Workshop
Developed for the RSDP Lab Management Workshop
May 12-13, 2017 in St. Louis, MO

The Reproductive Scientist Development Program (RSDP) provides career development support for obstetricians and gynecologists who are committed to a basic science career in academic medicine and research. The RSDP is committed to providing our scholars the necessary tools and training needed to further their careers in basic science and it has been brought to our attention that RSDP scholars are in need of additional support.

We have heard from numerous scholars (past and present) that, as they transition to their faculty roles as part of the Phase II requirement, they felt unprepared to tackle issues relating to their appointments, lab management, and grant writing. In an effort to assist scholars, we are putting together a “LAB MANAGEMENT COURSE” that will be mirrored off of a similar course provided by BWF in conjunction with HHMI back in 2006.

Visit: https://www.rsdprogram.org

RSDP Program Directors

<table>
<thead>
<tr>
<th>Year</th>
<th>Director</th>
<th>Institution</th>
</tr>
</thead>
<tbody>
<tr>
<td>1988 – 2013</td>
<td>Robert B. Jaffe, MD</td>
<td>University of California San Francisco</td>
</tr>
<tr>
<td>2013 – 2018</td>
<td>Kelle H. Moley, MD</td>
<td>Washington University</td>
</tr>
<tr>
<td>2019 – 2023</td>
<td>Danny J. Schust, MD</td>
<td>University of Missouri, Columbia / Duke University</td>
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Based on workshops co-sponsored by the Burroughs Wellcome Fund and HHMI, this book is a collection of practical advice and experiences from seasoned biomedical investigators and includes chapters on laboratory leadership, getting funded, project management, and teaching and course design.

The manual is available online at:
https://www.hhmi.org/science-education/programs/resources/making-right-moves
RSDP Lab Management Workshop

Friday, May 12, 2017

8:00 am to 8:15 am

Welcome and Introduction
Presented by
David Perlmutter, MD
Executive Vice Chancellor for Medical Affairs
Dean of Washington University School of Medicine

8:15 am to 9:00 am

Obtaining and Negotiating Positions
Presented by
Charles Lockwood, MD
Senior Vice President, USF Health
Dean, Morsani College of Medicine

9:00 am to 9:45 am

University Structure and Tenure
Presented by
George A. Macones, MD, MSCE
Professor and Chair, Department of Women’s Health
Dell Medical School
The University of Texas at Austin
Kelle H. Moley, MD
Deputy Director, Reproductive Health Technologies
Bill & Melinda Gates Foundation

10:00 am to 10:45 am

Laboratory Leadership in Science
Presented by
Robert N. Taylor, MD, PhD
Department of Obstetrics and Gynecology
Jacobs School of Medicine and Biomedical Sciences
University at Buffalo

10:45 am to 11:30 am

Lab Data Management
Presented by
Kjersti Aagaard, MD, PhD, MSCI
Professor and Vice Chair of Obstetrics and Gynecology
Baylor College of Medicine

1:00 pm to 1:45 pm

Mentoring and Being Mentored
Presented by
Colleen Miller, MD
REI fellow
Mayo Clinic
James H. Segars, Jr., MD
Howard W. and Georgeanna Seegar Jones Professor and Director
Division of Reproductive Sciences & Women’s Health Research
Department of Gynecology and Obstetrics
Johns Hopkins School of Medicine
1:45 pm to 2:30 pm  
**Time Management**  
Presented by  
Dineo Khabele, MD  
Chair, Department of Ob/Gyn  
Mitchell & Elaine Yanow Professor  
Department of Obstetrics & Gynecology  
Washington University School of Medicine

3:30 pm to 4:15 pm  
**Staffing your Lab**  
Presented by  
Anil K. Sood, MD  
Professor and Vice Chair for Translational Research  
Departments of Gynecologic Oncology & Reproductive Medicine  
MD Anderson Cancer Network

4:15 pm to 5:00 pm  
**Project Management**  
Presented by  
Michael C. Snabes, MD, PhD  
Senior Director, Men and Women’s Health  
AbbVie, Inc.

**Saturday, May 13, 2017**

8:00 am to 8:45 am  
**Getting Funded**  
Presented by  
Sam Mesiano, PhD  
William H. Weir, MD, Professor of Reproductive Biology  
Department of Reproductive Biology, Case Western Reserve University  
Vice Chair for Research, Department of Obstetrics and Gynecology,  
University Hospitals of Cleveland

8:45 am to 9:30 am  
**Getting Published**  
Presented by  
Jerome F. Strauss, III, MD, PhD  
Emeritus Professor of Obstetrics and Gynecology,  
Perelman School of Medicine, University of Pennsylvania

9:45 am to 10:30 am  
**Teaching and Course Design**  
Presented by  
Antonio Frias, MD  
Associate Professor of Obstetrics and Gynecology  
Oregon Health Services University

10:30 am to 11:15 am  
**Understanding Tech Transfer**  
Presented by  
Nichole Mercier, PhD  
Managing Director, Office of Technology Management (OTM)  
Washington University
Contents

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Chapter 1

Obtaining and Negotiating Positions

Dr. Charles Lockwood
Senior Vice President, USF Health
Dean, Morsani College of Medicine
First, Know Yourself—What do I want and need from my job?

Type of Institution
- Size (big fish in a little pond or vice versus)
- Reputation (may be inverse with salary)

Percent protected time for research vs. clinical, teaching, etc.?
- Are you a clinical, translational or basic researcher
- Do you need to maintain surgical skills (Gyn Oncology vs. MFM)
- How much salary will you need

What are your must-haves? (facilities, mentors, etc.)

Does Location Matter?
- Should be addressed after you decide “what?”
- What personal needs do you have? (close proximity to family, spouse, climate, etc.)
- Do you prefer urban, rural or suburban location?
- Aim to narrow down your search.

Second, Discover what is available
- Never neglect networking—mentors, mentors, mentors! They can help with the fit, make contacts and have knowledge of who is hiring.
- Internet sites like LinkedIn.
- Journal announcements.
- Professional organization websites.
- http://sciencemag.org/careers
- http://chronicles.com/jobs
- Employment websites of academic institutions.
Third, Evaluate Job Against Your Priorities

- Make sure your career goal expectations align with Dean, Chair and their vision for medical school and department, respectively.
- Do they have a track record of supporting researchers and a critical mass?
- What are the finances of the medical school, department and AMC?
- Make sure you meet enough other people with whom you will work to assess your “fit.”

Appointment, Promotion and Tenure

- If you have seen one A&P committee....
- Make sure you understand pathways available (tenure, non-tenure clinical research or educator tracks).
- Understand what tenure means at each institution.
- Get a copy of AP&T guidelines and/or review the relevant website so you will be able to ask appropriate questions.

The Process: Job Application

- Cover letter — not too long, be truthful about career vision.
- Keep your CV updated!!
- A word about 2 Career Couples — more complicated recruitment for chair.
- Research Proposal Description and “wish list” (do you have an NIH grant? If no—don’t over-ask for resources)
- Identify prospective mentor(s)/advisor.
  - Expert in field and familiar with your work
  - History of mentoring.
- Avoid media mistakes (Facebook may be your worst friend). Google yourself — or who the internet thinks you are.

Positioning Yourself

- Preparation for interview. Practice your skills. Practice makes perfect – role play the ask.
- Refine and practice your research presentation and update your slides.
- Think about what questions and prepare answers.
- Google departmental leaders with whom you will meet so you know what they are doing.
Use your network to find out information about who you are going to negotiate with.

Logistics—make sure you have after hours contact info in case of travel delay.

So you’ve made it to the table!

- BE YOURSELF.
- Show your passion for your work.
- Telegraph that you will be a trusted and productive colleague.
- Important to discover if you feel comfortable in the department.
- Treat everyone with respect; especially administrator assistants.

Post-Visit To Do List

- Thank you notes to appropriate individuals.
- Follow-up on any promises you’ve made; sending a reprint, sharing data, etc.
- Let search committee know that you are still interested, or if you have taken another job.
- Get to know search executives—bond

The Offer Letter

- When offered a position negotiate terms for offer letter.
- Salary, bonus, benefits (AAMC 50th to 75th%ile).
  - Retirement: many Univ. programs will match up to a 5% contribution 2:1 or more.
  - Insurances, moving costs, educational stipends
- Know the sources of your salary and how they may change (e.g., state, endowment, grants, start-up, clinical ($$ or RVUs) and teaching (hours vs. quality of evaluations).
- Distribution of time (% effort) and protected time.
- Appointment rank and pathway—you should have done this already.
- Lab space metric ($$/NSF) and quality of facilities, cores, vivarium (cage costs).
- Start-up funds, grant expectations and time to reach targets.
- Additional support—personnel.
- Expectations in terms of grant funding, peer-reviewed publications, service on committee, teaching responsibilities, etc.
- Check on the length of your initial contract and renewal terms.
- Once you receive an offer letter there is still time for negotiation.
- 9-month vs 12-month appointment.
- Outside consulting policy.
- Benchmark your salary offer with data from AAMC or AAVP. (www.aamc.org; www.aavp.org)

**Career Advancement**

- What type of initial appointment will you have? (Ass’t. Prof, Clinical Instructor, other)
- Caveat: your appointment type may affect benefits, with Ass’t. Prof the best choice.
- What is expected for reappointment and promotion? (Ask for a copy of promotion guidelines from Faculty Affairs)

**The Business of Medicine: Other Critical Topics**

**Productivity**

- Will billings and collections be tracked and compensation adjusted accordingly?
- Are bonuses distributed, and how are they calculated?
- What is the measure of academic productivity, and how is it tracked? Does it affect compensation?
- Is the Division/Dept. profitable?

**Restrictive Covenant**

- Definition: a clause in a contract that prevents one party from certain actions.
- Usually prohibits practice within a certain region if one leaves present employment.
- Cities, counties, distance in miles, may be subject to negotiation.
- May or may not be required.
Final Thoughts

- Some topics may be difficult to initiate, but better to have an early discussion.
- In negotiations, get a sense of limits, which vary. You must balance addressing your personal needs with avoiding the appearance of being “difficult.”
- Many people reveal their “true selves” in negotiations.
- Get a sense of your potential employer’s comfort with discussing some of these topics: do not push issues that are not important to you.
- Do not be surprised if your potential employer does not have ready answers to your questions.
- Do not be surprised if your employer appears just as uncomfortable discussing some of these issues as you are!

You have already made the most crucial decision: to enter academic medicine.
Chapter 2

University Structure and Tenure

George A. Macones, MD, MSCE
Professor and Chair, Department of Women’s Health
Dell Medical School
The University of Texas at Austin

Kelle H. Moley, MD
Deputy Director, Reproductive Health Technologies
Bill & Melinda Gates Foundation
Board of Trustees

May be multiple Boards
- Hospital/health system
- Medical School
- University

Composition
- Business leaders
- Esteemed alumni
- Sports/entertainment

Potentially important for philanthropy

People to Know
- Trustees, University President (doubtful)
- Dean (maybe....)
- Department Chair (for sure)
- Center Directors
- Division Chiefs
- Senior scientists within and outside department

Important Groups and Committees
- Human Resources
- Faculty Affairs
- Environmental Health and Safety
- IRB/Human Subjects
- Institutional Animal Care and Use Committee
- Office of Technology Management
- Risk Management
- Grants and contracts
- Public Relations
- Development
What is tenure?

Tenure: A tenured appointment is an indefinite appointment that can be terminated only for cause or under extraordinary circumstances. Tenure defends the principle of academic freedom, which holds that it is beneficial for society in the long run if scholars are free to hold and examine a variety of views.

Career Milestones

Year 1: Negotiate start up package

Year 1
- Set up lab; hire people
- Use start up funds—don’t hoard them
- Faculty mentor
- Understand expectations and "rules" for promotion
- Work hard
- Committees—be careful
- Grants—small pilot grants

Year 2
- Publish
- Use start-up funds
- Grants—think bigger; NIH/NSF/other
- Teaching
  - Be sure to get evals

Year 3
- Continued progress—resubmit grants
- Meet with mentors and dept chair regarding progress

Years 4-6
- National recognition
- National committees (study sections, meeting planning etc)
- Slow progress?
  - Meet with Dept leadership
  - Work hard
  - Career planning
Project Fuh Project Update with George Macones: May 11, 2017

<table>
<thead>
<tr>
<th>Project 1 (RDSP): siRNA screen for attachment with NOFs and CAFs (Greg Longmore)</th>
<th>Project 2 (CFF): DNA/RNA profiling with clinical prognosis (Elaine Mardis)</th>
<th>Project 3 AXL platinum-resistance in uterine ca — R428 (Palisoul — 2nd year fellow/Quinn)</th>
<th>Project 4 AXL/nanoparticle therapy in uterine cancer (Kate Mills — 1st year fellow)</th>
<th>Project 5 SQ1274 vs paclitaxel in chemoresistant uterine and ovarian cancer (Kate Mills)</th>
<th>Project 6 Role of DDR1 ovarian cancer (Beck/Grither/Quinn)</th>
<th>Project 7 Expression of DDR2/DDR1/AXL in BRCA2/- (New fellow)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screen completed on May 2016</td>
<td>( ) Analysis currently ongoing</td>
<td>( ) manuscript to be submitted in May 2017</td>
<td>( ) in vitro and in vivo experiments</td>
<td>( ) experiments ongoing</td>
<td>( ) experiments ongoing—preliminary data for R01</td>
<td>( ) manuscript to be submitted in June 2017</td>
</tr>
<tr>
<td>Performing experiments to validate hits (DDR1 and DDR2 — basis of R01)</td>
<td>( ) Waiting sequencing of good survivors</td>
<td>( ) manuscript to be submitted in June 2017</td>
<td>( ) manuscript to be submitted Jan 2018</td>
<td>( ) experiments ongoing</td>
<td>( ) preliminary data for R01</td>
<td>( ) basis of SPORE project</td>
</tr>
</tbody>
</table>

Project 8 AXL/ME R platinum-resistance in ovarian cancer (Jeanne Quinn)

Project 9 New pathway by correlating target from Project 1 + Project 2

Project 10 U10: Neoadjuvant vs primary debulking profiling and proteomics for PDX (DGM/Mardis/Townsend)

Project 11 U01: Prelim data — Omics of U10 specimens (DGM/Ding/Townsend)

Project 12 MERCK trial: Neoadjuv PD-1 inhib in endo cancer (Premal Thaker)

Project 13 NCI Match Trial: Dasatinib and DDR2

Project 14 Proteomics of Primary vs Met Uterine serous cancer (PNNL) (Mutch/Li Ding)

( ) XTT assays with shRNA cells to evaluate for restoring chemosensitivity

( ) PDX PB1 data

( ) Working with analysis team at Genome Institute

( ) Working with Li Ding to analyze the data for the manuscript

Grant submitted May 11, 2016

Enrolled first patient

( ) Optimizing tissue processing and need CyTOF panels

Translational Trial Arm PI on 10/15/2014

( ) Phone conf with Lab who have a project with Pacific Northwest National Lab who have a U01 for proteomics

Collaborative project with Pacific Northwest National Lab who have a U01 for proteomics

Submitted (not funded)

ICTS 2013

Siteman Cancer Res Development Award 2014

RSDP Suppl Fund — 10K (ended 7/2015)


SSC Resources Award — 3.5K (ended 5/2015)

Siteam Cancer Research Fund 5/30/14

FWC — 75K (5/2015-4/2016)

Elsa Pardee Award 6/1/14

Current Funding

Mallinckrodt Foundation 5/27/14

RSDP Phase II (8/2015-7/2018)

ACS-Irg 12/1/14

Merck endometrial trial — $237

BWF 9/2014

ACS-IRG — 30K (1/2017-12/2018)

Marsha Rivkin 3/2/2015

RSDP Supplement — 10K (ends 7/2017)

Damon Runyon Clin Investigator 2/2017

Submitted (funded)

3. Nanoparticle inhibition of AXL in uterine serous cancer Molecular Cancer Therapeutics 7/2017

4. Adaptive kinase to chemoresistant ovarian cancer (U10 project)

5. SQ1274 has improved treatment over paclitaxel in ovarian cancer Gynecologic Onc 1/2018

R01 ideas (October 2017)

1. DDR1 and DDR2 in ovarian cancer

2. Characterizing a new target from the siRNA screen and sequencing data

3. Mechanism of AXL and fibronectin secretion in the context of the tumor microenvironment

Pending/Future submissions

Submitted & Pending

1) Mary Kay Foundation (100K over 2 years) submitted 2/3/2017

2) Cancer Research Foundation (75K over 2 years) LOI submitted 4/13/17 — Invited to submit full application due 10/2017

3) OCRF Liz Tilberis (450K over 3 years) — apply last year of RSDP May 2017

To be submitted in 2017:

4) DOD — Early Career $725K over 4 years — LOI June 2017

5) DOD — Pilot grant vs Investigator Initiated Award $250 over 2 years vs $450 over 3 years

6) R01 June 2017

7) ACS-Research Scholar or Mentored Research Grant — October 2017

8) Conquer Cancer Found. Career Development Award 200K x 3 years

9) Sidney Kimmel December 2017

To be submitted in 2018:

10) SPORE project 1/2018

To be submitted in 2018:

11) Damon Runyon C2/2018

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2) Cancer Research Foundation (75K over 2 years) LOI submitted 4/13/17 — Invited to submit full application due 10/2017

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9) Sidney Kimmel December 2017

To be submitted in 2018:

10) SPORE project 1/2018

11) Damon Runyon 2/2018

Paper accepted

1. AXL-uterine cancer — Accepted 10/3/2016 to Oncotarget

Paper under review:

1. DDR2 ovarian — Oncogene submitted 4/25/17, under review 5/2017

Papers to be submitted:

1. AXL — EMT ovarian cancer: Scooped — more experiments plan to submit 5/2017

2. AXL and uterine chemoresistance paper Clin Ca Research 5/2017

3. Nanoparticle inhibition of AXL in uterine serous cancer Molecular Cancer Therapeutics 7/2017

4. Adaptive kinase to chemoresistant ovarian cancer (U10 project)

5. SQ1274 has improved treatment over paclitaxel in ovarian cancer Gynecologic Onc 1/2018

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1. DDR1 and DDR2 in ovarian cancer

2. Characterizing a new target from the siRNA screen and sequencing data

3. Mechanism of AXL and fibronectin secretion in the context of the tumor microenvironment
Tenure Requirements

Varies by institution
- Grants
- Publications
- National/international recognition

Promotion and Tenure Process
- Process:
  - Tenure dossier
  - Internal and external references
- Intra-Departmental process
- School process
- University and Trustees

Tenure Dossier

Develop template in year 1
- Update every 6 months

Content
- Extended CV
- Education and academic positions
- Publications and grants
- Teaching (courses, students, thesis committees)
- Internal and external service- university and nationally
- Statement of research goals and accomplishments
Chapter 3

Laboratory Leadership in Science

Robert N. Taylor, MD PhD
Department of Obstetrics and Gynecology
Jacobs School of Medicine and Biomedical Sciences
University at Buffalo
Introduction

Congratulations! You have completed your formal clinical and laboratory training, passed your subspecialty certification examination with flying colors, and now are ready to assume your first academic job as a translational reproductive scientist. Moreover, your preparation, creativity and technical talent have been recognized by an elite biomedical institution and you’ve been offered a generous “start-up package” with sufficient funds to create an independent research laboratory. How do you get started? This chapter is intended to provide advice based on some of my own experiences, successes and mistakes, but abetted extensively by an outstanding monograph “Making the Right Moves” published in 2006 and developed through a series of scientific workshops co-sponsored by the Burroughs Wellcome Fund and the Howard Hughes Medical Institute (BWF-HHMI), with which you should familiarize yourself.

One of the most respected authors of the BWF-HHMI guidebook is Thomas Cech, PhD, an HHMI investigator and Nobel laureate at the University of Colorado who shared the 1989 Prize in Chemistry for discovering the catalytic properties of RNA. He emphasized that “although you’ve been hired for your scientific skills and research potential, your eventual success will depend heavily on your ability to guide, lead and empower others to do their best work.”

The investigative continuum spanning the reproductive sciences is broad and interactive. I’ve provided a simple “circular” representation in Fig. 1, but had I been a better artist, a three-dimensional Möbius strip or “Klein bottle” (like our galaxy) would have provided a better visual conceptualization. In the modern scientific era it is critical that your research program incorporate several of the disciplines outlined in the figure. I’m a predominantly left-brained scientist, hence there is a bias in this chapter toward “T1” translation, but my right-brained colleagues with big data and population biology foci share many of the general opinions I espouse.

Location, location, location

You will be establishing your own research group in a unique place and time, and while you undoubtedly trained in an outstanding academic environment (and will be indelibly influenced by that setting), you now face an unprecedented opportunity (perhaps your only one) to create an entirely new team and
approach. Obviously, the core resources around you are incredibly important and it is critical that you draw from these, as careful purloining of extant facilities will allow your personal research funds to go much further. Try to locate your new laboratory space as strategically as possible, making sure that relevant core laboratories, clinical activities, vivarium, similarly-minded colleagues, and access to graduate students and postdocs are as proximate and propitious as possible.

Recruitment, group expansion and leadership

The rate of growth of your team, space and facilities will be variable and resource limited, but it is important not to expand your group too quickly. Identifying whom to hire will become your most important decisions, and assiduously vetting all candidates and ascertaining their references is paramount to building a cohesive, synergistic group. Until now, you’ve likely managed your own research projects and at most those of 1-2 technicians. Over time, your ability to efficiently direct the projects of multiple graduate students, residents, postdocs and technicians will evolve, but you should be careful not to become prematurely overwhelmed with trainees or your progress will falter. Think of your lab as a small business; you need to provide value for your clients (ie, your lab members, colleagues and administration). Ultimately, as the late rock-and-roll legend Chuck Berry predicted for his character, Johnny B. Goode, “you will be the leader of a big ol’ band…”

Leadership style

Leadership of an effective scientific team requires a combination of at least three critical skills: 1) You must have a clear vision of your scientific goals; 2) the ability to assume or delegate responsibility of tasks; and 3) a knack for cultivating productive and synergistic relationships among the members of your group. One of the most satisfying aspects of directing a team of bright young investigators is discovering how to best develop your personal leadership style. To some extent you will likely adapt your approach based on those of mentors.
that you’ve found to be effective and simpatico. Be prepared for your style to evolve over time. As you and your group mature and become more collegial and interdependent, authoritarian leadership is likely to give way to a scenario of shared responsibility. A hierarchical, Soviet-style, top-down management system might work well when your group consists of yourself as leader and one or two novice technicians that require constant direction. But as you add experienced post-docs and junior faculty colleagues, it is preferable to give them some freedom to exercise their own creative energies. Several validated instruments exist to aid in realizing one’s best leadership style, including Situational Leadership Theory and the Myers-Briggs Type Indicator. In the former, the leader is encouraged to adopt a relationship style (eg, “delegating”) that is consistent with the maturity of the follower, varying the emphasis on “task” vs. “relationship” behaviors. The Myers-Briggs assessment was created by a mother-daughter dyad in the 1940s, inspired by Jungian psychology and based on four dichotomous foils (eg, extroversion vs. introversion; sensing vs. intuition; thinking vs. feeling; judging vs. perceiving) that yield 16 personality types. It is important to understand that there are no intrinsically ‘good’ or ‘bad’ styles, and no ‘right’ or ‘wrong’ personality types. The idea is to identify a preferential behavior appropriate for one’s specific situation and persona.

Motivating and incentivizing your team

One technique that I have found to be a useful strategy to catalyze the coalescence of a nascent research group is to collectively develop a “mission statement,” a concise declaration of the purpose, focus and scope of one’s active research goals and values. Creating such a statement with your colleagues can be a unifying process and the end product can be used as a common mantra for your team to explain to people outside the laboratory your group’s unique approach and contributions. As their leader, it is imperative that you set, by example, a high bar of expectation. This includes clear communication of ethical integrity, industrious work habits and quality standards. Your protégés will attempt to phenocopy your work ethic and scientific rigor, much as you emulate your role models.

Establishing a consistent, monthly schedule of regular meetings can be a very effective organizational tool. Weekly lab group meetings, where primary experimental data are publicly presented and discussed critically among the entire team, are paramount. This can be a very appropriate place to provide constructive criticism and opportunities for all members of the group to respond with feedback, building their own confidence in data analysis and critical thinking. Do not underestimate the importance of organizing and running effective meetings. Each should have a predetermined agenda, ideally circulated prior to the convocation. Roles (eg, discussant or scribe) should be allocated to different team members beforehand, and conclusions and future action items carefully recorded, summarized and distributed at the subsequent meeting. These responsibilities provide excellent team-building experiences within your group. One-on-one discussions with your colleagues also are necessary, and
the latter are typically the best venue if focused negative feedback to a specific individual is needed. Monthly journal clubs, held jointly with another small lab group if warranted to provide a critical mass for rich discussion, assures intellectual stimulation and opportunities to promote new ideas. Celebratory events (annual retreats, picnics or parties) facilitate camaraderie, trust and cohesiveness in an informal environment. An end of the academic year “state of the lab” talk by you, summarizing the collective accomplishments of the team and laying out an overview of the ensuing goals, is an excellent way to recognize and congratulate your group and to tout your progress.

Networking and collaborations

With an increasing requirement for multidisciplinary, comprehensive approaches to achieve funding success, the effective laboratory leader also needs to be an accomplished collaborator. Developing these skills can be one of the most satisfying experiences in a biomedical science career and they are based on simple principles of honesty, fairness, generosity and good communication. Strong collaborators have shared goals and timelines and build their reputations on reliability and responsiveness. As these relationships and networks often span different institutions, states and even continents, it is necessary to be au courant and comfortable with the use of technical data sharing tools and communication modalities (eg, Skype™, Zoom™ and WebEx™).

How do new lab leaders make mistakes?

Common pitfalls encountered by lab leaders are avoidance of conflict or procrastinating too long when an impasse between lab members needs an intervention. These situations are often complex, so being transparent, honest and proactive can prevent conflicts from escalating and becoming erosive. You are the final arbiter (ie, “the buck stops here”), but you should remain open to counsel from your colleagues and other leaders in your institution and field. As with leadership styles, instruments to assess one’s proclivity for conflict resolution also exist. The Thomas-Kilmann Model elaborates five practical conflict management strategies (“competing, collaborating, compromising, avoiding or accommodating”) based on the leader’s relative assertiveness vs. cooperativeness. In a 2010 study of senior obstetrics and gynecology residents, those with “avoiding or accommodating” behavior styles were more likely to leave conflicts unresolved.5

It is important avoid the perception of being too critical or negative. Bestow praise and share congratulations liberally, when they are warranted. Finally, poor financial oversight and outstripping your resources can seriously jeopardize your success and reputation as an independent investigator.

Conclusions

As you forge ahead in your reproductive science career, I expect that you will rapidly become aware of how privileged a profession you can claim. I hope that you will take full advantage of the opportunity to apply your creative powers to
better understand reproductive pathophysiology and contribute to innovative diagnostic and therapeutic interventions for women. Welcome to a thriving, multigenerational pedigree and legacy of the mentors that preceded you and recognize that you have now assumed the responsibility of propagating that family tree. In Figure 2, I offer an exemplar of my own scientific heritage. The skewing of gender distribution in my P1 and P2 generations is mostly an historical artifact (note that I received my graduate degrees in 1981). Today nearly full sex parity exists, as is indicated by a representative subset of my F1 scientific offspring. This is particularly true of our own marquee operation, the Reproductive Scientist Development Program (RSDP), ably directed by Drs. Larry Longo, Robert Jaffe, Kelle Moley and Danny Schust over the past 30 years, of which 60 scholars are women and 40 are men. The future of translational research by obstetrician-gynecologists in cellular and molecular biology and related fundamental sciences remains promising and you will be its new leaders.

References

1) “Making the Right Moves” the Burroughs Wellcome Fund and the Howard Hughes Medical Institute (http://www.hhmi.org/developing-scientists/making-right-moves) 2006.


Chapter 4

Lab Data Management

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As science exponentially expands via large scale data acquisition and more academic collaborations with industry scientists, proper recording of laboratory activities and managing the volumes of data produced by a laboratory are becoming increasingly important. This chapter covers some of the basics from an investigator’s viewpoint: the importance of data management, good practice for laboratory notebooks, developing a system to track and manage information including dynamic and big data, and ensuring data integrity. Finally, we close with a discussion on data management from an institutional viewpoint, with some key considerations for the individual principal investigator to keep in mind.

**Importance of Data Management**

Every person working in a lab should keep detailed records of the experiments conducted each day. Here are some reasons why:

**Establishing good work practices.** Lab records allow your work to be reproduced by others. The records you keep should allow you and others to recreate the work and achieve the same results, thereby validating or extending your work. The records also allow you to prepare formal reports, papers, and presentations. They also serve as a source for assigning credit to lab members.

**Teaching the people in your lab.** Scientific training involves gathering information, forming hypotheses, designing experiments, and observing results. Lab notebooks, in which these activities are carefully recorded, can be a valuable aid in teaching your graduate students, postdocs, and technicians how to analyze results, construct new theories and tests, and retrace their steps to identify an error.

**Meeting contractual requirements.** From grants to contracts to patent applications, researchers have explicit terms and implicit expectations to meet, for which detailed records and data are essential. For example, the National Institutes of Health has the legal right to audit and examine records that are relevant to any research grant award. Accordingly, the recipients of research grants have an obligation to keep appropriate records.
Avoiding fraud. Lab directors are responsible for the integrity of their lab and everything it produces. Periodic checks of raw data in notebooks and project files can uncover and correct carelessness or outright fraud before they become huge problems.

Defending patents. U.S. patent law follows a first-to-conceive rather than a first-to-file system, which is why documentation to support the date of discovery or invention is critical and why pages of lab notebooks and other records should be consecutively numbered, dated, and signed. Careful records can save a patent.

Improving efficiency. Following robust data management guidelines will help you avoid wasted time and resources. From searching for a lost version of a file to ordering unnecessary reagents or repeating an expensive experimental assay, proper record keeping and organization can prevent costly mistakes and duplication of effort by members of your lab.

Ensuring reproducibility. Fundamental to the concept of robust research are reproducible results. While you may be intimately familiar with the intricacies of a protocol when performing it daily, when required to repeat it long afterward, you may have forgotten those details. With detailed records of experimental procedures and analytical parameters, you can be certain of your ability to reproduce your findings when needed.

Keys to Data Management: The Investigator Viewpoint

Good Practice for Laboratory Notebooks

Although individual scientists are responsible for maintaining their own notebooks, heads of labs are responsible for making sure that the notebooks of those under their direction are in order. The precise way in which to document scientific research varies from field to field and from institution to institution, but some general rules apply, such as the following:

- Use a permanently bound book, with consecutive signed and dated entries.
- When appropriate, witness entries as well.

The lack of reproducibility is not due primarily to intentional fabrication or falsification of data. Rather, in many cases there is a lack of awareness or adherence to sufficiently high standards in the planning and execution of scientific experiments, and in transparency in the reporting of science. Examples include inherently weak experimental designs and over-interpretation of statistically marginal differences and variability of materials, differing brands or even lots of reagents, differing or drifting strains of organisms and cells in culture, or other variables that have not been adequately controlled.

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Question: Why should I learn to write in the notebook?

Answer: You want to create an accurate, original, permanent record. There is a tendency to record information on the handiest piece of paper available, even on a paper towel lying on a bench, and then later transferring the information to a notebook.

Therefore, you should get into the habit of immediately recording data as they are being collected into your lab notebook.
For computer-kept logs, you can use a loose-leaf notebook, but pages must be consecutively numbered (using a sequential page-number stamp), dated, and signed.

Record entries chronologically.

Each entry should stand on its own to permit others to replicate the work.

Organize material with sections and headings.

Identify and describe reagents and specimens used.

Identify sources of those materials (e.g. reagent manufacturer, lot number, purity, expiration date).

Enter instrument serial numbers and calibration dates.

Use proper nouns for items.

Write all entries in the first person, and be specific about who did the work.

Explain nonstandard abbreviations.

Use ink and never obliterate original writing; never remove pages or portions of a page.

If a page is left blank or a space within a page is left blank, draw a line through it.

Permanently affix with glue any attachments (such as graphs or computer printouts) to the pages of the notebook; date and sign both the notebook page and the attachment.

Outline new experiments, including their objectives and rationale.

Include periodic factual, not speculative, summaries of status and findings.

Enter ideas and observations into your notebook immediately. Summarize discussions from lab meetings and ideas or suggestions made by others, citing the persons by name.

Where and How Long to Keep the Notebook

Lab notebooks that are “in progress” should be kept in the lab and reviewed periodically. Usually, notebooks are kept on a lab bench, but if there is concern about the risk of damage or contamination, all lab notebooks may be placed in a fireproof cabinet or other designated space at the end of each day.

Completed lab notebooks should be indexed, cataloged, and kept in a safe central repository, along with corresponding patent applications or patents. Every time someone takes a notebook, it should be checked out and then returned. A person who is leaving the lab for a position elsewhere should not take any original lab notebooks, but could be allowed to take copies of the lab notebooks he or she has maintained.

In general, the principal investigator should keep notebooks for at least five years after funding for the study ends. At that point, the notebooks can continue to be stored on site or moved to a storage facility. For anything that

Question: What’s the responsible way to document errors?

Answer: Make the required changes as soon as possible without obliterating the original entry. Electronic documents may require a new entry, not an override. If the error is logged by hand, do not erase or alter the initial entry. Correct the data at the point in the log where the error was discovered, refer to the original page, and go on (e.g., “Reagent was 50 percent of the strength we originally thought.”).

Question: How do I get people in my lab to keep good records?

Answer: All students, technicians, and postdocs should be issued their own laboratory notebooks, with instructions on how to record in them. Establish expectations early and reinforce them periodically. The job interview is not too early to describe expected lab record-keeping methods and media. Many lab heads have a system for regularly reviewing all lab notebooks.
has been patented, the general rule is that the corresponding lab notebooks should be kept for the life of the patent plus six years. Your institution may have specific policies for you to follow. If you move to a new institution, you should also check your old institution’s policies; some institutions require departing faculty to leave their original lab notebooks.

Managing and Tracking Information

Developing a Data Management System

Take the time to think about and produce a plan to track and store data generated by the people in your lab. Some requirements of your system will include the following:

- **Ability to sort and search:** If you want to be able to sort data in your system by a particular criterion, the information has to be entered as a sortable field. Try to identify at the beginning all the ways you might want to retrieve your data later. This is a challenging but productive exercise in thinking ahead.

- **Consistency:** For comparability, you need standards that are followed consistently. If everyone in your lab uses a different document-naming protocol, the departure of one person can create chaos. Decide on a consistent system for the file names of electronic and paper documents as well as the identification of samples and specimens — everything that your lab catalogs and stores. Figure X.X presents examples of coding systems for electronic documents and specimens.

- **Ability to update records:** It is important that you set up a system for logging reagents and ensure that everyone in the lab use the system.

Assign Responsibility

It’s not enough to have a data management plan; someone needs to make sure the plan is executed. Because this is your lab, it’s your responsibility — to handle personally or to delegate. Once you have made that choice, put quality assurance procedures in place, including scheduled spot checks of your established procedures. Make sure that everyone in your lab knows what to store where, how to do it, and who needs to log in that information.

Laboratory Information Management Systems and Electronic Laboratory Notebooks

The multitude of data generated by a single lab can be overwhelming. A growing number of software systems allow the user to collect, store, and visualize disparate kinds of information — ranging from mass spectrometry readings to sequencing data. The systems provide a central repository for all data generated in a lab. One of the critical features that sets different types of software apart is the degree to which stored data can be retrieved and manipulated in the absence of the original instrument software. Another important consideration is the degree to which the stored data meet the FDA

Many academic labs, especially small ones, track samples, reagents, and experiments through paper records and simple electronic spreadsheets. But as the amount and complexity of data increase, some investigators have turned to specialized software products such as databases, laboratory information management systems (LIMS), electronic laboratory notebooks, and tools to integrate the different applications.

In recent years, new LIMS products have been unveiled that are adaptable to the specialized needs of life sciences research (e.g., microbiology and genomics). LIMS can be used to

- Receive, log in, and label samples.
- Assign work (e.g., tests and analyses for each sample).
- Schedule work.
- Check status of work.
- Integrate data collection by interfacing with instruments.
- Track records and specimens.

Selecting a suitable program—one that fits your lab’s needs and budget—Involves something at which you excel: research. Consult colleagues who have been through this process themselves, and don’t be shy about involving your institution’s information technology office. Once you have narrowed the list of candidate software, arrange vendor demonstrations and visits to labs that use these systems. Your institution’s purchasing office may also be helpful.

Some of the questions that you should consider are

- Is the system compatible with your existing software and hardware?
- Are other users satisfied? (Talk to people in your field who have purchased a system.)
- What kind of support is available from the vendor?
- How much flexibility does the system offer? Can it be configured to satisfy your particular needs?
- How much training will be required?
- Is the company that sells the system established or is it likely to be out of business in a few years?
- Is it worth it, or can you get by with the system you already have? Do you really need more software?

Be aware that a flexible system may not be ready for use straight out of the box; you may have to configure it to your specifications first.

Electronic Laboratory Notebooks

Electronic laboratory notebooks (ELNs) do everything their handwritten forebears do but with the attractive bonus of search and organization functions. Through links to analytical software, ELNs can usually download and store data directly, and many ELNs also support secure access for multiple users and remote users. Choosing the right ELN for your lab requires homework.

One important consideration is whether the ELN complies with the FDA’s rules for acceptance of electronic documents, which were published in Code of Federal Regulations (Title 21 CFR part 11, available online at www.fda.gov/RegulatoryInformation/Guidances/ucm125067.htm). So far, few ELNs have been subjected to legal scrutiny, and it is doubtful that many would pass the test. For this reason, most researchers in academic and industry settings are sticking to paper records.
Maintaining a well-organized and documented digital record of your research is as critical as keeping a proper physical laboratory notebook. While there is no universal standard for structuring your data, a logical and consistent scheme can make your life easier, as well as facilitate collaboration and data-sharing before and after publication. This can be especially important as a person leaves the lab and responsibility for a project is transferred; incomplete documentation, disordered layout, and unclear file names may make reproducibility impossible. In general, all files relevant to a specific project should be located in a single directory. An example structure is presented in Figure 1. Ideally, you or a colleague should roughly know where certain files can be found upon your project directory.

At each step of the project—from generating data, to processing, to publishing—information should be recorded that would allow replication of the results. Some of the key information is as follows:

**Metadata:**
- how data was collected
- protocols
- sample information
- definition of variables, e.g. units, range, thresholds

**Processing:**
- quality control/analysis
- steps taken to process the data
- programs and versions used
- processing parameters

**Analysis:**
- statistical models used
- identification of outliers
- integration of data sets

As a rule, raw data should be considered read-only and preserved for future analysis. Inadvertent alteration of the original file could result in irretrievable loss of data. Processing, reorganizing, and analysis should be performed on a separate file.
Data Retention and Integrity

What to Store and How

You will likely want to store the following:

- Lab protocols
- Primary data, including images
- Lists of specimens and reagents
- Information about instruments

Where and how long you keep this information will likely be dictated by what type of information it is, but you also need to consider issues of lab space, fees and security issues for off-site storage, and the shelf life of the materials being stored. Here are some general guidelines:

Printed records. Records written in ink on acid-free paper and laser-printed records can be archived for a long time; ideal conditions are approximately 50 percent relative humidity and 21°C or cooler.

Lab protocols. Many labs keep a master collection of lab protocols, which is available either electronically or in print and is updated periodically. Lab protocols are rarely the type of records you need to store for the long term.

Reagents. It is important to have a system in place for keeping track of reagents that are used in your lab. While work is in progress, maintain records about the reagents used and keep the reagents themselves easily accessible in storage. Laboratory information management systems are available that are useful for keeping track of items such as oligos, antisera, plasmids, and cell lines. Many labs also use Excel spreadsheets or even paper records. Make sure the database is updated regularly, and when people leave the lab, have them place their unique reagents in storage boxes and document their location.

You will also need a reliable tracking system for the sharing of reagents—requesting them from other sources and transferring yours to other labs. This involves Request for Materials forms and Material Transfer Agreement forms (see chapter XX, “Understanding Technology Transfer”).

Instrument histories. The care and maintenance of equipment are important responsibilities that affect the entire lab. Make sure someone accepts them and follows through. Lab records should include instrument logs that contain purchase, upgrade, and repair information; a calibration schedule and results; a control chart for performance trends; and blind quality control and assurance checks.

Retaining study records and disclosures of study information:

For IRB clinical trial
- Retain records for 7 years after last subject completed study OR 7 years after date of last disclosure of identifiable health information from study records.
- If research subject is a child, retain until subject reaches age of 23.

For Investigational New Drug (IND) research
- Retain records for 2 years after marketing application approved for new drug or until 2 years after shipment and delivery of drug for investigation use is discontinued.

For Investigational Device Exemption (IDE) research
- Retain records for 2 years after the later of the following: date on which investigation is terminated or completed or date on which records no longer required for purposes of supporting a premarket approval application or notice of completion of a product development protocol.

Provide adequate data and safety monitoring (if activity represents more than minimal risk to participants).
Electronic records. To protect against data loss or theft, all of the electronic data generated in your lab should be regularly and securely backed up according to the guidelines of your institution and regulatory bodies. Of note, common storage media such as optical media, hard drives, and flash drives are subject to data corruption and failure over time, and should not be considered reliable on their own for long-term storage. Another consideration is whether the hardware and software needed to read the information will be available in the long term.

Data Backup and Security

Modern laboratories generate digital data of myriad formats and sizes, from small text documents to terabytes of high-throughput assay files. Establishing a backup plan can prevent loss of critical data through user error, hardware failure, theft, or disaster. When creating your plan, there are several key considerations to keep in mind to minimize the chance of catastrophic data loss.

Number of copies

General best practices for backup recommend keeping three copies of your data:

- **Local copy**: primary version stored on your computer
- **Local backup**: stored locally, e.g. external hard drive, flash drive, network attached storage
- **Remote backup**: geographically separate location, e.g. campus server, cloud storage

Privacy and security

To safeguard sensitive data in compliance with relevant intellectual property, privacy, and confidentiality regulations, such as HIPAA, you may need to take extra precautions.

- **Physical security**: restricted access to locations where data is stored
- **Encryption**: some data may need to be protected by encryption
  - Make sure passwords are available in a secure location or the file will be inaccessible
  - Enable encryption on any drive on which the files are stored
- **Access and security policies**: password protection; who can access the data?

You should consult with your institution to determine if there are existing policies and procedures for dealing with sensitive data, especially regarding remote storage of your data. Often institutions offer backup solutions or have existing agreements with commercial cloud storage providers that comply with security regulations.
File formats
When archiving your data, choose a file format that is likely to be accessible well into the future. This will generally be a non-proprietary, documented standard, such as ASCII text or comma-separated value files. If possible, data should be uncompressed and unencrypted, but when necessary, select a widely used compression format.

Make sure that backup procedures are documented and backups are performed often. Periodically test your storage media and verify the integrity of the data using checksums.

As principal investigator, you know that maintaining accurate and consistent laboratory records and managing the flow of data your lab generates are critical to the success of your research program. So, be proactive. As you are setting up your lab, determine the standards and procedures for record keeping and communicate these to the members of your lab. Develop a plan to efficiently track and store data and find a data management system to help you implement this plan. Once you’ve done this, you’re well on your way to keeping the avalanche of data organized and retrievable.

Now that we have covered the principal investigators viewpoint on data management, what about the institutional perspective?

Keys to Data Management: The Institutional Viewpoint
In this final section we will briefly cover key topics that your Institution may be considering with regards to data management. Keeping in mind that ultimately data belongs not to the investigator but to the Institution, keeping the mindset of the data holder in view when designing experiments and data storage will enable win-win situations for both investigators and their institutions.

Who actually owns the data and specimens?
Custody does not imply ownership, custody remains with investigator but an academic institution owns all data/specimens. However, both funders and other data sources have rights to the data, of which the investigator remains the primary custodian.

Considerations/issues in data ownership
Investigators should have a full understanding of various issues related to data ownership to be able to make better decisions regarding data ownership. These issues include paradigm of ownership, data hoarding, data ownership policies, balance of obligations, and technology. Each of these issues gives rise to a number of considerations that impact decisions concerning data ownership.
Paradigm of Ownership — A list of parties laying a potential claim to data:

- **Creator** — The party that creates or generates data
- **Consumer** — The party that uses the data owns the data
- **Compiler** — This is the party that selects and compiles information from different information sources
- **Enterprise** — All data that enters the enterprise or is created within the enterprise is completely owned by the enterprise
- **Funder** — The user that commissions the data creation claims ownership
- **Decoder** — In environments where information is “locked” inside particular encoded formats, the party that can unlock the information becomes an owner of that information
- **Packager** — The party that collects information for a particular use and adds value through formatting the information for a particular market or set of consumers
- **Reader as owner** — The value of any data that can be read is subsumed by the reader and, therefore, the reader gains value through adding that information to an information repository
- **Subject as owner** — The subject of the data claims ownership of that data, mostly in reaction to another party claiming ownership of the same data
- **Purchaser/Licenser as Owner** — The individual or organization that buys or licenses data may stake a claim to ownership

**Data Ownership Policies**

One of the challenges for many investigators is the fact that institutional policies often lack specificity, supervision, and formal documentation which can increase the risk of compromising data integrity.

Before research and research collaborations are initiated, it is important to delineate the rights, obligations, expectations, and roles played by all interested parties. Compromises to data accessibility and integrity can occur when investigators are not aware of existing data ownership policies and fail to clearly describe rights, and obligations regarding data ownership. Listed below are some scenarios between interested parties that warrant the establishment of data ownership policies

- **Between academic institution and industry (public/private sector)** — This refers to the sharing of potential benefits resulting from research conducted by academic staff but funded by corporate sponsors. The failure to clearly delineate data ownership issues early in public/private relationships has created controversy concerning the rights of academic institutions and those of industry sponsors.
- **Between academic institution and researcher staff** — Research funding is awarded to research institutions and not individual investigators. As recipients of funds, these institutions have responsibilities for overseeing
a number of activities including budgets, regulatory compliance, and the management of data. Researchers cannot automatically assume that they can take their data with them if they move to another institution. The research institution that received the funds may have rights and obligations to retain control over the data. It is recommended that institutions clearly state their policies regarding ownership of data, and present guidelines for such a policy.

- **Collaboration between research colleagues** – This is applicable to collaborative efforts that occur both within and between institutions. Whether collaborations are between faculty peers, students, or staff, all parties should have a clear understanding of who will determine how the data will be distributed and shared (if applicable) even before it is collected.

- **Between authors and journals** – To reduce the likelihood of copyright infringement, some publishers require a copyright assignment to the journal at the time of submission of a manuscript. Authors should be aware of the implications of such copyright assignments and clarify the policies involved.

**What is a Data Use Agreement? When should it be used?**

A Data Use Agreement (DUA) is a legal document that establishes the legal and program authority that governs the conditions, safeguards, and procedures under which Federal Agencies agree to use data that has been previously established through a system of records. A DUA may require an Institutional Review Board (IRB) to oversee data use activities, particularly if the data involves personally identifiable information, informed consent documents for potential research applicants, and to have members of joint projects be trained on safeguards to protect confidential information. The DUA encompasses all IT projects. DUAs must be developed when any data covered by SOR will be exchanged or used across agencies. In addition, DUAs must be developed when matches involve Federal personnel or payroll records. In concurrence with a DUA, a project must also prepare an Inter/Intra-Agency Agreement (IA) when the SOR(s) involved in the comparison are the responsibility of another Federal Agency.

**Elements of a DUA**
- Name
- Legal Authority for Data Use
- Program Authority for Data Use
- Purpose
- Background
- Mutual Interest of Entities
- Responsibilities of Entities
- Funding Information
- Costs and Reimbursement
- Custodian of Data
Question: For patent purposes, what’s an “original” record?

Answer: An original is the first human-readable form—for example, a printout of a measurement but not a photocopy of it. It should be dated, signed, and filed.

Question: Genomics produces massive amounts of data. If the data are burned on a disk, are they considered “original”?

Answer: In this era of computer-assisted research, many pieces of data are collected, stored, and analyzed by computer. The problem with electronic records is that it is hard to prove that the data are not added to, deleted from, or in some way tampered with. The Food and Drug Administration (FDA) has published clear guidelines for maintaining electronic records in a way that will meet legal scrutiny. If you have really important results, it is probably safer to print them out, sign and date the documents, and indicate why they are significant.

Practice Activities

For software development projects the following practice activities are appropriate:

- Identify—Identify the need for a DUA
- Document—Document the fields / systems that will be exchanged
- Consistency—Ensure that data-use-agreements are consistent with the contents and format of NHIN CONNECT DURSA agreements
- Develop Agreement—Prepare the Inter/Intra-Agency Agreement (agreement between the sending and receiving agency)
- Review—Review the DUA for completeness and accuracy
- Submit—Submit the DUA to the OCISO and Institutional Review Boards for formal review and clearance

What is a BAA? When should it be used?

A Business Associate Agreement (BAA) is an agreement between a covered entity and a BA that governs the terms of their relationship.

Under the U.S. Health Insurance Portability and Accountability Act of 1996, a HIPAA business associate agreement (BAA) is a contract between a HIPAA-covered entity and a HIPAA business associate (BA). The contract protects personal health information ( PHI) in accordance with HIPAA guidelines.
Since 2010, in accordance with the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009, a BA’s disclosure, handling and use of PHI must comply with HIPAA Security Rule and HIPAA Privacy Rule mandates. Under the HITECH Act, any HIPAA business associate that serves a healthcare provider or institution is now subject to audits by the Office for Civil Rights (OCR) within the U.S. Department of Health and Human Services (HHS) and can be held accountable for a data breach and penalized for noncompliance.

**Examples of HIPAA business associates**

According to the HHS, examples of HIPAA business associates include:

- When a health plan uses a third-party administrator to help with claims processing.
- If a CPA firm provides accounting services to a healthcare provider and they have access to protected health information.
- When a hospital has a consultant perform utilization reviews.
- When a healthcare clearinghouse translates a claim from a nonstandard format to a standard format for a healthcare provider then sends the process transaction to a payer.
- When a physician uses an independent medical transcriptionist’s services.
- When a pharmacy benefits manager managed a health plan’s pharmacist network.

BAA apply to research when the data contains or retains elements of PHI. This has become noteworthy in many arms of current subject-propagated data attainment, such as mobile applications since healthcare mobile applications handle PHI.

For example, imagine a research study when a subject is instructed to download a health app to her smartphone. The app developer and the provider have a contract for patient management services which include remote patient health counseling, patient messaging, monitoring the patients’ food and exercise, and electronic health record (EHR) integration and application program interfaces. Furthermore, the information the patient inputs into the application is automatically incorporated in the EHR. With this in mind, a HIPAA business associate agreement should explicitly spell out how a BA will report and respond to a data breach, including data breaches that are caused by a business associate’s subcontractors. In addition, HIPAA business associate agreements should require a BA to demonstrate how it will respond to an OCR investigation.

Another example where a BAA for research would be needed is where a clinical research team at the Health System serves as the data coordinating center for a multicenter clinical trial and the researchers wish to use cloud based vendor as their data storage solution. The Health System would contract with the cloud vendor for use of their services and would execute a BAA with the cloud vendor. No BAA would need to be executed with each clinical research site which would access, upload or download data from the cloud as they meet an exception to the business associate standard.
In such scenarios, the agreement must:

- Describe the permitted actions between a covered entity and required uses of PHI by the BA.
- Provide that the BA will not use or disclose the PHI other than as permitted by contract or by law.
- Provide contingency for response to an OCR investigation
- Provide scenarios for management of data breaches

In addition, there are requirements that the BA will use appropriate safeguards to prevent a use or disclosure of the PHI. Covered entities are required to enter into written agreements with Business Associates in order to:

- Limit use and disclosure of PHI
- Safeguard PHI
- Ensure Patient Rights

**Exceptions to the Business Associate Standard.** The Privacy Rule includes the following exception to the business associate standard [refer to 45 CFR 164.502(e)]: A covered entity (e.g. Health System) is not required to have a BAA or other written agreement in place before PHI may be disclosed if PHI is disclosed to a person or entity that is a researcher or for research purposes, as long as one of the following have been met: 1) patient authorization has been obtained, a waiver under 45 CFR 164.512(i) has been obtained, OR 3) it is a limited data set pursuant to 45 CFR 164.514(e). Because the researcher is not conducting a function or activity regulated by the Administrative Simplification Rules, such as payment or health care operations, or providing one of the services listed in the definition of “business associate” (refer to 45 CFR 160.103), the researcher is not a business associate of the covered entity (e.g. Health System), and no business associate agreement is required.

**BAA Summary.** To summarize, a BAA may be needed when PHI of research subjects are disclosed to external entities performing a service on behalf of the health system that is not itself research including:

- Service provided by a 3rd party (that are not research collaborators) performing functions such as data entry/analysis or laboratory analysis of data/samples that contain PHI that is engaged by the investigator or health system rather than by the sponsor
- Services provided by a 3rd party vendor for storage, web hosting or maintenance of records/data containing PHI (e.g. Iron Mountain, CitiStorage) that is engaged by the investigator or health system rather than the sponsor
- Recruitment or billing services engaged by the investigator rather than by the sponsor
- External consultants engaged by the investigator or health system that are providing services that require access to PHI (e.g. perform audits, coding review, etc.) or external lawyers
Summary

We have covered a broad spectrum of data management in this chapter. While many have been part and parcel to what you first learned in high school biology (keep a legible lab notebook), many are new to the big data science era. With that in mind, resources of NIH data science related events and news, include information about NIH’s Big Data to Knowledge (BD2K) initiative and NIH Commons. The BD2K Training Coordinating Center offers resources and tools for biomedical researchers to navigate data science field. These BD2K Guide to the Fundamentals of Data Science Series can provide a basic understanding of data science for biomedical researchers.

Resources

Chapter 5

Mentoring and Being Mentored

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Introduction

Mentors, trusted guides or counselors, have been around since the time of Homer in the 9th Century B.C. In Homer’s Odyssey, Odysseus charged Mentor, his trusted friend, with educating, tutoring, and guiding his son when Odysseus left for the Trojan War. However, the idea of mentorship in the United States is a relatively new concept. The first mentoring programs were not developed until the 1970’s when large private-sector corporations introduced mentorship as a way to support junior staff. The development of mentorships continued in the 1980’s as colleges, universities, school districts, and states created mentoring programs to enhance the quality of their faculty and administrators. In the 1990’s, mentoring began to be introduced into the medical profession, mainly in nursing programs. Formal mentoring programs for medical students and physicians are a more recent development. Although mentorships has been studied in other fields such as business and education, this chapter will focus on the literature concerning mentorship among physicians and physician-scientists. We will examine what constitutes an effective mentor relationship, the positive effects of mentorship, and what can be done to foster mentorship in the United States.

What is a Mentor?

A mentorship is a relationship in which information is exchanged between a mentor, who is equipped with greater experience, influence, or achievement, and a mentee (see Figure 1). The purpose is to address the needs of the mentee while providing benefits to both parties. The benefits may be tangible or emotional, but not financial, and include individual growth, career advancement, and transformation “from an understudy to a self-directing colleague.” The most successful relationships are those formed by similar personal and professional interests which are enhanced by compatibility or “chemistry” and challenged by significant differences.

Mentoring is different than other forms of leadership or coaching by the broadness of its function. Mentorships can include emotional and psychological support, direct assistance with career and professional development, and role modeling to achieve the mentees’ long term goals i.e. promotion or graduation. The mentor changes and improves the protégé’s approach to tasks rather than supervising their completion in the way of a
Figure 1
Definitions of Mentoring

Healy (1990)
a “dynamic, reciprocal relationship in a work environment between an advanced career incumbent (mentor) and a beginner (protégé), aimed at promoting the career development of both.”

Berk (2005)
a voluntary relationship “that may vary along a continuum from informal/short-term to formal/long-term in which faculty with useful experience, knowledge, skills, and or wisdom offers advice, information, guidance, support, or opportunity to another faculty member or student for that individual’s professional development.”

Sambunjak (2015)
a “face to face dyadic, hierarchical relationship whose primary purpose is personal growth and professional development of the mentee, but whose beneficial impact extends to the mentor and a broader environment in which the relationship is embedded.”

Figure 2
Three Contextual Levels Shaping Mentorships

Mentor-related intrapersonal: Psychological profile, mentoring style, motivation to mentor, mentoring experience
Mentee-related intrapersonal: Psychological profile, resources, needs
Interpersonal: Frequency of interaction, similarity, congruency of expectation
System-related: Field or discipline characteristics, government policies
Organization-related: Mentoring climate, reward structure, work design
Cultural: Power distance, individuality v. collectivity, ethics
Political: Freedom of thought, political favoritism, racial or ethnic issues
Economic: Growth, recession
supervisor or teacher. In this way, the mentor does not necessarily need to carry the formal authority of these other forms of leadership. Mentorships are also meant to have a high level of commitment over a longer period of time than educational relationships.

3 Levels of Mentorship Influences

Mentorships form and grow within a broad social and environmental context comprised of multiple influences that shape the mentoring relationship. Sambunjak et al. proposed a model that categorized these various external and internal elements into three levels: Macro/societal, institutional/meso, and intra/interpersonal (see Figure 2). This three-tiered model created a holistic view of mentoring to explain the complex influences shaping the development, processes and outcomes of mentoring relationships.

Macro/Societal

The first level is the macro/societal level which encompasses economic, political and cultural factors. Economic factors like job security and wage reduction may influence the formation of mentorships as a turbulent job environment with threatened job security may make mentors reluctant to invest their time and energy into a mentee. Political factors include both the official political system in a country and the unofficial politics and policies in an academic institution. Formal governmental politics are an issue mainly in “transition countries” that have recently changed their political systems from a communist regime to a more democratic society. For example, a mentor may have never learned to speak truth to power or participate in democratic discourse. This may make the mentor ill-equipped to empower their mentee to critically think and question the society around them which is an important role of mentors even in countries with a long democratic history. Unofficially, having a mentor from within the ruling “party” of an institution may facilitate career progression on the academic ladder whereas choosing a mentor in opposition may result in career difficulties, even to the point of the mentee leaving academia.

Power distance, individuality, and work ethics affect mentoring relationships in a cultural sense. Power distance between the mentor and mentee influences the mentees’ willingness to challenge what they are told and also their ability to find an effective mentor. Therefore, implementation of a formal mentoring program may be more effective in cultures with a high power distance. In regards to individuality, the degree to which a society emphasizes an individual’s personal responsibility to develop relationships determines how responsive mentors may be to their mentees’ needs. For example, highly individualistic cultures may devalue efforts by mentors to develop their mentees or discourage mentors from responding to mentees seeking help. Lastly, a mentor’s ethics in their work perpetuates the ethics or moral codes that their mentees must follow, which may or may not be compatible with international values of academic medicine. For example, a mentor may value
high research productivity above all else which could lead to a “publish or perish mentality” and ultimately scientific misconduct by the mentee.

**Institutional/Meso**

The second level is the institutional/meso level which describes the discipline characteristics, government policies, and organizational factors that affect mentorships. Differences in medical disciplines or specialties may modulate the functions of the mentorship. Surgical disciplines need mentorships to increase practical skills in performing operations, research-oriented disciplines will need more solid training in research activities, and clinically-oriented disciplines like internal medicine need mentors to foster their clinical performance and professional socialization. Government policies on healthcare, science and higher education may or may not be conducive to the growth of mentorships. Policies that provide funding for research have positive effects as they encourage the recruitment of younger scientists who are able to be connected to experienced mentors.

Organizational factors include the mentoring climate, work design, and reward structure. Institutions can create a climate supportive of mentoring through creating formal mentoring programs or by providing the structure, process and expectations for mentorships to facilitate spontaneous formation of these relationships. Additionally, a mentorship culture can be cultivated by mentors acting as role-models, instilling the department’s values in their mentees. The structure and processes, or work design, of an organization can either facilitate or interfere with building mentorships. Although academic medicine encourages collaboration, the hierarchical structure can deter newcomers from approaching senior faculty. Institutions should find ways to facilitate these interactions through semi-formal meetings or journal clubs, for example.

The reward structure at an institution describes what is valued and rewarded. For example, often an academic institution values research productivity more than education excellence, which can discourage mentoring. Alternatively, it is difficult to reward mentorships. The nature of a reward could encourage mentors to be halfheartedly involved, thereby lowering the effectiveness of the mentorships. It is also difficult to objectively judge a mentorship due to its individualized nature.

**Intrapersonal/Interpersonal**

The third level is comprised of the intrapersonal/interpersonal characteristics that affect the development and quality of mentorships. These relate to the mentee’s and mentor’s psychosocial characteristics. Mentee-related variables are broadly grouped into the mentee’s resources and needs. Mentor variables include mentoring style, motivation to mentor and past experiences as the mentee in a previous mentorship. Additionally, several factors influence the quality of the relationship including perceived similarity between the mentor and mentee, frequency of interactions, and congruency of expectation.
Is Mentoring Effective?

At the personal level, mentees report higher levels of self-efficacy and self confidence in their skills and ability to advance in their career\(^3,9-12\) (see Figure 3). Mentees have reported expansion of their professional, communication, and research abilities\(^13,10,14\) and improved handling of the specialist literature.\(^3,11\) Mentoring has been shown to have a significant effect on career choice, particularly in selection of medical specialty, but also in whether mentees enter academia.\(^6,9,15\) Mentorships can provide psychosocial support, role modeling and career advice needed to overcome the challenges of working in academic medicine.\(^6\) Additionally, mentored faculty report increases in personal development\(^6,9\) and vitality,\(^10\) as well as a renewal of their inspiration to further their research and scholarly activity.\(^16\)

Mentoring has been shown to be a catalyst for career success.\(^15,9\) It is clear in the literature that participating in a mentorship or faculty development program can increase academic productivity, promotion rates and success including awards, grants, and publications.\(^10,11,13,16\) In the study by Jackson et al.,\(^7\) 98% of faculty participants ranked “lack of mentoring” as the first or second most important factor hindering their career progress in academic medicine. Faculty also reported having a mentor would have led to promotions or a higher salary if they had been able to convey their worth to the administration.\(^7\)

At the institutional level, mentoring is effective at increasing productivity and enhancing retention of faculty (see Figure 4). Mentoring is associated with reduced faculty intention to leave institutions\(^9,11,14,16\) possibly as a result of an increased sense of belonging, trust in relationships and belief of value alignment with the faculty’s institution.\(^10\) Palepu et al.\(^13\) surveyed faculty

**Figure 3** Personal Benefits of Effective Mentoring

<table>
<thead>
<tr>
<th>Increased self-efficacy, confidence</th>
<th>Skill development, enhancement</th>
<th>Career advancement</th>
<th>Career choice, participation in academia</th>
<th>Psychosocial support</th>
<th>Personal development and vitality</th>
</tr>
</thead>
</table>

**Figure 4** Institutional Benefits of Effective Mentoring

| Faculty retention | Faculty sense of belonging and trust | Perception of institutional support | Occupational satisfaction | Research and clinical productivity | More involvement from young, creative scientists |
from 24 US medical schools in 1998 finding that mentored faculty “rated the adequacy of professional support from their institutions for teaching, research and administrative activities significantly higher than did the faculty without mentors.” Enhanced retention may also be due to a higher rate of occupational satisfaction found among mentored faculty.\textsuperscript{10,11,12,15} In 2015, Pololi et al.\textsuperscript{10} reported 35% of faculty surveyed seriously considered leaving their institution due to dissatisfaction, a majority of whom reported lack of mentoring.

Mentored faculty are more productive\textsuperscript{6,9,15} as lack of mentorship has been found to be among the systemic barriers that limit researcher productivity.\textsuperscript{17} Investigators with mentors are more likely to allocate increased time to research, have more publications and grants, and complete their thesis.\textsuperscript{9,10} Clinician-educators with mentors have reported significantly more time spent on scholarly activity.\textsuperscript{10} Additionally, young investigators are more creative, innovative and energetic than their older peers and less daunted by new ideas and technologies. These characteristics often lead younger investigators to the discovery of dimension-enhancing breakthroughs which provide direct benefit to their institution and to their field.\textsuperscript{18}

Importantly, for all the benefits of mentorship described above, Sambunjak et al.\textsuperscript{9} found research fellows who were themselves mentored were more likely to provide mentorship to others, thereby continuing the cycle of benefits to individuals and institutions.

**Qualities of Effective Mentorship**

The most effective mentorships are comprised of mentors and mentees that share certain characteristics (see Figure 5). Successful mentors are advocates for their mentees, dedicated to their success and well-being. Mentors “have a huge responsibility not to transform (the mentee’s) potential into (where) the mentor sees it should go but to be detached from that, making sure it’s in the best interest of the mentee.”\textsuperscript{19} Importantly, mentors need to have the knowledge, skills and resources to help mentees network and be productive in their field.

Mentees, most of all, should be proactive and take the initiative to institute and cultivate the mentoring relationship. Being proactive not only helps mentees find a mentorship that meets their needs but it also makes it more likely that mentors will be open to pursuing a relationship.\textsuperscript{15,19} Mentees get the most out of a mentorship when they are prepared for meetings, willing to learn and responsive to feedback.\textsuperscript{8}

**Strategies for effective mentoring**

In a survey of 1,520 faculty, Pololi et al.\textsuperscript{11} found a positive association between six mentoring activities and mentee satisfaction with both the amount of mentoring and the quality of mentoring received. These core functional components of effective mentoring can be seen in Figure 6.
### Figure 5

**Qualities of Effective Mentors and Successful Mentees**

<table>
<thead>
<tr>
<th>Effective Mentors</th>
<th>Successful Mentees</th>
</tr>
</thead>
<tbody>
<tr>
<td>Altruistic, displays integrity</td>
<td>Proactive/takes the initiative</td>
</tr>
<tr>
<td>Active listener</td>
<td>Shows commitment to success of the mentorship</td>
</tr>
<tr>
<td>Honest and willing to give constructive feedback</td>
<td>Willing to learn and open to feedback</td>
</tr>
<tr>
<td>Accessible, available</td>
<td>Respectful to mentors’ input and time</td>
</tr>
<tr>
<td>Approachable</td>
<td>Passionate about their field and future success</td>
</tr>
<tr>
<td>Knowledgeable, respected in the field</td>
<td>Prepared for all meetings</td>
</tr>
<tr>
<td>Supportive, encouraging, an advocate</td>
<td>Patient and courageous</td>
</tr>
<tr>
<td>Dedicated to the mentorship</td>
<td>Displays perseverance</td>
</tr>
<tr>
<td>Experienced in mentoring</td>
<td>Selective in accepting advice from mentors</td>
</tr>
</tbody>
</table>

### Figure 6

**Core Components of Effective Mentoring**

- Having a sponsor or champion
- Self-directed planning to achieve personal goals
- Finding resources
- Formulating career goals
- Learning skills to achieve goals
- Planning how to achieve career goals
Attention should be paid to identifying and addressing both career and personal goals of the mentee. Career development should be stage-specific and goal oriented. Mentors should guide rather than supervise grant and manuscript writing while challenging their mentees to expand their own abilities. Mentors need to provide resources like experts, source materials in the field of the mentee and, most importantly, networking opportunities. Mentoring actions should be aimed to enhance mentees’ visibility and connections within the academic environment. Many mentees desire an advocate who will protect them from adverse influences and harsh interactions. Effective mentors create a safe environment for welcome expression of thoughts and feelings where mentees can perform self-reflection and explore appropriate work-life balance. Mentors should provide constructive criticism while also encouraging and acknowledging their mentees’ ideas, uniqueness and contributions.

The literature suggests certain strategies to achieve these activities. Straus recommended developing a communication framework to “reiterate and review” at meetings and a checklist to frame discussions ensuring time is spent addressing career, administrative, education, and personal issues. A formal contract may make the relationship more inflexible but mission statements and signed agreements can set boundaries and enforce accountability. Mentors should schedule regular appointments with communication in between meetings and keep a list of action items. The mentee should keep the mentor engaged with quick emails to communicate goal achievements such as grant approvals or publications.

Choosing Whom to Mentor

Mentors can be chosen informally or paired formally. However, formal assignment of mentoring pairs may ignore the very important interpersonal aspect. Chemistry is emphasized as of the utmost importance in the relationship and lack of this interpersonal connection could make the mentorship ineffective. Therefore, self-identification in many cases is beneficial but institutions could assist mentees in forming relationships by providing early guidance and instruction. Locating a mentor early in one’s academic career is crucial. Mentees should search for a mentor in many places including inside and outside their department and institution, and among both peer colleagues and senior faculty.

(My) advice to new faculty is to go set up a half hour appointment with everyone in the department. Just go sit and talk with them and that way you start to find out who would be the natural mentors.

— Jackson et al. (2003)
When the relationship is not working out

As the mentoring relationship evolves, both parties will learn more about one another. These discoveries may enhance the relationship, but others may make it impossible to continue. If an effective mentorship is a mutually rewarding relationship based on shared values, respect and a personal connection, then a failed mentorship is a relationship complicated by poor communication, personality differences, and conflicts of interest19 (see Figure 7). Additionally, a lack of commitment on one or both sides, perceived (or real) competition, and a mentor’s lack of experience with mentoring can all lead to a failed mentorship.

Although some mentees may feel compelled to stay in a failing relationship, Straus et al.19 described several consequences of a poor relationship including failure to obtain grants, to retain a promising junior faculty member, or to maintain collegiality in the department. In extreme cases, a poor relationship could lead to a junior faculty’s disillusionment with academic medicine and contribute to their departure from the institution.19 It is, therefore, critical that mentoring be a “no-fault relationship” for this reason.7,19 Both parties should have the option to terminate the relationship for good reason at any time without risk or harm to their careers.7
In most cases mentees are able to find another mentor, although they may feel more cautious when approaching new potential mentors. Mentees may need to ask the department chair to act as a broker to help defuse a potentially tense situation or to help them find a new mentor. Additionally, mentees should be open to the idea of multiple mentors as a more than one may be better able to meet their needs.

Gender and racial considerations in mentoring

Gender Issues

Women in academia face unique challenges including substantial barriers to career development and promotion both in research and clinical practice. Fewer women are promoted to tenure-track positions, full professorships, or leadership positions. Barriers to advancement include feelings of isolation from the greater academic community, gender discrimination, and gender bias. Women may also be less likely to self-nominate for awards, higher positions, and other opportunities than men.

Lack of effective mentorship is a significant barrier to career advancement and promotion for women. In 2006, Sambunjak et al. found women were less likely to have an active and consistent advisor than men, with Caucasian women being the least likely group to have a mentor. These women stated that lack of a mentor was one of the two most negative experiences in their career. Unfortunately, even when the women in the study had mentors, the relationships were fraught with more issues than the men’s. Women more often than men felt that their mentor was using their work to advance the mentor’s own career. Women were also less likely to be invited to informal work-related sporting events from their mentors which could have provided increased opportunities for networking and informal sharing of information.

Women have unique mentorship needs. In 2009, Sambunjak et al. found that women felt gender was more vital to their mentorship when those mentees had or intended to have children. Men were not always perceived as able to provide guidance on work/life balance i.e. maternity leave timing or managing a career while raising a family. Additionally, men and women have different experiences in academia due to the presence of gender bias and discrimination and so it may be that a female mentor can advise a female mentee better on these issues.

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*It is very difficult, I think, for a man whose wife has been able to support him at home and take care of the kids. I realize I have to do all of this on my off time at night and on weekends. He understands that on one level. But it is difficult because he has really never had to face it or do it.*

— Jackson et al. (2003)
A mentor can significantly improve a woman’s future success. Women who did have successful mentorships and participated in career development programs demonstrated increased scholarly achievement and increased knowledge/skills/abilities (KSA). This may be due to the skill development which occurs in a mentorship but may also be attributed to a reduction in feelings of isolation and increased sense of interconnectedness, empowerment, and connection to the greater academic community. Mentorships allow women to be increasingly exposed to research and career opportunities while also giving them an outlet to explore and address the unconscious and conscious gender biases in their career. Positive mentoring not only facilitates retention and advancement of an institution’s female faculty members, it also aids in recruitment of more female faculty. Not all women need a mentorship based on gender, but the option should be available for those who desire it.

**Mentoring Underrepresented Minorities**

Underrepresented minorities (URM) are severely underrepresented on medical school faculties and at the doctoral level in the sciences. African Americans, Hispanic Americans, and American Indians represented 25% of the US population but less than 10% of all physicians in 2013. URM groups are promoted at lower rates, report lower career satisfaction, are less likely to obtain R01 grants and spend more time in patient care with less time in research than white counterparts.

URM faculty who leave academic medicine report various driving forces in their departure including diversity pressures, isolation, racism and lack of mentoring. URM physicians are less likely to have mentors which may be due to unfamiliarity with the significance of having a mentor or because there are very few URM mentors available. Additionally, those mentors that are available may lack the commitment to the success of URM faculty. According to Rodriguez et al, URM physician-scientist faculty were more likely to have negative or absent mentoring experiences especially if they spent less than 20% of their time in research.

Mentoring is one way that institutions can better promote and retain minority faculty while increasing their productivity. Mentoring programs have been associated with increased recruitment, increased promotion rates and increased retention of URM faculty. In previous studies, URM faculty that were found to have a strong network of mentors to cultivate their professional development advanced the furthest, achieving and maintaining positions of influence and leadership in academia. A study at University of California, San Diego found that 11/12 participants (92%) in a formal mentoring program attained promotion to associate professor. They attributed their success to the support of senior faculty mentors and leaders at their institution, networking with peers, professional skill development and a better understanding of their institution’s culture.
It is important to discuss how to increase diversity, both in gender and race, in academic medicine. In 2005, Carnes et al.\textsuperscript{24} explored increasing diversity through the paradigm of the stages of change model (see Figure 8). An institution is in pre-contemplation, or the first stage of change, when it does not recognize that a problem exists. The goal is to help members of an academic community see that lack of diversity is a problem in the first place. The second stage, contemplation, occurs with recognition of the problems associated with a lack of diversity. The recognition of the problem creates attitudinal shifts at individual and institutional levels as individuals begins discussing strategies to change their own behavior and that of their institution. The third stage is the preparation stage in which individuals and institutions plan to undertake specific actions that foster diversity. This stage may include writing a departmental strategic plan for hiring more women and underrepresented minority faculty or developing workshops to train search committees how to attract a broad and diverse pool of applicants. The fourth stage is the action stage in which institutions take specific actions to achieve diversity. The ultimate goal of academic medical centers would therefore be to build a faculty that reflects the diversity of the students and both a faculty and student body that reflect the diversity of the United States. The fifth stage is the maintenance stage in which positive reinforcement and encouragement continues the actions of the fourth stage. Carnes et al.\textsuperscript{24} suggested that successes should be repeatedly and publicly praised and tangibly rewarded by continuous collection, analyzation, and publishing of institutional diversity data. The goal would be to change cultural norms so that reinforcement for desired behavior is ubiquitous and undesirable behavior becomes socially unacceptable.

**Cultural Differences**

There are many cultural differences that can affect the success of a mentorship. As stated by Sambunjak et al.,\textsuperscript{6} mentors from a culture that emphasizes individuality rather than collectivity may inhibit the mentor’s responsiveness to mentees’ needs. Additionally, efforts put into the development of others may be devalued. Experiences that members from a different gender, race or ethnicity bring to the mentorship should be seen as opportunities that allow for greater mutual growth of the mentee and the mentor.\textsuperscript{8}
The Mentorship Gap

In his 2015 study, Pololi et al. found that 43% faculty surveyed reported inadequate amount and quality of mentoring with only 30% reporting adequate mentoring. Senior faculty were just as likely to be dissatisfied and desire effective mentoring as assistant professors were. Lack of mentorship may be a problem that begins in medical school, as in 2006 less than 50% of medical students were found to have a mentor. Additionally, less than 20% (9 of 46) Clinical Translation Science Award (CTSA) institutions had comprehensive mentorship training programs for clinical and translational scholars in 2010. There are interpersonal and institutional factors that may lead to the discrepancy between the need for mentorship and the opportunities available (see Figure 9).

Personally, mentors face significant time restraints due to the significant responsibilities they have outside of their mentorship. Higher education consists of teaching and research activities but academic medicine has the added responsibility of providing healthcare to patients and populations. It is becoming increasingly difficult to balance all of these responsibilities in a single career. Changing clinical practices leads to more time spent on hospital committees and implementing quality control measurements, dealing with insurance, and in engaging in EMR systems. Physicians are required or pressured to see more patients which limits patient contact time even though service expectations from patients are rising. Even though research is highly valued, the work often extends to unpaid time both after hours and during leave and as mentoring relationships are typically uncompensated, it becomes even more difficult to find time for them. Additionally, research and clinical performance are more important in career assessment and promotion at the expense of mentoring goals. These challenges of working in academic medicine are reducing the already limited number of mentors as they have a detrimental impact on job satisfaction and attractiveness of academic careers.

Figure 9 Causes of the Mentorship Gap

<table>
<thead>
<tr>
<th>Personal</th>
<th>Interpersonal</th>
<th>Institutional</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time restraints</td>
<td>Mentors are difficult to find and engage</td>
<td>Decreased NIH funding available</td>
</tr>
<tr>
<td>Difficulties balancing multiple roles and responsibilities</td>
<td>Successful relationships require chemistry</td>
<td>Increasing age of grant recipients</td>
</tr>
<tr>
<td>Rewards for clinical or research success, not mentorship</td>
<td>Mentors need to be skilled at mentoring</td>
<td>CTSA budget cuts</td>
</tr>
</tbody>
</table>
The heroic and patriarchal model in academic medical settings can make finding a mentor difficult. Faculty may feel as though seeking help shows weakness or inability to cope while some senior faculty may hold skepticism for mentorships as many have succeeded in spite of having a mentor themselves. It is a challenge alone for mentees to access faculty, but they have the added challenge of finding a mentor among the limited selection who fits their need and with whom they have good chemistry. The lack of knowledge and experience in a mentorship is a barrier to both parties. Mentees do not know how to identify mentors, engage in a mentorship and maintain a relationship and mentors do not have the appropriate mentoring skills to grow an effective relationship. Additionally, Buddeberg-Fischer et al. reported other concrete problems with mentoring including anxiety caused by constantly being checked on, the danger of worsening of communication between a mentor and mentee, and difficulties arising from an insufficiently flexible relationship.

At the macro level, there has been a dramatic shift in government funding. The age of principal investigators has increased as government research support to early career investigators has diminished. The average age for first-time independent investigators increased from age 37 in 1980 to 44-45 years in 2014. In 1981, 25% of NIH Ro-1 grants were awarded to those aged 36 years and younger versus 2% in 2014. Additionally, according to Santen, there has been a 23% reduction in NIH funding (adjusted for inflation) from 2003 to 2013 with a decrease in independent-investigator NIH grants funded from 57.9% in 1963 to 14% in 2013. Many CTSAs are also experiencing budget cuts to their programs and mentor training programs are a common casualty of the cutbacks.

What can be done?

It is clear that effective mentorships provide benefits to individuals and to their institutions, but that the prevalence of these relationships must increase to meet the demands. There are various approaches institutions can take to increase the prevalence of effective mentorship (see Figure 10). The first important step is to create a standardized method of evaluating mentorships to ensure that mentees and mentors are in beneficial relationships and that programs created to grow mentorships are effective. Next, institutions can develop formal programs to train mentors as a lack of appropriate mentoring skills is a significant barrier to increasing mentorships. Mentors and mentees can then be matched through formal mentoring programs that meet the needs of mentees and mentors either in the form of the traditional dyad model or in alternative forms i.e. speed mentoring or peer mentoring.

Standardized methods of measuring effectiveness

Fleming et al. created the Mentoring Competency Assessment (MCA) to help standardize the measurement of a mentor’s efficacy. Mentors participated in an 8 hour training curriculum and were evaluated before and after the
training through self-reflection and by their mentees. Three instruments previously described in the literature were combined to create the MCA, which consisted of 26 items evaluating the mentor’s competency in six areas: maintaining effective communication, aligning expectations, assessing understanding, addressing diversity, fostering independence, and promoting professional development. The MCA was found to have reliability and validity when assessing mentoring skills as perceived by both the mentor and the mentee. However, the authors note the MCA should only be used as one measure of mentor performance and other outcomes including mentee publications and grants should also be taken into account.

Meagher et al.\textsuperscript{27} proposed a model that took these other measures of success into account. Their model measured a mentorship objectively and subjectively. Individual objective measures were promotion, publications, grants submitted/awarded, academic awards/recognition, leadership success, and financial success relative to national averages. Collective objective measures were the retention of faculty and financial return on investment in mentorships. Subjective success were measured by personal career satisfaction, rate of career progress, career prospects/trajectory, work life balance, and overall quality of life. These outcome measures were recorded along with individual and environmental factors about the relationships that had been known to determine success i.e. personality traits, education, demographics, institutional resources and institutional attitudes. The model is meant to be used prior to a mentorship’s initiation and continuously at regular intervals throughout its lifecycle, providing feedback to mentors and program directors to maximize the relationship’s efficacy.
Successful Mentor Training Courses

In 2013, Pfund et al. noted the lack of an established evidence-based, user-friendly training curriculum for mentors. Based on the “Entering Mentoring” seminar developed to train biology faculty to become more effective research mentors, Pfund et al. designed a curriculum more appropriate for mentors of postdoctoral researchers and junior faculty. Their training was based on six core mentoring competencies: maintaining effective communication, aligning expectations, assessing understanding, fostering independence, and promoting professional development. Eighty-eight percent of those that completed the program felt that the training was a valuable use of their time and 84% rated each session effective. Mentors reported significant learning gains in all six mentoring competencies and noted specific impacts of the training on their mentoring practice with 87% implementing at least one behavioral change in their mentoring style. The training program was further examined through a randomized control trial and showed significant improvement in communication, expectations and professional development of mentors both by their own report and the report of their mentees. Importantly, the original study found that even though mentors have limited time for mentoring activities, mentors did participate in the training and reported it as a valuable use of their time.

Busy, successful people do make time for educational activities they find valuable.
— Pfund (2013)

Feldman et al. developed the Clinical and Translational Science Institution’s Mentor Development Program (MDP) at the University of California, San Francisco to train mid-career and early senior clinical and translational research faculty in mentoring. The MDP was an improvement on the previously developed campus-wide UCSF Faculty Mentoring Program launched in 2006. The MDP consisted of five months of case-based seminars with time for mentees to network with peers and senior mentors. Mentees were placed in a mentoring team composed of a lead mentor who developed the research career of the mentee, up to two co-mentors, the mentee’s departmental career mentor and an advisory team. Ninety-six percent of mentees agreed that the program helped them to become a better mentor, 92% agreed it enhanced their understanding of mentoring issues at UCSF and most reported they would be making changes in their mentoring styles based on the program. Mentees reported improvement in overall confidence in mentoring skills and improvement in their mentoring abilities.

Successful Mentorships

Burns et al. established the Clinical Research Training Institute (CRTI) for Physician Scientists in Hematology. The program was a year-long experience with the purpose of the development of an original research proposal and a
career development plan by the mentees. The mentees first developed these plans at a week-long conference and then returned to their home institution to further implement their research project. One hundred and thirty-three trainees who participated in the first 7 years of the CRTI published 1,035 peer-reviewed articles, 173 chapters, 115 review articles and 69 other publications since the calendar year in which they attended the summer workshop. They were recipients of 78 NIH grants, 133 foundational grants, and 32 other external grants. The program was found to be successful at preparing investigators to be significant contributing researchers to the field of Hematology. However, the program was resource-intensive both in terms of trainee and faculty time and financial resources. At the approximate cost of $15,000 per trainee, this program was noted by the authors to be a challenge to sustain and improve.

Lewellen et al.22 developed the Peer-Onsite-Distance (POD) model, designed to promote retention and career development of URM medical school faculty at Arizona State University. Researchers created two inventories: the Mentee Need Inventory (MNI) and Mentor Readiness Inventory (MRI) to match a mentee’s needs with a mentor’s expertise. The primary goal was to develop a professional network for both mentees and mentors. The application process was self-directed and initiated when a URM faculty member completed a MNI and was matched with a mentor who indicated readiness to mentor. The mentee was taught content and interaction skills by peer mentors, onsite mentors, and distance mentors who were leaders in the fields of healthcare, business, academia, or government. The POD had the benefit of exposing new faculty to the culture of academic medicine while also offering interpersonal and intrapersonal support to nurture the mentees’ development. Channels of support and communication developed within, and between a network of mentors to convey success strategies and site specific guidance while creating a protective environment.

Kupfer et al.20 created the Career Development Institute (CDI) to provide skills and support for successful research careers in academic psychiatry. The CDI was designed to improve and augment participants’ repertoire of “survival skills,” provide support in their transition to independent investigator, foster shared learning experiences with other investigators at similar developmental stages and establish a network of junior investigators and senior mentors across the US. The program started in 2009 with a cohort of 20 participants who were matched with mentors based on career stage, research interest and goals. Among the 2004 to 2006 class, 23 were appointed assistant professor and 7 went on to a research fellowship. Seventy-seven participants from 2004 to 2007 received 27 NIH awards (11 of which were K awards) and 22 received NARSAD Young Investigator Awards. Of the 16 mentees in Class of 2012, 9 received promotions to Assistant Professor during the two year experience, and 5 received new K23 or KL2 awards.33 The CDI was one approach successful at using a broad range of experts’ perspectives to develop the next generation of mental
health researchers.

**Mentoring in Forms Other Than the Traditional Dyad Model**

Many of the challenges with creating a successful mentoring relationship can be due to the nature of a traditional dyad relationship. There may be conflicting goals, expectations, levels of commitment, personality clashes and insensitivity toward gender or cultural differences. The inherent power differential can be problematic, pressuring protégés to evolve into clones of their mentors who perpetuate the status quo rather than developing their own values and goals. Therefore, studies have sought out alternative forms of mentoring other than the traditional dyad model to meet the needs of mentees while removing some of the previously described challenges. These new forms include speed mentoring and peer mentoring.

**Speed Mentoring**

Speed dating began in 1998 as a matchmaking method to help Jewish singles meet and marry. Speed dating was effective as individuals appeared to make decisions in as little as 30 seconds. Good chemistry leads to a successful mentorship and Cook et al. asserted that the mentor and mentee must have a chance to try out the relationship to make this interpersonal connection. The event was organized between junior and senior faculty with each junior member spending 10 minutes with each of six senior faculty members. Only two mentees contacted a participating mentor after the event although establishing and maintaining mentorships were the most common theme of discussion. Overall, the speed dating event did not stimulate durable mentor-mentee relationships but it did provide a valuable networking opportunity for its participants.

Serwint et al. described a similar event at the 2012 Pediatric Academic Societies (APS) meeting. Sixty mentors and 60 mentees participated in the event and were matched within a designated track: Career Development, Clinical Research, Community-Based Research, Educational Scholarship, Health Services Research, Leadership Skills, Qualitative Research, Quality Improvement Scholarship, Scholarship from Everyday Work, or Work-Life Balance. Both mentors and mentees agreed their time was well spent and that they would participate again. Mentees stated the event allowed them to receive advice from multiple mentors in a short period of time while mentors gained new insights, reflected on their own careers, and felt that they gave back to their field. Importantly, chemistry was identified as major factor in pursuing ongoing relationships. Serwint et al. asserts it is difficult for many mentees to initiate a successful mentoring relationship and speed mentoring was successful at removing this barrier.

**Peer Mentoring**

Peer mentoring has been described as a unique form of mentoring most beneficial in areas with fewer resources, as it only requires time and commitment. Pololi et al. conducted a study of facilitated group peer mentoring programs from 2010 to 2014. The junior faculty were placed in a year-long learning community with
the goal of understanding their own identity and core values. Faculty participated in reflective practices and wrote personal progress goals so that each participant possessed a detailed career development plan by the end. Participants were productive, with 66 scholarly manuscripts created by 19 participants in two cohorts. The program fostered strong positive relationships and trust among faculty which were reported to be important outcomes that could change the culture of academic medicine. Additionally, the peer mentoring format solved the high attendance difficulties present in dyadic mentoring programs but had the disadvantage of requiring facilitators to guide the learning communities.

Fleming et al.21 discussed the success of a peer mentoring program at Vanderbilt in 2015. The program was designed to both provide a skill development curriculum and mentorship experience to improve career advancement skills. The program was voluntary and open to all junior faculty in the Department of Pediatrics at Vanderbilt. Small groups of 8-10 mentees per mentor met once per month for a year. At the end, KSA scores increased most significantly in the professional and scholarship development domains and mentees reported increased ability to identify resources for problem solving. Female faculty in particular noted significant KSA improvements compared to their male peers. Faculty interconnectedness and retention increased across academic ranks and participants reported increased involvement in academic activities related to their goals. Twelve participants were selected to the Vanderbilt Academy for Excellence in Teaching compared to 3 members in the 2 years prior to the program. According to Fleming et al.,21 this study showed the importance of pairing resources and desired outcomes with the unique needs of an institution and its faculty, rather than relying on a “one size fits all” model for mentoring.

Conclusion

Mentoring is the formation of a relationship that serves to increase growth and professional development among both mentors and mentees. Evidence suggest that effective mentoring is important especially for young investigators pursuing research careers. Successful mentorships require commitment and chemistry between the participants. The benefits to both parties may be tangible including promotion, increase in skills, and publication, or emotional in the form of a support system. Importantly, these relationships also support and sustain academic institutions by increasing faculty retention and productivity.

It is clear that mentors are essential, but there still is a gap between the need for mentors and the prevalence of mentorships, which may be attributed to barriers at the personal, interpersonal level, and institutional levels. Particularly, women and underrepresented minorities are less likely to have mentors and have greater challenges accessing mentors. It is important that institutions increase the availability of mentors by making mentoring a priority and increasing the diversity of faculty and staff. The implementation of formal mentor training or mentoring programs may serve to create a culture supportive of mentorship. However, the needs of the institution’s community are paramount in implementing a mentorship program and institutions should be open to using alternative forms of mentorships like
speed mentoring or peer mentorship, which may provide the best benefit.

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Chapter 6

Time Management

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Introduction

As a beginning investigator, you face many competing demands for your time. You are expected to build your career and you may be under time constraints for tenure. At the same time, you are at risk for overwhelm and burnout in your personal life. You already work many hours and there are only 24 hours a day. One of the most daunting challenges is how to prioritize your time to achieve a successful career and a fulfilling personal life. This chapter reviews practical strategies for prioritizing time, such as setting long-term and short-term goals, day-to-day planning, and workflow efficiency. Issues that are unique to physician-scientists are also covered.

Time management is an oxymoron. Time is beyond our control, and the clock keeps ticking regardless of how we lead our lives. Priority management is the answer to maximizing the time we have.
— John C. Maxwell

Strategies for Planning Your Activities

Defining Goals

Planning is a process that begins with a goal. Once you have set a goal, you can identify the necessary steps to move toward it. Goals come in descending sizes, each of which informs the next: long-term goals (years), intermediate-term goals (months), and short-term goals (weeks and days).

Take the time to craft a formal plan, beginning with your long-term goals. Then set interim goals along the way that are realistic indicators of progress. By setting achievable goals, you avoid having too much to do and not knowing where to begin. Accomplishing just one goal can serve as a powerful motivator to tackle the next goal.
Write down all your goals, with each achievement tied to a specific time frame. Putting your ideas into words can help refine your thinking and provide a concrete checklist to keep you on target. Every so often, take a look at your plans, reflect on them, and revise them as appropriate to changing circumstances. Priorities shift; be prepared to reevaluate yours but also to defend them.

**Long-term goals.** Start with a ‘blue sky’ view (>30,000 ft) to identify your long-term goals. Long-term goals are likely to be a combination of tangibles (e.g., faculty promotions) and intangibles (e.g., a satisfying personal life). Many of these goals can be achieved in three to five years. Before jotting down your long-term plans, first ask yourself where you want to be after this stage in your career. For example, if you are a postdoc, do you plan on an academic or applied position? At what type of institution—a research-intensive institution, teaching college, or other? Now ask yourself, “What will I need to accomplish to make myself competitive for that job?” If you are an assistant professor, you probably want to work toward tenure. Knowing when you’ll be up for tenure, ask yourself, “What will I need to do by then—how many papers, invited seminars, professional meetings, and other accomplishments?”

In defining your long-term goals, you are also defining yourself—who you want to be and how you want to be perceived. What is your vision, mission, and purpose? Why do you do what you do? Are you really doing what you want to do? Review these goals annually as they may change over time.

**Intermediate-term and short-term goals.** The ‘take off’ view (0-30,000 ft) defines how you get to the long-term goals. Assess your current projects and ongoing responsibilities. These are your medium-term and short-term goals. Intermediate goals can be achieved in six months to one year. For example, as a postdoc you should be thinking about the experiments needed to complete your next paper or to put together a poster. Completing publishable chunks is an essential intermediate-term goal for faculty. Other such goals are obtaining preliminary results for a grant, putting together a new course, and organizing a meeting. Short-term goals can be achieved in one week to one month. They include preparing figures for the paper you’re writing, completing an experiment, preparing reagents for the next set of experiments, or writing letters and making phone calls to secure a seminar invitation. If you find it hard to get organized, make a daily or weekly to-do list and check tasks off as you complete them. Review these goals quarterly (intermediate), monthly and weekly (short-term) to ensure that these goals align with your long-term goals.

**Day-to-day.** The ‘runway’ view on the ground (0 ft) defines the small, concrete, finite tasks that can swallow your time day-to-day. What are your routine duties? What are your urgent responsibilities? What needs to be done now? Review your daily activities weekly to determine if you are moving towards your goals. If not, re-assess and re-arrange your activities and your goals to ensure that they are aligned.
Getting from Here to There

Prioritizing (Making Choices)

What do you do with constant requests for your time, attention, and energy? One useful strategy for prioritizing your time is a grid that allows you to rank short-term claims on your attention according to urgency and importance (see figure 6.1). Try to control the not urgent/not important quadrant. You get relatively little value for the time spent doing tasks in this quadrant. The urgent/important quadrant puts you in crisis mode, where few people operate best. For maximum efficiency, you should be spending most of your time in the upper right-hand quadrant on tasks that are important but not urgent.

If it’s important but not urgent, remember your priorities and schedules:

- Plan ahead and know your deadlines
- Set aside blocks of time for specific tasks
- Break large tasks into smaller tasks
- Delegate tasks
- Complete tasks on time

Practical tips for completing tasks, especially if you feel overwhelmed.

- Stop and take a deep breath
- Slow down
- Turn to a high priority task
- Implement a stabilization method
  - Make a list of everything you have to do
  - Clear your work space
  - Find a 10% solution
  - Face up to the AWOL syndrome (show that you are still alive and re-negotiate a new deadline)

Figure 6.1 Time Management Grid

<table>
<thead>
<tr>
<th></th>
<th>Not Important</th>
<th>Important</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Urgent</td>
<td>Most e-mail</td>
<td>Ongoing experiments</td>
</tr>
<tr>
<td></td>
<td>Weekend plans of lab members</td>
<td>Preparing for a committee meeting</td>
</tr>
<tr>
<td></td>
<td>The Super Bowl pool</td>
<td>Next month’s grant deadline</td>
</tr>
<tr>
<td>Urgent</td>
<td>“You’ve got mail” alert</td>
<td>A lab fire</td>
</tr>
<tr>
<td></td>
<td>Ringing telephone</td>
<td>Tomorrow’s grant deadline</td>
</tr>
<tr>
<td></td>
<td>Inquiring colleague</td>
<td></td>
</tr>
</tbody>
</table>

Source: Sandra L. Schmid, The Scripps Research Institute, adapted from Stephen R. Covey’s time management matrix in The Seven Habits of Highly Effective People: Powerful Lessons in Personal Change.

The key is to identify what matters to you in terms of interests and values and then to apportion your activities throughout the day and week to address all of them.

— Richard Reis, Stanford University
Another method of prioritizing is The Law of Priorities: The 3 R’s. This tool helps determine what you must do, what provides the greatest return by you doing the task, and what brings the greatest reward to you.

- **Requirement:** What must I do?
  - If it’s not necessary → eliminate
  - If it’s necessary, but not required of me personally → delegate

- **Return:** What is the greatest return?
  - If something can be done 80% as well by someone else → delegate

- **Reward:** What brings the greatest reward?
  - Professional and personal goals/interests/passions

**Say NO, so you can say YES**

When someone asks you to help them on a major project and you are clear it is not related to your goals and priorities, say No quickly. If you are tempted in any way to say Yes, take some time. Do not say Yes immediately. Take time to think. Review the required time and energy commitments with your significant other and family. Then, say Yes if the project is aligned with your goals and makes sense to you.

- Figure out what you really want (know your own priorities)
- Listen carefully to what they want (understand the request)
- Say NO immediately and clearly (quick NO)
- Be reasonable (offer what you can)
- Find the YES (slow YES or an alternative, only if it makes sense to you)
- Don’t babble
- Move on (stand firm and don’t be swayed)

**Managing Your Time Day to Day**

Many people find long-term goals easy to set—for example, “I want to be a full professor by the age of X.” More difficult is the daily flood of small chores that can threaten to drown even the most organized professional. This section covers how to overcome overwhelm and make the most of the time you have.

**Finding Time and Energy**

To be able to focus and think creatively, you need blocks of uninterrupted time. Here are some tips to help you do this:

- Create a Schedule based on your time and energy: Time and Energy Map
  - Make a grid of the week (time log)
  - Mark time for work and personal activities (target open blocks for specific work)
  - Add buffers between activities
- Block “free time” (25–75% of it for emergencies and for uninterrupted time with “Professor MS” – My Self)
- Respect your own body clock; schedule certain key tasks for times when you are most productive and have the most energy
- Get enough exercise, sleep, personal/family/friend/community time
- Don’t let perfect be the enemy of good

Get Rid of Time and Energy Drains

- Multi-tasking
- Constant email/social media (do an important task before checking email)
- Disorganization
- Not enough planning
- Over planning
- Perfectionism

Five Principles of for Organizing Work

1. Do it now (especially if it takes less than 2 minutes)
2. Work from a clear space
3. Keep track of all your work commitments as a running list
4. Use a single master calendar
5. Plan by the week

Improving Your Lab Staff’s Time Management Skills

Here are some tips for helping your staff work more efficiently:

- Establish clear goals and expectations early, starting with simple tasks your staff can handle. Make sure they understand the tasks. Reward and correct them as appropriate, expand the tasks, then repeat the process.
- Help them seek advice without taking up unnecessary time. Teach them how to describe projects, issues, and problems accurately and efficiently.
- Develop an agenda for every meeting—and stick to it. Start meetings with a clear description of the purpose of the meeting and when it will end.
- After meetings, send a follow-up letter containing a summary and to-do list. Use these informal minutes to start the next meeting and gauge progress. (Meeting minutes are also useful for patent protections in establishing proof of an idea, attribution, and date.)
- Once the members of your lab learn the importance of time management, you can also delegate to a key staff person the task of summarizing meetings and assigning follow-up actions.
Unique Issues for Physician Scientists
The Triple Load of the Physician-Scientist: Lab, Class, and Clinic

Although physician-scientists may have some teaching duties, these duties usually aren’t extensive. The larger challenge for a physician who is running a research lab is managing lab and clinical time. An even split between the lab and clinic is increasingly rare; it can be as much as 80 percent lab and 20 percent clinic, but it varies considerably from person to person and by the nature of the work. Here are some tips for straddling the lab and the clinic.

**In the lab:**
- Consider investing in a lab manager. These individuals usually have an advanced degree or a lot of experience and are thus more expensive, but a good lab manager will help keep the lab on track while you are on clinical duties.
- Establish a system where you can review the lab members’ notebooks and data even if they are not there (e.g., if clinical duties keep you from being in the lab until late in the evening).
- Explain to your lab members that you will not be around much when you are on clinical duty.
- Try to schedule times when you can meet with your students and postdocs to keep yourself apprised of their progress.
- Focus your research program on what you’re uniquely qualified to do.

**In the clinical:**
- Tell patients how you want to be contacted.
- If you have access to support staff (and many junior faculty do not), use them effectively.
- Educate nurses and other clinical support staff to do as much of the preparation as possible before your appointments, as well as the follow-up.
- Learn to tell patients when you have to stop.
- Educate patients and colleagues about your dual roles.

Remember, in the lab, in the clinic, and at home—the most important thing you need to learn is to be flexible with your priorities.
Profession and Personal Life: Can You Have It All?

This question applies to many professionals in high-pressure careers, including scientists pursuing academic career tracks.

Family communication. It helps to start with a supportive partner and family. Have clear discussions about career and personal goals—yours and those of your family—early on. To avoid the resentments of unspoken and unmet expectations, be as explicit as possible about your aspirations with those who are important to you. Shared goals for work and family make compromises easier.

In addition to sharing your long-term goals, keep your partner and family aware of your short-term plans and projects. Letting your partner know in advance about an impending grant deadline can buy some understanding. Here are some ways to keep your family informed of your schedule and you involved with your family:

- Post a calendar at home with your travel dates and big deadlines.
- Schedule activities with your family and keep those commitments (e.g., Friday date night).
- Extend business travel into a vacation. Have your partner join you after a scientific meeting and take a few days together to unwind.
- Involve your partner in your work if he or she is interested. Having partners read over a grant application allows them to contribute, and you benefit from a fresh set of eyes to find typos.

Managing work and children. Having a supportive partner, high-quality day care, domestic services, and shopping conveniences make raising a family and having a challenging career sustainable and enriching. Indeed, being the boss (e.g., running a lab) can give you the flexibility and the financial resources to make the choices and adjustments necessary to manage work and maintain a balanced lifestyle.

Here are some tips for balancing work and family life:

- Take advantage of options for assistance in cooking, cleaning, and other domestic chores, and don’t waste energy feeling guilty. When your budget allows (and in the early years, it may not), buy yourself time: Hire help with housecleaning—even if you can afford only semimonthly scouring of the bathrooms and kitchen. Until then, a messy (but reasonably clean) house won’t hurt you or the kids. Later, a nanny or housekeeper (who also does laundry) is worth the investment.
- Eat out with your family once a week or once in a while. This is an easy family-focused activity you can enjoy together outside the house.
□ Pick up carryout meals or have meals delivered to eat at home. This break from cooking will stretch the dinner table time you have to share information about everyone’s day and allow you to play with younger children and put them to bed.

□ Teach your children how to help out with age-appropriate chores (e.g., putting their clothes in a hamper, putting away clean laundry, setting the table).

□ When you do cook, keep meals simple and make large quantities that can be frozen in meal-size portions for use throughout the week.

□ If you and your partner both work outside the house, make the best childcare arrangements you can. If you’re away from your children and partner all day, it’s especially important to carve out inviolable family time on evenings or weekends.

Is it possible for ambitious scientists to have it all? Yes, but perhaps not all at the same time. The key—admittedly easier said than done—is to identify what matters most to you and then to apportion your activities throughout the day and week to address them over time. The most important thing is to set your priorities and learn to be flexible.

Resources

Articles


4) Milewicz, Dianna et al. Rescuing the physician-scientist workforce: the time for action is now. J Clin Invest 2015
Books

Web
15) www.sciencemag.org/careers
16) www.aamc.org
17) www.medscape.com
18) www.thehappymd.com
19) www.tthivingamidstchaos.com
Chapter 7

Staffing Your Lab

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Overview

- Getting started
- Recruiting applicants
- Screening and interviewing
- Asking staff to leave

Difference between employees and students

It is important to appreciate the differences between employees and students since this relates to expectations and performance evaluation. Employees can be “hired” and “fired”; students are typically assigned to a lab.

Employees:

- Research technicians
- Post-doctoral fellows

Students:

- Learner to teacher relationship
- Gain research experience

Avoid discrimination

The Human Resources (HR) group at your institution can be highly valuable to understanding laws and guidelines related to avoiding discrimination in the workplace. Moreover, it is increasingly clear that a diverse group tends to function at a higher level. Therefore, careful consideration of diversity and inclusion can make a team stronger.

- Federal, state, and local laws determine many aspects of employer/employee relationship
- Apply to many employment-related decisions—interviewing, recruiting, selecting, hiring, training, evaluating, promoting, disciplining, or terminating
- Work with HR and department administration
Determine your staffing needs

Factors to consider:
- Your start-up package
- Stability of external funding sources
- Progress of your research
- Personal preferences

Avoid rushing and hiring just to fill an empty lab

Carefully consider needs and consequences
- Recruiting the caliber of people you need
- Time to train and mentor others
- Time and space

Often the first hire is a research technician
- Can help with time-consuming initial tasks — equipment, cell culture
- Administrative and regulatory compliance

Subsequent hires
- Graduate student — will require substantial time for mentoring
- Post-doctoral fellow — once you have enough projects under way
- Undergraduate students — typically large time investment needed

Write the job description
- Identify and prioritize lab tasks/needs
- Qualifications needed
- Work with HR and department administration for job description

Recruiting applicants

Getting the word out:
- Word of mouth
- Ideally applicants would seek you out — meetings, seminars
- Your web site
- Rotation students
Formal advertisements

In addition to the venues noted below, some labs also use social media sites to “advertise” available positions. However, different institutions have varying policies related to use and access to social media.

- Journals
- FASEB (Federation of American Societies for Experimental Biology)
- Scientific society web site
- Association for Women in Science

Check institutional policies

What do you have to offer?

- Promote your vision
- Communicate your lab culture
- Commitment to mentoring
- Flexibility when possible
- Reassurance regarding stability of funding

What they are looking for

Research technicians:
- Beginning lab to work closely with PI
- Learning new techniques and being included on papers
- Future opportunities — graduate or medical school, other

Graduate students:
- Work closely with PI
- Can be very time consuming
- Consider starting with a limited number — create positive experiences

Undergraduate students:
- Academic credit
- Recommendations for subsequent career development
- Consider carefully

Post-doctoral fellows:
- Established vs. early labs
- Interest in research area
- Furthering their career
- Ability to “take” some aspect of their project(s)
Screening applicants

- Many PIs do their own screening
- HR for initial screening
- Check skills against qualifications, transferable skills
- Gaps in employment?
- Job-hopping?
- Publication quality (not just quantity)
- Applicant’s contribution
- Interactions with other lab members

References

- Letters are rarely negative
- Contact references by phone:
  - Ask open ended questions
  - Probe for further information and ask for examples
  - Ask about reference lab’s philosophy, values

Interviewing applicants

It is helpful to discuss your expectations for this position with others who will also interview the selected applicants. Ideally, have a structured interview process to give each applicant a fair opportunity and for a fair evaluation of the applicants.

- Interview with the PI
- Spend time with other lab members and colleagues without you
- Consider having the applicant deliver a seminar

Interviewing applicants: Structured interview

- Outlined ahead of time and ask basically same questions of each applicant
- Job-related and legal (avoid asking personal questions)
- Short and open-ended
- Focused and designed to elicit information
**Topics to avoid**
- Questions related to race, color, national origin, sex, religion, disability, or age
- Sexual orientation
- Marital status
- Pregnancy or plans for having children
- Non-work-related matters

**Types of questions**

**Experience and skills**
- Significant accomplishments
- Role in specific project(s)

**Commitment and initiative**
- Why do you want to come to this lab?
- Near- and long-term goals
- Leadership in lab
- How you took initiative

**Working and learning styles**
- Motivations
- Team vs. individual work
- Problem solving

**Commitment and initiative**
- How do you prioritize your work?
- How do you handle competing priorities?

**Decision making and problem solving**
- Challenges in your current job? How do you deal with them?
- Example of a situation where you had to gather other opinions before making a decision

**Interpersonal skills**
- Working with colleagues
- Handling difficult situations
Tips for conducting an interview

- Make the applicant feel comfortable
- Develop professional rapport — explain the selection process
- Take brief notes
- Listen carefully — let the applicant do most of the talking
- Give the applicant many chances to ask questions
- Avoid making promises or giving commitments

Special considerations

Visas:

- Requirements are complex and change frequently
- Work with departmental administration and institutional visa office

Evaluating applicants

Maintaining objectivity — try to avoid:

- Making decision too early
- First impressions
- Judging the applicant in comparison to yourself
- Allowing a positive characteristic to overshadow your perception

What to look for

- Consider the “chemistry”— able to get along with others?
- Whether the applicant is a good fit — skills and personalities
- Passion for science and work ethic
- Career plans

Red flags

- Demanding privileges not given to others
- Unwilling to take responsibility for something that has gone wrong
- Complaining about an adviser and co-workers
- Delaying answering questions, challenging your questions
- Incongruence between what you hear and what you see
- Inappropriate behavior
Making the offer: Considerations

- Which items are negotiable
- Find out institutional salary ranges for the position
- Contact the applicant directly to extend the offer
- Inform all the applicants

Difficult decisions

Asking staff to leave

- Before considering dismissal, consider various avenues to help the person
- Scientific techniques, counseling for behavioral issues
- Be certain that your dissatisfaction is based on objective observations

Be fair

- Notice about unsatisfactory performance
- Avoid surprises
- Give a reasonable opportunity to respond and turn things around
- Keep a record—conversations, attempts to help the person improve performance
- Deliver a warning—commit your action plan to writing

Asking staff to leave: Questions to consider

- Have you given some type of notice or warning?
- Have you made it clear what he or she is doing wrong?
- Has the person received counseling or assistance?
- Are you treating the person differently than other staff?
- Are you following written procedures and institutional policies?
- Does the documentation in the personnel file support the reason for discharge?
Chapter 8

Project Management

Chapter from *Making the Right Moves: A Practical Guide to Scientific Management for Postdocs and New Faculty* by Burroughs Wellcome Fund and Howard Hughes Medical Institute, Second Edition
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.
- **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.

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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.
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?

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.
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.

**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

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**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.
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.

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.

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.

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.
Resources

1) 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.

2) 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.


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Chapter 9

Getting Funded

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You have secured a faculty position at an academic institution with internal support for your research program and your career as an academic scientist has begun. Your laboratory group is in place and performing experiments, and your research program is moving forward. The pressure is now on to obtain financial support for your research from sources other than your institution. To do this you need to be proficient in the writing grant applications. It’s time to learn the art of getting funded. This Chapter will discuss tips for preparing a solid research funding proposal and what to do if your application is not funded.

An important part of writing a successful grant application is understand how your research matches the mission of the funding organization and the types of projects it supports.

Although numerous public and private sources support biomedical research, 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 largest funder of academic biomedical research in the U.S. The NIH funds multiple research grant types depending of the applicant’s career level and the NIH funding priority. However, the R01 grant, an investigator-initiated research project grant for which most beginning academic researchers will have to apply, will serve as a prototype for this discussion.

**NIH Funding**

**NIH Institutes and Centers**

The NIH comprises Institutes and Centers (ICs) each with a specific mission and research agenda. Currently there are 21 Institutes and 6 Centers (see: [https://www.nih.gov/institutes-nih/list-nih-institutes-centers-offices](https://www.nih.gov/institutes-nih/list-nih-institutes-centers-offices)). The ICs administer their own budgets according to their research agendas and fund programs for extramural awards (i.e., research conducted outside NIH facilities), including R01 grants.

**Find an IC for Your Application**

Although not essential, it is important to identify an IC that is likely to be interested in your research. To do this you should:
Check the NIH Guide to Grants and Contracts (http://grants.nih.gov/grants/guide/index.html) and funding opportunities for relevant and recent funding opportunity announcements (FOAs). These are usually in the form of Request for Applications (RFAs) or Program Announcements (PAs). RFAs and PAs reflect the IC’s research priorities.

Check the NIH Research Portfolio Online Reporting Tool (https://reporter.nih.gov) database for projects like yours that have been funded. This will provide important insight into the types of applications that are funded in your field and the ICs involved.

Once you’ve narrowed the list of potential ICs, go to the website of each IC to determine current areas of research interest. IC sites commonly describe scientific areas of interest as well as identify the staff members who are responsible for each program area and the portfolio of grants in that area.

The IC Program Officer (PO) is the best person to help you decide what type of grant to apply for, and which Study Section (see below) may be most appropriate for its review. The PO also can be your best advocate and adviser throughout the application process.

Most ICs post their funding plans on their Web sites. The funding plan is the percentile (see below) to which the IC anticipates being able to fund applications on the basis of its current budget, recent funding history, and program priorities. Regardless of whether the IC to which your application was assigned posts its funding plan, you may want to ask the PO responsible for the administrative management of pending applications/revisions and funded grants about the likelihood that your specific proposal will be funded.

Your application can be reviewed by more than one IC. You can ask for assignment to a second IC if you’ve had encouragement from another PO or think that your application fits within another IC’s scientific areas of interest. However, your application can be funded by only one IC, but more than one advisory council can review it to broaden your chance of funding. In such cases, the application will be assigned a primary and a secondary IC. The secondary IC can consider it for funding only if the primary IC opts to relinquish first right of funding.

Review of NIH Grant Applications

NIH applications are subjected to a two-level peer review process (outlined in Figure 9.1) administered by the Center for Scientific Review (CSR). Application are submitted by your institution on your behalf to the CSR where they are processed for the first-level review. The CSR assigns the application to a Scientific Review Group (SRG; also referred to as a Study Section) for evaluation and scoring based on scientific and technical merit. Each Study Section comprises 12-25 experts in a specific biomedical/clinical field. The Study Section reviews the grant application for scientific merit, rates it with a numerical priority score based on specific review criteria (see...
below) from which a percentile ranking is derived. The percentile ranking process is the way that ICs account for variation in scoring behaviors between Study Sections. For the second-level review, outcomes of the Study Section review are sent to one or more ICs for funding consideration based on IC programmatic relevance and Study Section funding recommendation (see below).

To increase your chance of funding, your application should be assigned to the appropriate SRG/Study Section for your specific research area. 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 is best suited for your application. Include the name of the PO who supports this request. CSR staff members will consider your suggestion for a Study Section, and if your suggestion is logical, it is likely it will be honored. You can also recommend the type of expertise needed to evaluate your application, but you should not provide specific names of potential reviewers. If you do not submit a cover letter key words in the Title, Abstract, and Specific Aims will be used to direct your application to a suitable Study Section. The contact person at this stage of the review process is the Scientific Review Officer (SRO) who works for the CSR and is responsible for organizing the Study Section meetings and serves as a liaison between the Study Section and the applicant.

After you have been notified about the study section to which your application has been assigned, check the member roster to make sure the expertise you consider essential to a fair and thorough evaluation of your application is represented. If someone who you regard as an important interpreter of your research has dropped off the roster, you can request that someone with similar expertise be added. 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 the person you are excluding will be informed that you made this request.

A typical Study Section is assigned 70-90 application each review cycle (See Figure 9.2). All Study Section members have access to all applications. However, for each application three Study Section members are selected by the SRO based on scientific expertise to perform a detailed and knowledgable review of the application.

**Figure 9.2 Typical Timeline for a New R01 Application**

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<tr>
<th></th>
<th>Cycle 1</th>
<th>Cycle 2</th>
<th>Cycle 3</th>
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<tbody>
<tr>
<td>Application Submitted</td>
<td>February</td>
<td>June</td>
<td>October</td>
</tr>
<tr>
<td>SRG (Study Section) Review</td>
<td>June</td>
<td>October</td>
<td>February</td>
</tr>
<tr>
<td>Advisory Council Review</td>
<td>September</td>
<td>January</td>
<td>May</td>
</tr>
<tr>
<td>Earliest Award</td>
<td>December</td>
<td>April</td>
<td>July</td>
</tr>
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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 into the solicitations.
This review occurs prior to the Study Section meeting via the Internet Assisted Review site in NIH Commons (https://public.era.nih.gov). For most Study Section meeting, applications are ranked based on the average preliminary overall impact score and subjected to streamlining; a triaging process to select the highest ranking applications (usually the top ~50%) for discussion at the Study Section meeting. Through streamlining, applications that are deemed to be in the lower half of those assigned for review are not discussed at the Study Section meeting. Streamlining was instituted to allow more time for discussion of applications near the fundable range and to shorten the Study Section meetings.

At the Study Section meeting (see Panel 1: Behind Closed Doors and http://www.csr.nih.gov) each grant that survives streamlining is presented to the Study Section members for discussion by the three assigned reviewers. The usual protocol is for each assigned reviewer to first state their preliminary overall impact score. The primary reviewer then presents the proposal to the Study Section and provides a rationale for the critique and preliminary score. The secondary and tertiary reviewers then voice their opinion and critique. All Study Section members (except for those with conflicts of interest) then join the discussion to fully critique the strengths and weaknesses of the proposal. Members then confidentially provide an overall impact score based on the recommendations of the assigned reviewers and the discussion. The average overall impact score for the Study Section is then multiplied by 10 to produce the final Study Section score (i.e., 10 = high impact; 90 = low impact). The NIH uses a 9-point scoring scale (1 = exceptional to 9 = poor; whole numbers only) for review criterion and overall impact (see: https://grants.nih.gov/grants/policy/review/rev_prep/scoring.htm). Each application receiving an overall impact score is then allocated a percentile ranking reported as a whole number. The percentile ranking is usually calculated by ordering the overall impact score of an application against the scores of applications in the current and preceding two Study Section meetings. For example a 5th percentile ranking indicates that the application scored better than 95% of all applications in the current and previous 2 Study Section meetings.

**Behind Closed Doors: Demystifying the Study Section**

**Study Section**

- Managed by a scientific review officer (SRO), a professional at the MD or PhD level with a scientific background close to the Study Section’s area of expertise.
- Has 12 to 24 members recruited by the SRO, most of whom are from academia and have expertise in the Study Section field. Some have long-term appointments to the Study Section ad others are temporary members.
- Review 60 to 100 applications per meeting.
- Each application is usually assigned to three reviewers with expertise in the area of research addressed by the application.
The meetings process includes:

- Orientation and discussion of general business and procedures.
- Provisional approval of the list of streamlined applications.
- Discussion of remaining applications.

The Discussion

- Reviewers with a conflict of interest are excused.
- Assigned reviewers present the proposal and discuss strengths, weaknesses, and their preliminary scores.
- Other members discuss scientific and technical merit of the proposal.
- 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.
- Range of scores is expressed by the assigned reviewers.
- Every member then confidentially scores the application.
- The SRO documents the results in a summary statement, which is forwarded to the IC and the principal investigator.

Summary statements contain:

- Overall summary of review discussion (for applications that were discussed and scored).
- Priority score and percentile ranking.
- Critiques by the assigned reviewers for each review criteria.

Grant Review Criteria

Applications are evaluated by Study Section reviewers using 5 criteria: 1) Significance; 2) Investigator(s); 3) Innovation; 4) Approach, and 5) Environment. Read the application guide/instructions thoroughly. In most cases instructions are carefully worded to guide the application narrative toward the review criteria. It is helpful to consider questions that reviewers may ask about your proposal for each of the review criteria. For example:

**Significance:** Does the proposal address an important problem? Will it advance scientific knowledge? Will it affect concepts or methods in this field? Does it have clinical/translational impact?

**Approach:** Is the experiment design and methods appropriate to achieve the proposed specific aims? Do the proposed experiments test the proposed hypotheses? How will outcomes and data be interpreted especially if the hypothesis is not supported? Does it acknowledge problem areas and consider alternative tactics?
Innovation: Does the proposal employ novel concepts, approaches, or methods? Does it challenge existing paradigms or develop new methodologies?

Investigator: Is the work appropriate to the experience of the principal investigator and research team? Does the principal investigator’s track record in the field reflect an ability to perform the proposed studies?

Environment: Does the institutional environment contribute to the probability of success? Is there evidence of institutional support?

Every “yes” answer strengthens your application; every “no” answer represents an area of vulnerability.

Second-Level Review: IC National Advisory Council

After Study Section review, your application undergoes a second-level review by an IC Advisory Council. The Advisory Council is composed of people outside the IC. 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 Advisory Council assesses the quality of the Study Section’s scientific review, makes recommendations to IC staff on funding, and evaluates the application’s relevance to IC 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 IC director, acting on behalf of the NIH director, takes final action on award decisions. The director usually (but not always) follows the advisory council’s recommendations.

Preparing a Strong NIH Grant Application

Getting Started

Before you start writing your grant application it helps to keep in mind that the document will be used by the Study Section and Advisory Council to determine whether the NIH should invest in you and your idea(s). The reviewers’ perception of your academic track record and the quality of your research proposal is what ultimately gets you funded. Evidence of your expertise in the field and importantly your ability to perform and complete research projects is critical. Publishing research and literature reviews (especially with co-authors who may eventually be part of your research...
team for the grant proposal) related to the proposed research, and your activity at relevant scientific meetings help to bolster your research track record. This is a career path process for which guidance from mentors and colleagues is important. The goal is to develop your research niche: an area of research where you are a recognized leader. Once you have decided to move forward with an NIH grant application you should discuss with the IC PO the relevance of your specific research idea(s) to the IC research agenda and the grant mechanism that is most appropriate for you (based on career level) and the proposed research. Providing the PO a draft of the Abstract and/or the Specific Aims page of your intended proposal may be helpful for these discussions. Figures 9.3 and 9.4 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.

**Figure 9.4**

**The Application: From Submission Through Funding Decision**

- Submit your application on time; follow instructions carefully
- Review confirmation of receipt/assignment notification letter for accuracy and concerns
- Review the summary statement
- If score, percentile ranking, and recommendations are positive, do nothing (but celebrate)
- *If notified that application is in funding range, get IRB and IACUC approvals if not obtained before*
- Receive notice of final funding decision
- Application is funded: Begin your research
- *OR*
- Application isn’t funded: Consult your program officer for guidance and either revise or apply what you’ve learned to a new concept
- If revision and resubmission are recommended, consult colleagues at your institution and the program officer for guidance
- Learn from the summary statement and program officer; write a stronger application next time
- *OR*
- If appropriate, consult the program officer about challenging a review you think is flawed

IACUC: Institutional Animal Care and Use Committee
IRB: Institutional Review Board
Preparing Your Application

Grant writing should be a virtuous iterative multi-cycle process. A simple mantra is: write, read (include colleagues), process feedback, revise, repeat. The iterative approach can be summarized as follows:

1) Create a provisional Title.
2) Write a draft of the Specific Aims that includes the overall significance of the research and its central hypothesis.
3) Write the Research Strategy. Start with the Significance and Innovation sections. Then draft the Approach section considering the personnel and skills/technology needed for each experiment to test hypotheses to achieve each Specific Aim.
4) Consider appropriate Preliminary data to support your proposal and demonstrate your ability to perform specific assays.
5) As you design experiments, reevaluate your core hypotheses, Specific Aims, and Title to make sure they still reflect a coherent plan.
6) Evaluate your Specific Aims and Research Strategy in light of your expected budget.
7) Prepare your Abstract (a summary of your Specific Aims).
8) Complete the other forms.

This will take time (allow 2-3 months) so start early. Know the due date for your specific grant mechanism and establish a task list and completion timetable that includes sufficient time for your colleagues to review drafts and for you to process feedback. It is also important to carefully follow the instructions for your specific grant application and be sure to use the most current application form(s) and the correct formatting. The quality of the application narrative, formatting and layout reflect on you and your attention to detail. Avoid unnecessary repetition, spelling, grammar and consistency errors, and ensure that figures are necessary, clear (publication quality) and well-labelled with a concise legend. Make the application easy to review. Some question that you may ask as you write the proposal are:

- What do you want to do? What hypotheses will be tested? Has this area been studied before (and if so, what has been done)? Where are the gaps in knowledge? Will the research fill those gaps? Why is it important (especially in the context of the IC research priorities)?
- Are you (and your research team) able to perform the research? What are the strengths of research team? Why do you think the research is feasible in the context of the research team expertise and experience, resources available, proposed budget, and proposed timetable?
What approaches will you use, and why? Are they feasible and available? Are there alternative approaches to measure the same parameter? Are contingencies in place if an approach fails?

Are experiments designed with appropriate controls (positive, negative, background, assay, biological) to adequately test the proposed hypotheses? Are experiments adequately powered with sufficient replicates to produce statistically meaningful outcomes?

How will you interpret outcomes that disprove your hypothesis? How will outcomes (positive and negative) move the field forward?

What resources and expertise are available at your institution that will facilitate the research?

To facilitate the reviewer process use language and formatting to create signposts for the reviewer and provide narrative that directly addresses the review criteria. For example:

- **Significance**: The long-term objectives of this project are...; These studies are important because outcomes will...; The clinical significance of the research is...

- **Innovation**: The proposed research is innovative because: 1) ... 2) ...

- **Approach**: The specific aims of the proposed study are to...; The general strategy to achieve the specific aims is to...; The research approach is thorough and encompasses, molecular genetic, biochemical, and structural analyses to determine...

- **Investigator(s)**: The investigative team has the experience and expertise to perform the proposed studies based on...

- **Environment**: The environment at ... offers extensive intellectual and infrastructure support for the research including: 1) ... 2) ...

Assume that reviewers are advocates of your proposal. Tell a compelling story about your proposed research and how it will broadly benefit basic and clinical science. Avoid antagonizing the reviewer with poor writing. Some general writing tips are:

- Get advice and feedback from your mentor and colleagues
- Follow instructions
- Study the style of successful grants
- Do not over-write; it’s not a literature review
- Avoid jargon and don’t assume that the reviewer will be an expert in your field
Write for the benefit of the reviewer; make your proposal easy to review by using the review criteria in the narrative

Present high-quality figures that clearly show your message

Write with humble authority with regard to your area of expertise

Organize your ideas around associated specific aims linked to your central hypothesis

Present a coherent set of ideas predicated on previous work

Be ready to take legitimate risks, preferably based on preliminary data, to move the science forward

The most substantive scientific elements of your research proposal is the Research Plan. This section will be highly scrutinized by the assigned reviewers and will weigh heavily on the priority score. Therefore, the bulk of your preparation (e.g., obtaining preliminary data and forming the research team) and writing/re-writing effort should be devoted to this section.

The most important sub-sections of the Research Plan are: 1) Specific Aims, and 2) Research Strategy.

**Specific Aims:** As its name states the Specific Aims section is statement of your project aims (usually 2-4). The section is limited to one page and should summarize the goals of the proposal and include its basic and translational significance. The Specific Aims page is important because although all Study Section members have access to your application, only the assigned reviewers usually read the full application. Most Study Section members will read only the Specific Aims page of your application. Consider the Specific Aims section as an abbreviated version of the full grant that provides a summary of the proposal. Therefore, the narrative should be succinct, easy to read and highlight the aims of the proposal and the key elements of your research plan in light of the review criteria. An excellent discussion/guide on how to write the Specific Aims section can be found at: https://www.niaid.nih.gov/grants-contracts/draft-specific-aims. Some tips for writing a strong Specific Aims page are:

- Consider the Specific Aims as the executive summary of the proposal in 1 page.
- Emphasize the rationale, justification, and significance of research
- Propose 2-4 mutually exclusive Specific Aims that are directly related to testing the central hypothesis of the proposal
- Summarize how each Specific Aim will be achieved and how outcomes will be interpreted
- During the writing process iterate back to the Specific Aims to adjust/improve as the Research Strategy evolves.
Research Strategy: This section is a detailed description of your proposed research. For an R01 it is limited to 12 pages and comprises 3 sub-sections: 1) Significance; 2) Innovation and 3) Approach (note that the sections match the review criteria). Preliminary data can be included in any sub-section and should be clearly identified in the narrative.

The Significance and Innovation section should echo and expand on points presented in the Specific Aims section. This is the place to highlight why your research is important, why the approach is novel and innovative, and how outcomes will impact basic and clinical knowledge.

The Approach section should reflect a high level of scientific rigor (e.g., model and assay validation, statistical power, appropriate control conditions, alternative approaches). This can be supported by preliminary data that demonstrated your ability to perform the proposed studies. Variables that may affect outcomes such as gender and age, also should be acknowledged. Help the reviewer be your advocate by stressing these attributes of the proposal. Some general tips regarding the Approach section are:

- Organize the approach section by Specific Aim
- Ensure that methods, models and clinical cohorts are in place.
- Experiment design should produce unbiased results with consideration of relevant biological variables
- Key biological and/or chemical resources are authenticated
- Expected outcomes, potential pitfalls and alternative strategies are described. Expected outcomes included a response to data that do not support the hypothesis.
- As you write the Research Plan check that it maintains consistency with the Specific Aims.
- Produce a high-quality easy to read document with no spelling and grammar errors and clear and well annotated table and figures.

Budget

Most institutions have a central grants office with experienced staff who can devise budgets suitable for the scope of the research proposed and in keeping with your institution's policies. Take advantage of that expertise.

Direct and 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 shipping. Indirect costs (informally termed “overhead”) comprise the expenses that are paid to your institution by the funding organization to support your research but cannot easily be charged directly to a specific grant. These include administration, utilities, computer infrastructure, building
maintenance, security, and custodial services. Generally, institution negotiates indirect costs with the funding organization that allow these costs. The funding organization then provides funds for indirect costs to the institution, along with funds to cover direct costs charged to the research grants.

Modular budget: To simplify the budgeting process, research budgets may be 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.

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: Level of expertise, job description and percent effort for each position.
- Equipment: Why do you need this piece of equipment? What equipment did you use to get preliminary data and why is that equipment not sufficient to support R01-level effort? Cost sharing for new equipment is advisable. Equipment should be budgeted into Year-1 and may require additional modules for the Year-1 budget.
- Supplies: Categorize based on specific techniques (e.g., cell culture, animal surgery, molecular biology.)
- Other large expenses: Describe other large expenses that exceed supplies such as DNA or RNA sequencing, microbiome analyses etc...
- Travel: Describe and justify proposed meetings, travelers, and estimated cost/trip. Justify any foreign travel.
- Animals: Detailed description of animal purchase, treatment and per diem costs.
- Clinical studies: Detailed description of costs to perform clinical studies.

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 IC program staff (via the PO) rather than to the CSR for peer review.
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 are considering this mechanism, ask your PO about the feasibility of getting those funds from the sponsoring IC.

Equipment: Your institution owns equipment funded by your grant only after the award period ends. If you relocate, the equipment generally goes with you. A grants management specialist at your institution may provide more advice regarding equipment. Equipment costs also may be funded through the Shared Instrumentation Grant Program (S10) or the Small Instrumentation Grants Program (S15) run by NIH’s National Center for Research Resources.

Interpreting the Summary Statement

After the study section meeting, the SRO will draft a summary statement that contains a summary of the Study Section discussion and each of the assigned reviewers’ written critiques for the overall proposal and the strengths and weaknesses of each review criteria. It also reports the priority score/percentile if the application was discussed which will provide an indication of funding probability. If your application receives a score below the IC funding level then you need to decide how to proceed with the proposal. In this case the summary statement, and especially the weaknesses noted by each reviewer for each review criteria, must be considered when deciding whether and how to prepare a revised application. You may need help interpreting the reviewers’ critiques. 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 PO, who usually attends the study section meetings can help you interpret the results of the scientific review. Your colleagues can also help you evaluate the summary statement. After the Advisory Council meeting, you can discuss with the PO the potential for funding or whether you the application should be resubmitted.

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 PO 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 PO’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 PO and your colleagues, reconsider your project and approach, and write a stronger application the next time.

Applications can receive poor priority scores for various reasons, including:

- 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

**Resubmitting Your Application**

If the PO 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 (e.g., vertical line in the left margin) of the revised application where you have addressed reviewer critiques

Although your first instinct may be to request that the revised application be assigned to a different Study Section, you would need a compelling scientific reason for that request to be honored. Furthermore, there is a 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. However, as the funding cycles progress and IC 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. If you submit a revised application and the PO later tells you to withdraw it because your funding chances now look good, do so. Check with the PO regarding the rules for the number of allowable resubmissions.
Conclusion

Preparing a strong NIH grant, especially an R01, requires careful preparation and attention to detail so start early. Seek mentorship and heed the advice from someone with successful NIH funding and review experience who can provide a knowledgeable critique of your proposal. The process is highly competitive and as such poor applications will almost certainly fail. Don’t waste your time, and that of the reviewers, by submitting a flawed hastily written proposal. This will antagonize the reviewers and reflects poorly on you. Application quality not quantity will bring success. The path to a fundable application is iterative and usually virtuous. The application should improve with every edit cycle and re-submission. Persevere, work smart, let your data drive the proposal. The steps to getting funded can be summarized as follows:

- Find your research niche: Develop your “idea” with the advice from mentors and colleagues and establish your research track record/credentials in your specific field
- Choose an appropriate funding source (e.g., NIH)
- Prepare early and with the advice/feedback of mentors and colleagues write a strong grant application
- Submit the grant
- Learn from the review critique
- If necessary adjust, rewrite, resubmit
Chapter 10

Getting Published

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Introduction

Peer reviewed publications describing original research have long been the traditional currency of academics. They chronicle the investigator’s record of creative thinking and technical prowess, and serve as a platform for professional reputation and career advancement. They are also part of the return on investment of sponsors of biomedical research, tangible products and a yardstick of investigator effort and project success.

The advent of the electronic publishing era has transformed the process of dissemination of scientific information at all levels. This has turned publication from a process that was once static after peer review was completed and a paper was released to the public, into a continuing dialogue, with peer reassessment the work after publication. The electronic publishing era has also expanded global access to science, and created new pathways to “publish” data.

This chapter describes options for information dissemination, the changing process of peer review, with comments on the responsibilities of authors, reviewers and editors. It does not deal with other forms of information dissemination including meeting presentations, seminars, or videos not associated with a publication. The latter are important vehicles for exchange of scientific information.

What to publish? When to publish? Where to publish?

These questions raise a myriad of issues, including whether a study is complete, convincing and ripe for public dissemination; whether intellectual property needs to be protected; whether the work is part of a grant application yet to be reviewed in which the publication would turn a specific aim into an accomplished goal; and what is the major audience and the message?

The selection of the journal is discussed below. Remember, whether your manuscript is returned without review in an initial editorial review, or submitted to further evaluation by referees will depend upon whether it fits with the journal scope and editorial policies. Read the journal’s statement of its scope carefully to make sure your work is relevant to the journal’s mission and
readers. The journal will likely require a cover letter from the authors, which is your opportunity to articulate how your manuscript fits into the journal’s scope, what is new, and why it is deserving of publication.

**Types of publications**

The scientific community, institutions and research sponsors place highest value on original peer-reviewed articles published in reputable journals. Since broad dissemination of your findings across disciplines and geography will benefit science and your career, I recommend that open access publishing should be foremost in your mind.

There are many formats for publishing original research, including full articles and brief reports. Papers that tell a complete story are generally perceived as having higher impact than brief and technical reports. There is an important caveat with respect to technical reports, since the description of new methods can have a transforming effect on research and garner broad recognition (e.g., the “Bradford” method for protein quantitation published in *Analytical Biochemistry*).

Hybrid publications, containing original research as well as reviews have existed for some time, as in case reports coupled with a review of the literature. These hybrid publications are increasing as a result of candidate gene studies and genome-wide association studies that include reports of original findings with a meta-analysis of previously reported findings.

The number of venues for presentation of original findings has increased dramatically. This includes “video journals” that may be particularly well suited to presentation of methodological advances. As discussed below, the investigator must carefully consider the venue which is most appropriate for dissemination of the information and the best format for presentation as discussed below. That decision should be driven by likelihood of reaching the target audience, as opposed to the reputation or impact factor of a journal.

**Which Journal?**

Peer review journals are general in their coverage or specialty specific. They may be freestanding or associated with a learned society/organization. Among journals with general coverage, there are publications that have broad appeal because of their selectivity, impact factor, and reputation. There are, however, other journals with high standards that are critically reviewed and publish solid research, like *PLoS ONE*, that may not have the wow factor that is often a selection criteria by the single name journals. A number of periodicals that are highly selective have “second growth” journals, and will offer transfer of papers (and sometimes reviews) to these journals if the science is thought to be rigorous, but the topic or conclusions not perceived to be of broad interest or high impact for the “grand cru” publication.
Your research findings may not be appropriate for an “elite” journal, but still can have a large impact if presented to a “specialty” journal. The $r^2$ for the correlation between journal impact factor and citation rate is high, but not equal to 1. As an example, my most cited publication, which appeared in *Endocrinology* (a journal with a current respectable impact factor, but one that is a quarter of the elite journals), described a method for isolating and culturing cytotrophoblasts from human term placenta and their in vitro differentiation into syncytiotrophoblasts. The citation numbers for that paper outstrip papers I have published in *Science, Nature, and the New England Journal of Medicine*, journals that would have considered the topic far too specialized for their general readership. The “Bradford” method for protein quantitation is another example of a highly cited publication in a journal without a gaudy impact factor.

Newer venues for information dissemination have arisen, including publications that deal with work in progress. They include public databases like ClinicalTrials.Gov and “precedings”. *Nature Precedings*, launched in 2007, was a preprint server that offered investigators the opportunity to share information prior to formal publication. It is no longer functional but other “precedings-like” publications are active. These publications offer the opportunity for investigators to describe study designs and to receive input from the community. This type of open dialogue is an example of the electronic era’s impact on exchange of scientific information, particularly the potential for broad-based international comment. Imagine if this opportunity had been available prior to the final design of the Women’s Health Initiative or the National Children’s Study?

In addition to traditional peer review journals, research data should be deposited when required or appropriate into public databases (e.g., dbGAP) and novel concepts that are subject to protection as intellectual property should be patented. In the latter case, the patent protection should be sought prior to any public disclosure (e.g., meeting presentation, abstract, seminar presentation) of the idea and supporting data to insure broadest possible protection. If in doubt, consult with your organization’s tech transfer office. Also remember that patents are usually considered a form of publication by tenure and promotion committees, and many institutions and research sponsors prize discoveries that can be commercialized.

Several journals publish images with a brief description of the image. A picture can be worth a thousand words, and these contributions are recognized as scholarly contributions.

Journals affiliated with learned societies frequently publish abstracts from their annual meetings. Meeting abstracts are often reviewed by the organizing committee and thus represent a form of peer refereed publication that can be cited, although they do not have the perceived value or gravitas of a full peer reviewed publication.
Reviews and Commentaries

Review articles and commentaries play an important role in summarizing the state of research in an area. They are helpful to trainees and experienced investigators alike, who need an objective perspective of what is currently known and what is not. Writing a well-crafted review requires considerable effort in evaluating the existing literature, and synthesizing it into a coherent framework. Standards for narrative and systematic reviews have evolved over the years and they should be carefully studied before contributing a review.

Reviews do add to an investigator’s reputation, especially if they are invited and present a new synthesis, new concepts, or offer unusual insight. Their impact is evident by the fact that “Review Journals” have proliferated, many reviews are highly cited, and as a result peer review journals crave well-crafted reviews because the high citation rate increases the journal’s impact factor.

Most journals solicit reviews and subject them to rigorous evaluation to insure that they are accurate and provide a conceptual framework, not simply a recitation of previously published work. Unsolicited review articles are considered by some journals, but the editors may not be enthusiastic about pursuing publication if the authors are not considered to be thought-leaders in their respective fields.

Although less extensive, commentaries are also not easy to write since a significant amount of information may need to be distilled into a few pages. There is also significant work in the preparation of figures that convey concepts or mechanisms. These figures greatly enhance the value of the review/commentary.

Citation Metrics

There has been increasing interest in quantifying the scientific output and importance of investigators and their institutions. This has spawned a vigorous debate over the methods to be employed, their relevance, and their influence on publication practices in specific disciplines (Pendlebury, 2009). The journal impact factor, a measure of how frequently the “average article” in a given journal has been cited in a particular year or other time period is one of several types of data available. The impact factor, which is updated annually, is calculated by dividing the number of current-year citations by the number of citable items published in that journal during the previous two years.

Although the impact factor is often used to provide a gross approximation of the prestige of a journal, many other factors can influence a journal’s impact and ranking. For example, as noted earlier, review articles are generally
cited more frequently than research articles are, because the former often serve as surrogates for citation of earlier literature, especially in journals that discourage extensive bibliographies. As a result, the inclusion of review articles in a journal will usually increase its impact factor.

The Web of Science (Clarivate Analytics) tracks author level citation metrics. Other methods for measuring citations include Google Scholar and CrossRef. In addition to citation numbers, cumulative or annual, other metrics are available from The Web of Science, including the h-index. To calculate the h-index, two pieces of information are needed, the total number of papers published and the number of citations for each paper. An h-index of 100 indicates that an author has 100 published papers that have been cited 100 times or more.

Citation information and journal impact factor have become important in career advancement since some institutions ask candidates for promotion and tenure to list the number of citations for each of their published articles, and the impact factors of the journals in which they were published in their dossier as part of the overall evaluation process.

Authorship

Authorship brings with it recognition and responsibility. As science becomes increasingly complex and multi-disciplinary, multi-authored papers are increasing. Many journals require a statement of author contributions to be included. Even with the statement of specific contributions of each author, most journals hold all authors, no matter what their roles, accountable for the paper in its entirety. The glory and the shame, if there is an issue of credibility/misconduct, is shared by all. Honorific authorship is decried. The statement of author contributions helps the scientific community, including sponsors and promotion and tenure committees, assess the relative value added by each member of the authorship team. It helps to reward team science, even when the author is a “meso-scribe” (an interstitial author). For laboratory heads, there is the additional responsibility of educating trainees in the process of information dissemination from outlining the manuscript, preparing data and supplemental information, performing the data analysis and interpretation, selecting the bibliography, deciding on the format and publication venue, and insuring that other journal requirements are met. These are teachable moments of great importance and can have a long-lasting impact on the future careers of the trainee.
Title and Abstract

The title of your manuscript and the abstract are two of the most important parts of your manuscript. Do not underestimate their significance. They influence how your paper will indexed in bibliographic search engines like PubMed, and whether searchers will be able to determine if your paper contains information of interest to them. Unfortunately, the title of the paper and an abbreviated abstract, if not well constructed can relegate an important paper to relative obscurity. A number of journals have enhanced their abstracts to include graphics. This represents an opportunity for authors to peak interest in their manuscript and provide a visual summary of their findings which may help the reader place the findings presented into an approachable biological context.

Materials and Methods

In the print era, with page limitations, the Materials Methods sections became cursory, often referencing prior publications, which in turn cited previous papers. Getting to the exact methodology and any modifications was an exercise in archeology. In the electronic publishing era there is no limitation to space and therefore an opportunity to present full methods either in the body of the paper or supplemental material, including validation of reagents. This bears directly on the issues of rigor and reproducibility of research discussed below. Institutional Review Board and Animal Use and Care Committee approval should be documented.

Results and Data Analysis

In the era of print journals, page numbers were often limited, requiring authors to be selective about information presented. In the electronic publishing era there are fewer limitations since observations can be archived in supplemental data. However, this means that careful attention must be given to what is presented in the Results section of your paper and what should be deposited as supplemental information.

Presenting findings in a manner in which they are easily understood and flow in a coherent manner is essential for delivering the messages from your discoveries. In approaching the results section of your manuscript it may be helpful to use the story board approach where you lay out the presentation in sequence with figures and table as if it were a series of scenes in a play. This will allow you to visualize the sequence and the way in which a number of findings relevant to a specific message can be placed into multi-paneled figures, and what should be relegated to supplementary material.
If you are not well trained in statistical methods, seek the consultation of an expert to review your analyses or to suggest the most appropriate statistical approach. For example, correcting p values for multiple tests is essential. Many papers present positive results with a p value of <0.05 when the corrected p value would not meet the minimum threshold for statistical significance.

**Data Archiving and Data Sharing**

Universities and research sponsors generally have rules about mandatory maintenance of data/research records. It is rare that they extend beyond 5 years. In the paper era, this might have been reasonable, but in the electronic era there is no reason why the record of research, including all raw data, should not be maintained for eternity. This would meet the most stringent requirements for data sharing and create opportunities to mine and reanalyze data. This is a topic that is covered elsewhere, but should be considered in the publication process since journals have varying requirements for accessing data. The Open Science Framework is evolving platforms to facilitate data archiving and data sharing ([https://cos.io/our-products/open-science-framework/](https://cos.io/our-products/open-science-framework/)).

The archiving of raw data has also assumed importance because several studies concluded that much of the scientific literature is not reproducible (Ioannidis, 2005 & 2017). This does not appear to be large due to fraud or fabrication, but a zealous search for a significant p value, use of un-validated reagents, or inadequate presentation of methods. Consequently, journals are paying closer attention to statistical methods and may have papers submitted for publication simultaneously reviewed by a statistical expert, and require complete information on potentially variable reagents (e.g., antibodies) in addition to requiring broad access to raw data.

**Conflict of Interest**

Almost all journals require authors to disclose in the manuscript if they have conflicts of interest relating to a research study. This is usually a condition for considering a manuscript for publication. Sponsor involvement in studies, particularly those sponsored by industry, was not uncommon in the past, but is now generally prohibited unless approved by the journal editors.
Peer Review

Once a journal has been selected, attention needs to be paid to its review process. Many journals require the authors to select potential editors to manage the review, and in some cases members of the journal editorial board. The authors are often asked to suggest potential referees not affiliated with the journal editorial board. This gives you an opportunity to identify reviewers who you think will give an informed review that will hopefully improve the quality of the work. Citing those individuals’ work in your bibliography may encourage their selection by the reviewing editor since it would show familiarity with the topic of your paper. However, this practice should never corrupt objectivity. Indeed, the manuscript review process is unpredictable; even your presumed friends will and should deliver a harsh review if justified. Many journals will offer you the opportunity to request certain individuals not review your paper because of known conflicts. Again, while you may assume that they may be hostile, that is only an assumption. The responsibility of the editors and editorial board are to identify competent unbiased referees, and to instruct them on how to prepare a review that improves the quality and value of the publication. Journals with experienced editors and reviewers will improve the final product.

The editors of reputable journals act as editors, not postmen shuttling manuscripts between authors and reviewers, basing their decisions solely on the comments submitted by referees. Consequently, the selection of the reviewing editor of a manuscript is critical to the process. Some journals request that authors designate potential editors from their editorial board, others assign reviewing editors based on the manuscript content. If you have the opportunity to recommend a reviewing editor, it is wise to know his/her areas of expertise to insure informed interpretation of referee comments and the final disposition of your manuscript.

The peer review process has been challenged recently by an epidemic of fake reviewers, individuals suggested by authors who have an e-mail address that routes papers back to the authors for review or to shills for the authors. Thus, reviewer credibility is important. Editors will more likely invite individuals who are established to serve as referees.

PhotoShop abuse has also challenged the peer review process. Because of gel splicing and image reuse, a number of journals routinely scan submitted papers for figure manipulation and duplication as well as for plagiarism. As noted below, the scientific community is also on the prowl, and sites like PubPeer (https://pubpeer.com/), a post-publication “chat room” chronicle
figure/image “construction errors,” oftentimes leading to major corrections or retractions, which are reported in Retraction Watch (http://retractionwatch.com). There is current debate as to the time limit on such review. At the time of this writing, The Office of Research Integrity will not investigate concerns of misconduct that are more than six years old, and some journals have adopted this standard. Others currently have no time limit, which is challenging since standards for figure construction (e.g., gel splicing) have changed over time, as have requirements for data preservation.

**Reviewing Manuscripts**

Reviewing manuscripts is a responsibility of the scientific community. Constructive commentary raises the bar and insures that sponsors of research are rewarded with a product of high quality and societal value. An invitation to serve on an editorial board (except from a predatory journal—see below) is an honor, and serving in that capacity is a merit badge recognized by promotion and tenure committees. It also represents a serious commitment to participate in peer review, which can be time consuming if done well. Generally, appointment to editorial boards follows some record of quality service as a referee (i.e., it is an honor that is earned).

If you are asked to review a manuscript and believe it fits within your areas of expertise it is prudent to accept. No matter what the outcome of the review you will learn something, remembering that it is confidential communication and the intellectual property of the authors.

I have a process that I follow when I have accepted an invitation to review a manuscript. First, I make sure I am familiar with the journal’s publication policies and editorial standards. I focus on the question, the data and the interpretation of the findings. Is the question important? Has it been framed appropriately? To make these assessments, I do a literature search on PubMed to determine if work on the topic has recently been published so I can get up to speed if the topic is not one that I review frequently. In terms of data, is everything that is essential presented in the text or supplemental material? Are the data compelling? Are all studies properly controlled? Are the statistical methods used appropriate? Is the presentation lucid, including figures and tabular material? Are the conclusions justified and supported by the data? Have the authors identified strengths and weaknesses of their study? Has anything been overlooked including the existing literature? Finally, I make sure the manuscript title and abstract accurately project the content of the manuscript and its conclusions.
I usually organize my reviews into general concerns/comments and then specific points. I avoid judgemental comments and do my best to provide a justification for each concern, suggesting opportunities to improve the manuscript, either through new or additional experiments, a new approach to data analysis or data presentation in figures and tables. If the data do not support the conclusions I request that the authors either add new information or reframe their conclusions. If presentation is an issue, many journals offer services to authors who are not native English speakers to address the communication barriers that may negatively impact the transmission of knowledge. The editor will ultimately decide whether the contribution has merit and is worth publication, or revision and re-review. Some journals offer referees the opportunity to identify themselves. This is a personal choice and I suspect more referees do so when they deliver a positive evaluation than a negative review. That said, anonymity should not be used as a shield for biased or vindictive commentary.

**Post-Peer Review**

Journals with editors and editorial boards have been the mainstay of quality control for scientific publication. It is assumed that the peer evaluation process will constructively improve the presentation and content. Once that process is completed, commentary through letters to the editor can serve as a post-publication peer review. The electronic age has brought opportunities for continuous “peer review” post-publication through journal sites, alternative dialogue venues like PubPeer, and science blogs. On-line comments are encouraged by a number of journals, providing an on-going form of peer review and scientific exchange. It has taken the letter to the editor about a publication to a new level by reducing the barriers for communication.

Journals are interested in the quality of their editorial process and some offer authors download and citation tracking tools that are journal specific and offer information in addition to that retrievable from Clarivate and Google Scholar. Remember, absolute numbers of citations are highly influenced by research discipline, self citation, the journal, and whether the article is a research paper or review. A citation does not necessarily reflect affirmation of the conclusions or the importance of your work, since many findings that have not been substantiated or confirmed are highly cited.

**Post-Publication Hype**

Most institutions want recognition for the discoveries made by their faculties. Institutional press releases are common for significant contributions. These in turn attract interest from news services, which allow the authors to explain their findings to the public. Some journals offer videos of Ted Talk presentations by the author. This helps make the science more accessible to the public, who
after all are often paying for the research with their tax dollars or philanthropic gifts. Indeed, well done presentations do much to advance the cause of biomedical research.

Social media (e.g., Twitter) has been used increasingly. Importantly, overselling findings can be damaging, so it is important to place the study conclusions in an appropriate context so there is no misunderstanding about how a finding in cultured cells or mice will cure cancer tomorrow.

Remember that not all interest from the lay public is good. Animal rights activists troll the literature for studies on certain species (particularly infrahuman primates and companion animals) as do advocacy groups that hold unique and sometimes controversial views. As noted above, insuring IRB and IAUCC approvals are noted in the paper will provide you some protection, but may not prevent the exorcized activist from trying to target you or your research.

**Predatory Journals**

The electronic publishing era and growth of biomedical research across the globe has spawned a dramatic increase in electronic journals, many of which are classified as “predatory” since they actively solicit submissions, have a questionable peer review process, and exist mainly to generate revenue from publication charges. These journals fish for “editorial board” members and may even misrepresent their editorial boards by including individuals who have no affiliation or have withdrawn from editorial positions on their websites (see [http://beallslist.weebly.com/uploads/3/0/9/5/30958339/criteria-2015.pdf](http://beallslist.weebly.com/uploads/3/0/9/5/30958339/criteria-2015.pdf) for a description of practices of predatory journals and publishers). Caution should be exercised before submitting papers to these journals or joining their editorial process to avoid being tainted. That said, the introduction of new journals is a dynamic process and some journals currently considered predatory by the above noted criteria could become legitimate in the future.

**Resources**


Chapter 11

Teaching and Course Design

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Introduction

Building an educator portfolio is an important, often overlooked, endeavor for the young research investigator. However, as a new junior faculty member, demonstration of effective teaching is a critical component of the promotion and tenure process. More importantly, learning how to teach well provides a myriad of other benefits including stimulating interest in science and academic medicine, inspiring the next generation of research scientists, informing the public on the scientific method, and potentially identifying students and mentees for your laboratory. Unfortunately, most laboratory based young investigators do not receive formal education in teaching, curriculum development, and assessment of learners so the prospect of adding teaching to the many demands of a researcher is often daunting. That is the bad news; the good news is with the advent of ubiquitous access to electronic educational resources there are now better resources available to facilitate training in effective education.

This chapter provides suggestions on how to develop a teaching style, how to implement and design a curriculum, and how to create an educator portfolio. While debating the merits of different teaching modalities and methods of assessment are beyond the scope of this chapter, a fundamental component of effective teaching is learning to assess your own strengths and weaknesses, continually assessing the effectiveness of the teaching from the learners, and adapting as new ideas emerge from educational experts on the design, implementation and assessment of scientific education.

Why Should I Endeavor To Teach Effectively?

As a new junior faculty with many research demands including publishing in respected journals, applying for research funding, managing a laboratory, and conducting experiments, a legitimate question is why should I endeavor to teach? There are several important reasons beyond contractual obligations to teach well:

1) **A strong teaching record can help with promotion and tenure.** Citing evidence that you are a good teacher will help advance your scientific career.
2) **Identify potential student learners for your laboratory.** Teaching can help identify undergraduates, graduate students, medical students, residents and fellows who may want to join your lab.

3) **Increase scientific literacy.** Depending on the venue for your teaching, learning how to communicate about science and the scientific method can inform the public and educate students who will not be scientists but may gain an appreciation for the value of scientific investigation that could inform them in future roles as citizens, teachers, policy makers and business leaders.

4) **Inspire the next generation of investigators.** The need to stimulate sustained interest in science, technology and engineering from students is a high priority as graduates in these fields continue to drop in the United States. As a teacher, if you can communicate your topic effectively, creatively, and passionately, you can inspire students from many backgrounds to pursue science as a career.

5) **Personal growth.** Interacting with new students will provide new or improve existing skills. For example, learning how to teach will improve your communication skills, which is a required skill as a research scientist.

**How Do I Become An Effective Teacher?**

Teaching is an art informed by the scientific method and influenced by the teacher’s personality. Every teacher brings something unique to their interaction with the learners, part of it influenced by their personality. Some teaching venues may appeal to or present certain hurdles to different personalities. For example, an extrovert might find the prospect of teaching in a massive lecture hall filled with students invigorating while an introvert might approach such a task with some trepidation. Similarly, an introvert might find a small group setting more appealing than an extrovert. Rather than make assumptions about teaching performance based on personality, the new teacher must learn how to teach effectively in different settings whatever their personal preference. One way to adapt to different settings is to focus on common themes that can be applied in multiple settings and focus on the method utilized to disseminate knowledge, stimulate interaction, and encourage student engagement with the material. This section will outline some ideas on learning how to teach with a particular focus on encouraging active learning, a teaching method that can be applied in multiple settings.
Make Use Of Educational Resources
To help you become a better teacher, utilize professional assistance and resources that are available at your college, university, medical school, and online. Many universities have teaching and learning centers staffed by professional educators to provide instruction on lecture design, course design and assessment methods including sample test questions. Additionally, these centers provide instruction on methods to optimize methods of feedback which will be important for improvement of teaching methods. Many of these centers provide online resources on curriculum development, teaching methods, and learner assessment. Some sample online resources include: the University of Michigan Center for Research on Learning & Teaching and the Cornell University Center for Teaching Excellence. Some professional organizations include online educational resources, such as the Association of Professors of Gynecology and Obstetrics (APGO).

Seek Feedback On Teaching
In the research field, you learn by modeling the behavior and methods of scientists who are successful, and your work is informed and improved by feedback from journal and grant reviewers. Similarly, utilize expertise at your institution to help you improve as a teacher. Some methods to do this include:

1) Ask a peer for feedback. Visit another teacher’s class or lecture to observe and learn. Similarly, have that peer teacher observe you in a teaching setting and ask for frank feedback.

2) Observe a senior teaching colleague. Identify a senior faculty member at your institution known for their teaching prowess. Observe how they teach and ask them to watch you teach and then provide frank feedback. Successful teachers can provide insight on how to enrich your material and methods.

3) Ask your students for feedback. Student evaluations are a standard method for assessing teaching effectiveness. Review the student evaluations and consider informal surveys as you try new things. Do not be discouraged by your initial student evaluations as they will not likely be your best. Remember, like a first draft of a manuscript or a first grant, your initial forays will likely not be your best. Utilize the feedback to assess yourself and your methods and like your grant writing, you should improve with time and feedback.

How Do I Document That I Am A Good Teacher?
Documenting and citing excellence in teaching is the rationale for building an Educator’s Portfolio. The following educator portfolio model is adapted from the Oregon Health & Science University Educator’s Portfolio, which was influenced by the AAMC’s Group on Educational Affairs Consensus Conference on Educational Scholarship (2/06, Charlotte, NC).
The educator activity is divided into five categories documented below. For each category, two main criteria are utilized to document an educator's activities:

1) **Excellence**: Defined both by the *quantity* of activities and *quality* as documented using available comparative methods (course reviews, student comments).

2) **Engagement with the education community**: Demonstrated by a scholarly approach to the educational activity including education regarding available literature and best practices and scholarship, such as making the lecture/program available for review.

**Educator Activity Categories**

Five educator activities are documented for inclusion in the portfolio:

1) **Direct Teaching**: Defined as any activity that fosters learning including teaching and creation of instructional materials. Examples include lectures, workshops, small group facilitation, instruction in clinical settings (outpatient & inpatient), procedural skills. Document both the frequency and duration of the activity, your role and summarize the teaching activities, learner evaluations, and teaching awards.

2) **Curriculum Development**: Defined as a longitudinal set of systematically designed and evaluated educational activities. A curriculum includes both the content and the methods for facilitating development of the requisite knowledge and skills. Describe your role and summarize the learner evaluations.

3) **Mentoring and Advising**: A mentor relationship is defined as a sustained, committed relationship where both parties obtain reciprocal benefits. Advising is defined as a more limited relationship. Once again document the frequency and duration of the relationship, outline the outcomes for the mentees (publications, grants), and include a summary of any evaluations.
4) **Educational leadership and administration**: Leadership of educational activities including director of courses, clerkships, residencies, fellowships, graduate programs and participation in education and admissions committees. Describe the leadership and administrative role and summarize any data demonstrating effectiveness including program outcomes.

5) **Learner assessment**: Any activity associated with developing or improving a learner assessment process or instrument. Provide a description of the activity or method and summarize how it has been implemented to improve performance.

While the above educator portfolio is specific to OHSU, the components cited above are typical for the metrics utilized to assess educational performance. As a new faculty member, one of the first things you should do is obtain your specific institutions guidelines for documenting educational excellence which will be an important part of the promotion and tenure process.

**References:**


2) OHSU Educator’s Portfolio, 2017.


Chapter 12

Understanding Tech Transfer

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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 if 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 determines that market and/or patent diligence does not support commercialization of the idea, 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.
- **Patent prosecution:** An ongoing dialogue between the patent office, the university, and the inventors to modify and amend claims until the parties arrive at a patentable and acceptable specification and claim set.
- **Marketing:** The TTO will identify and contact potential licensees. Also during this step the TTO can provide feedback to the inventors as to what might make the technology more valuable or easier to commercialize.
- **Licensing**: The TTO will negotiate and manage licenses to companies.

- **Licensee Management & Agreement Compliance**: The TTO will continue to engage with the licensee over the terms of the agreement. Often this includes obtaining annual or bi-annual reports on product development and tracking against the development plan to ensure the licensee is being diligent and compliant with the license. It also includes collection of patent costs and payment under the license agreement.

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 medical device, 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.
- You may wish to form a company around the technology arising from your laboratory. In this case, initial patent protection can often be the start of a “fence line” for the company.

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

- Dealing with the TTO, patent attorneys, and eventually, licensees, can be 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). The TTO will never ask a researcher to delay publication, but some have chosen to.
- The TTO will work with the inventors to craft the opportunity and communicate the specific use and potential value to prospective license partners.
- 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.

**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.

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](http://www.uspto.gov) to screen for similar inventions in the files of patent applications.

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**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.
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.

Universities are increasingly seeing more copyrighted technology, mostly in the form of software and apps. Copyright protection does not require formal protection through the USPTO, but rather protection through copyright vests with the author(s) at the time the work is fixed in a form of media. With patents, a joint patent owner may license and solely gain the benefits of the license, but with a joint copyrighted work, if one author licenses the work, that author is obligated to share the revenue with all other joint authors. If you are asking someone else to write code or perform a copyrightable task for you, it is a good idea to put a “work-for-hire” agreement in place so that in exchange for payment of the work, the copyright is assigned away from the author to you (or the university). This will ensure that you are able to work with the copyright in the manner you intend in the present and might want to do in the future.

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

**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.

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**Question: Who owns inventions at a university?**

**Answer:** 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.

**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. Many times the license agreement has reimbursement of past patent costs as a separate line item. Only then does the income-sharing formula for the inventors kick in.
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.

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 3-5 years. Criteria for patent issuance can change too based on court
rulings that surround patent litigation. This can impact the types of rejections
the patent office asserts and can inform the arguments that need to be made
by patent attorneys for successful claims issuance.

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.

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.

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.
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.

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.

A startup company is a valid option for licensing sometimes. Often university technology is very early stage and requires additional validating experimentation before a traditional company will take a license. Startup companies can apply for special government grants that enable the initial invention to be shepherded further down the commercialization pipeline. However, inventors need to be aware of conflicts that can arise if the inventor tries to retain his/her position at the university and take a directive role in the company. It is a preferable model to partner with an experienced business person for best results for the startup company. TTOs can usually help inventors attempt to find entrepreneurs that can partner with the inventors for company formation.

**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.
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.

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. Sometimes the work can be established as more collaborative.

- **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. Usually this is through an option to the technology developed.

- **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 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.

**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.

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 startup, 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


Chapter 13

Setting Up Collaborations

Chapter from *Making the Right Moves: A Practical Guide to Scientific Management for Postdocs and New Faculty* by Burroughs Wellcome Fund and Howard Hughes Medical Institute, Second Edition
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.)

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 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 video conferences 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:

- 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?

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.
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 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 reneg, 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

1) Adams, Michael J. “Mutual Benefit: Building a Successful Collaboration.”

2) ScienceCareers.org (October 6, 2000), http://sciencecareers.sciencemag.org/career_development/previous_issues/articles/0630/mutual_benefit_building_a_successful_collaboration.

