Robert Wood Johnson Foundation

A Guide to **Strengthening and Managing Research Grants**

Written by Mary Nakashian

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Executive Summary

One out of every four grant dollars provided by the Robert Wood Johnson Foundation (RWJF) funds research and evaluation. The goal of this report is to enhance the capacity of potential and current grantees to strengthen and manage research grants.

Research can be exciting, creative and important work, but it is not without challenges. While some problems are impossible to anticipate, others are predictable and can be addressed in grant proposals or as part of project management.

In 2003, RWJF analyzed lessons from past grants and then conducted interviews with program officers, grantees and staff of other foundations to identify challenges and frustrations in data collection and analysis. It became clear that many of the more intractable problems related to grantees' challenges in managing projects, and that few researchers had been trained in project management.

While much has been written about how to conduct sound research, we have found little about techniques to help researchers manage projects that involve juggling and balancing factors such as working with community organizations, recruiting program participants, analyzing data, meeting deadlines, creating and keeping to budgets, coordinating with multiple funders, and collaborating with partners.

Some experienced researchers have found ways to reduce the likelihood that such problems will delay or derail their projects. These researchers tend to anticipate and address problems head-on in grant proposals and they use good management practices once projects are funded.

Preparing the Proposal

Grant proposals are important vehicles for translating broad research questions into work that is scientifically sound, feasible and attractive to funders. Some problems cannot be anticipated or addressed in proposals. For example, in one RWJF national program, the organization providing health care services to people enrolled in the project folded, leaving the project without a source of patients. In another situation, the managed care organization merged with another organization to offset the effects of federal funding cutbacks. The resulting consolidated organization served a large geographic area and was unable to provide sustained attention to the project.

Some problems can be anticipated at the proposal stage. Those problems include:

- The program does not start up on time or participants do not enroll in it.
- The person who promised the data leaves his or her job or does not deliver.
- Institutional review board approval requires more than one submission.
- People do not return calls or respond to e-mails.
- The program relies on public agencies, subcontractors and others not under the principal investigator's jurisdiction.
- Community organizations give priority to serving clients over collecting reliable data.
- Data assumed to be available is in fact difficult or time-consuming to obtain.
- Databases that need to be synthesized are incompatible.

When preparing proposals, the most important steps to undertake to address these problems are:

- Be brutally realistic when developing project timetables. Timetables should assume that many of the problems listed above will occur.
- Conduct "due diligence" on the data you plan to collect and analyze. Look at it yourself or have an expert look at it. Examine case files in community agencies.
- Pay adequate attention to project management: administrative oversight, reporting relationships, fiscal monitoring and personnel policies.
- Talk with an RWJF program officer or national program office staff about assumptions, timetables and data-collection strategies included in the proposal.

Managing the Research Project

Research that veers off course is not necessarily failed research. Detours may yield unexpected but important insights and lessons. Even the strongest proposals are not likely to anticipate everything that will happen over the duration of the project.

Problems likely to arise after work begins include:

- Project staff is not adequately invested in research or in this project.
- Staff at community agencies do not comply with research protocols because they are uncomfortable with random assignment or some aspect of the research design.
- Practice drifts away from the program model that is being researched.
- Key staff members leave their jobs.
- Tensions between research staff and organizations arise.
- The interests of multiple funders differ.

The most important steps to take in managing research grants are:

- Set a mission and vision for the project and create a work environment that inspires and motivates staff.
- Lead and manage all aspects of the project—work plans, communications, feedback, the big picture and the details.
- Do the hard work—dig in up to your elbows if needed.

Section 1: Background and Introduction

If we knew what it was we were doing, it would not be called research, would it?

Albert Einstein

To Improve the Health and Health Care of All Americans

Mission of the Robert Wood Johnson Foundation

Researchers strive to find meaningful answers to important but thorny questions. The road to these answers can be filled with potholes, curves and unexpected detours—and brave travelers may find themselves at dead ends or at a destination quite different from the one they anticipated at their journey's start. Or the car may run out of gas before the trip is finished.

Research provides our society with new road maps and paths to address our most pressing problems. Researchers have identified causes of and cures for diseases, insights into human development and motivation, and options for improving the quality of our lives. Researchers often probe our country's most important and intractable problems, forcing all of us to think and even act differently.

One out of every four grant dollars provided by the Robert Wood Johnson Foundation (RWJF) funds research and evaluation. These funds help new and emerging researchers build careers in health research; they bring together groups of researchers to mobilize around an issue that warrants serious attention by policy-makers; and they support new ideas that might inform future grantmaking.

RWJF research grants have three elements in common. They are:

- **Applied studies** designed to inform policy and practice.
- **Objective and independent grants** designed to build evidence. RWJF does not interfere with the researchers or evaluators it funds.
- **Easy to understand and widely shared findings.** RWJF commits resources to ensure that findings are understandable and useful to public and private decision-makers. RWJF also shares the results of grantees' sponsored research on its Web site.

RWJF is interested in supporting projects that engage new and existing researchers, promote different ways of thinking, encourage creativity and debate, and advance both knowledge and practice in health and health care. It is equally committed to supporting projects that are completed on time and in accordance with the work plan presented in the proposal. This paper aims to help grantees (and potential grantees) strike the best balance between these legitimate and at times conflicting interests.

When projects change direction or run late, grantees may find that:

- They have run out of grant money before they run out of work. This means there is not enough time to analyze data and increases the likelihood that the insights from the research will not be fully explored or disseminated.
- Their findings are no longer timely, and are therefore less relevant. The field may have moved beyond the work that researchers conducted.
- They lose out on opportunities to apply for or conduct new projects because they must attend to unfinished work on current grants.

At the same time, RWJF recognizes that few discoveries take place on schedule—innovation by its nature pushes researchers into unknown territory. Projects that take longer than expected or change direction may yield benefits for both researchers and RWJF, for example:

- Researchers who identify unexpected implications of their projects and are able to change course appropriately without compromising the quality of the results find support from RWJF in publishing findings and methods in peer-reviewed and popular journals.
- Taking extra time or pursuing an unanticipated research path may yield insights that lead researchers to explore new topics in their work or that inform future grantmaking by RWJF.

RWJF has not typically penalized grantees when projects are late. Indeed, research grants frequently involve no-cost extensions.

Researchers with track records of striking the best balance between completing projects on time and as proposed, on the one hand, and being open to important but unexpected situations, on the other, are the ones RWJF is more likely to seek out for special projects and consultations.

This report was prepared because RWJF is interested in sharing with grantees some of the lessons learned over 35 years of making and overseeing grants. The goal of the report is to enhance the capacity of potential and current grantees to propose and manage research grants. The report takes a broad look at challenges researchers face in strengthening grants and managing their projects. Specific challenges such as projects that have large information technology components or that are nested within other research projects, are not covered.

In 2003, RWJF analyzed lessons from past grants and interviewed program officers, grantees and staff from other foundations in order to identify challenges and opportunities in data collection and analysis. That review yielded insights into problems grantees face in strengthening and managing research grants—problems such as timeliness, quality and feasibility of gathering data, working in community-based settings, managing complex projects, and identifying problems early on.

The current report draws from the prior review, from a review of the literature to learn what has been written about the real-world challenges that arise in conducting research, and from interviews with grantees who have had success in designing and managing complex research projects.

This report uses the terms *research* and *data* broadly. For example, data spans the gamut from large, well-established and reliable public data sets to primary data collection of a qualitative nature. This guide includes guidelines and suggestions that are equally applicable to large, complex research projects and to the smaller projects that comprise a large portion of RWJF grants.

The intended audience for this guide is experienced researchers who have applied for research grants and who know how to design research projects. A secondary audience is researchers who have conducted research but have had limited experience preparing proposals or managing research projects.

The remainder of this report features four sections, three appendixes, and a bibliography and resource list.

Section 2: Preparing the Proposal. This section describes problems that can be reasonably anticipated and addressed in proposals. It offers suggestions regarding steps researchers can take to ensure that the data they need exists and will meet research needs. It also offers suggestions for proposing project management structures that increase the chances that projects will proceed as proposed.

Section 3: Managing the Research Project. This section describes problems that arise once projects are under way but that are not easily addressed in proposals. It offers suggestions regarding steps researchers can take in managing grants to minimize delays or changes in research design.

Section 4: After the Grant. This section provides guidance to researchers in disseminating lessons as they emerge, in sharing data, and in archiving data with the Inter-University Consortium for Political and Social Research (ICPSR).

Section 5: Conclusion. This section provides information on how readers can offer comments and feedback on this report.

Appendixes. This section provides one example of a *Data-Sharing Agreement and Project Management Guidelines* that address common issues that arise in projects. The appendixes also point to considerations regarding institutional review boards and the Privacy Rule of the Health Insurance Portability and Accountability Act.

Bibliography and Resources. This section includes an annotated list of literature regarding designing research projects and guidelines to specific data sets prepared by RWJF grantees.

Section 2: Preparing the Proposal

Research is candy for the curious. Researchers constantly ask questions or develop theories about why something is the way it is. Designing and managing research projects is a process of narrowing broad conceptual inquiries into concrete questions that can be explored, if not answered, through gathering and analyzing data.

The Main Points

Grant proposals are important vehicles for translating broad research questions into work that is scientifically sound, feasible to conduct and attractive to funders. After the work gets under way, however, projects do not necessarily unfold in accordance with the story line put forth in the proposal—in other words, the movie often is different from the book.

Some challenges cannot be addressed at the proposal stage, but others can. This section points to challenges that can be anticipated and offers some suggestions for ways to prepare for and address those challenges in grant proposals.

The three most important strategies to undertake when preparing proposals are:

- **Be brutally realistic when developing timetables** for project start-up and implementation. Do not use "best case" scenarios.
- **Pay adequate attention to project management:** administrative oversight, reporting relationships among project staff and partners, fiscal monitoring, and personnel policies.
- **Talk with an RWJF program officer or national program office staff** regarding assumptions, timetables and data collection strategies that will be included in the proposal.

Things That Go Wrong

It is safe to assume that during the grant at least one of the following situations will arise. Therefore, to the extent possible, they should be addressed in the proposal:

- The program you are researching does not start on time—telephones are not installed, computers are not hooked up, new staff members are giving notice at their old jobs and cannot start when expected.
- The program opens its doors, but participants are not enrolling—they don't know what the program is, what is expected of them or how they will benefit by enrolling.
- The person who promised that the data would be available leaves his or her job. The replacement requires more time to learn about the project before releasing data.
- Institutional review board (IRB) approval is delayed because an unrelated IRB request "blew up" and the institution is re-examining its IRB protocols. Nothing will be considered until the review is complete.
- People do not return calls or e-mails, and do not send reports according to the schedule you thought you had negotiated with them.
- Although you are the principal investigator on the grant, you are not in control of the data. You rely on government agencies, managed care organizations, survey firms or others who do not report to you.
- Written agreements about how data will be provided are either not executed or are not adequately specific so that data assumed to be available is in fact difficult to obtain.
- Data sets you had proposed to synthesize turn out to be incompatible.

- Community organizations fail to collect data they had agreed to collect because staff is pressured to meet urgent human needs of clients.

Preparing Proposals to Address These Problems

Following are suggestions for strategies that can be included in proposals to deal with these problems. Reviewers and program officers respond favorably when proposals indicate that researchers have a realistic grasp of what is likely to happen as projects unfold.

- **Be brutally realistic when developing timetables.** It is tempting to use "best case" scenarios under the assumption that those scenarios make projects more attractive to funders. Researchers seeking grants and RWJF program officers wanting to launch projects often feel pressure to specify deadlines or workloads that are optimistic or even unrealistic. It is difficult but important to resist these pressures. Following are steps researchers can take and incorporate into proposals:

  - Build realistic schedules for recruiting and training staff. Frequently, proposals do not reflect the time it truly takes to develop job descriptions, publish hiring announcements, interview candidates, and allow staff to give notice at prior jobs.

  - Ascertain how long it really takes for telephones to be installed, computers to be purchased and hooked up, furniture to be secured. Universities and community agencies tend to have formal procedures that often take longer than they appear on paper.

  - Allow time for more than one presentation to your IRB. Researchers often have to revise questionnaires or modify their projects to satisfy IRB concerns. Be aware of your IRB's meeting schedule and the average time it takes for a project to receive IRB approval. See **Appendix 2** for more information about IRBs.

  - Particularly when working with community-based organizations, build in time to help staff and boards of directors become comfortable with the research design, data collection requirements, and Health Insurance Portability and Accountability Act (HIPAA) requirements. Community agencies are often nervous that they will inadvertently violate HIPAA rules and tend to be more cautious and conservative than the rules require. See **Appendix 3** for information about HIPAA.

- **Ensure that the project is well organized and effectively managed.**

  None of the people interviewed for this report had taken a course in project management while in school, and none could recall a professional conference that featured a workshop on managing complex projects. One researcher responsible for a multi-million-dollar, multi-site, project that involved interviewing thousands of people and conducting secondary analyses of large data sets commented: "Until I started this project, my management experience consisted of supervising two research assistants. I learned by doing it."

  When problems occur in projects, they may not be solved by devoting time to understanding or analyzing the data. Problems get solved if they are anticipated and identified early by a team of people who communicate regularly, trust each other, and keep close tabs on how the project is evolving.

  Elements of good project management that should be featured in proposals include:

  - Detailed information regarding how the project will be organized and supervised—**an organizational chart**. Proposal reviewers should be able to understand which employee is responsible for assuring adherence to project schedules, monitoring expenditures and addressing delays.

- Specific descriptions of how **channels of communication** will be created and supported—including the combination of face-to-face meetings, conference calls or e-mail listservs to be employed. Some principal investigators require weekly in-person or telephone meetings for several months at the beginning of projects.
- Identify all prospective subcontractors and **specify which pieces of the project they will handle**.
- Explanations of **who is in charge of supervising subcontractors** and how subcontractor performance will be monitored, including strategies for keeping the project on track if subcontractors fail to meet performance standards.
- Adequate **funds for a competent, senior project manager** or administrator. The amount of time required for this work varies according to the project, but often these are half- or full-time experienced managers.

Researchers without project management experience should ask someone with a track record in overseeing complex projects to review the proposal before it is submitted. These managers do not need to be data experts, but they should be skilled in creating high-performing work teams and in completing projects on time and within budget.

- **Conduct "due diligence" on the data you plan to collect and analyze.** Have you used this data set before? Have you seen it before? Have you read publications based on this data? Do you know others who have used this data? The proposal should demonstrate that you either have had experience with the data or that you have sound strategies to secure and analyze data.
  - **Look at the data.** If your project involves analyzing public data sets or administrative or case records from community agencies, examine the data set thoroughly to be sure it is what you need, that you understand it and that you will be able to get it in a timely manner.
  - If you have not had experience with the data set you will be using, **ask an expert in that data set to examine it** and confirm that the data are accurate and accessible. Note in the proposal that you have done this.
  - **Provide evidence, such as signed agreements***, that you will have access to the data.* Agreements should include information such as when the data will be released, costs, dates the data covers, etc. They should specify that the organization, and not an individual, is agreeing to release the data so that if an individual leaves the organization, the agreement will still be in force.
  - **For data that is not public**, such as data from managed care organizations or primary data you will collect from interviews or surveys:
    - Learn as much as possible from the entity that has or will be expected to generate the data.
    - Examine samples or approximations of the data.
    - Include funds to pay the entity for collecting, recording or reporting data. In particular, community organizations often do not have sophisticated computer equipment and their staff is not trained or interested in collecting data. Some data requirements may involve changes in agency procedures that mean more work. Staff should be compensated for this work.
    - Consider tying some portion of payment to performance. In one case, agencies were given bonuses when staff reached specified targets for program enrollment and data collection.

- **Consult the Inter-University Consortium for Political and Social Research (ICPSR)** at the University of Michigan ***www.icpsr.umich.edu*** to determine whether data required for your project is already available from this source. ICPSR receives and archives data from social science researchers across the country. ICPSR is a member organization that includes most colleges and universities that have significant social science research programs. Data sets collected and archived from dues paid by members are available to nonmembers for a fee. All data generated with public funds are available to everyone without cost.

The ICPSR Web site also includes the *Guide to Social Science Data Preparation and Archiving: Best Practice Throughout the Data Life Cycle*. The guide is available to nonmembers.

For projects that involve collecting data, RWJF may require researchers to submit public use data files to ICPSR at the end of the grant. Be sure the project budget includes resources to meet this requirement or that you have funds and staff from other sources to complete this work. Build the "data dictionary" from the outset, with enough documentation and detail that an outsider can understand your steps and processes. You can use this later yourself as documentation of the study.

- **Request funds for project planning, a pilot project or a pre-test.** If you are using unfamiliar data or if you are uncertain about protocols for collecting data, chances are that you will run into the problems described here. In these cases, you should request planning or pilot test funds, with full funding contingent upon success in resolving problems during the planning or pilot phase.

- **Design workflow so that a snag in one aspect of the research will not hold up the entire project.** Work plans should include more than one critical path, allowing researchers to shift resources to other activities while resolving problems that arise in one area.

- **Allocate enough time and funds to analyze and archive the data for use by other researchers.** In describing how you will analyze the data, assume that you have experienced some of the problems described above—problems that are likely to have absorbed resources or added time to the project. If you rely on best case assumptions by the time the data are ready for analysis, the grant could have ended and all the funds could have been expended.

- **Include plans for disseminating findings.** Identify key stakeholders for the research and describe how you will share findings with them. Wherever possible, plan to release qualitative or preliminary findings at critical points during the project rather than waiting to disseminate information only after the project is over.

- **Describe clearly and completely the limitations of the data.** Researchers and funders alike will have more accurate and realistic expectations for projects if they understand the potential and the limitations of the data.

For all of the activities described in this section, if you are unsure whether some will be funded or approved, consult the RWJF program officer or the national program office staff for guidance.

Section 3: Managing the Research Project

The goods news is that you got the grant. Although preparing proposals is difficult and frustrating, the really hard work starts only after the project begins. When the excitement of getting a new grant wears off and reality sets in, principal investigators may at times feel that their projects are punishment for past sins. But, it is in guiding research projects that researchers become their most creative and inventive. They learn to push their own limits and doggedly pursue intriguing clues. These clues can prompt further inquiry and research into new areas.

The Main Points

Following is a list of problems that arise after the work begins and some strategies for addressing them. The two most important strategies are:

- Set a tone and standards that actively support communication, trust and sharing among staff, partners and subcontractors.
- Do the hard work—dig in up to your elbows if that's what it takes.

Things That Go Wrong

- The staff you hired is not invested in research or in this project. They may be interested in other research areas or focused on completing dissertations, getting accepted into doctoral programs or finding jobs that do not rely on grant funds. In one project, a critical research position was filled by someone who was working half-time on another project that was of greater personal and professional interest. When priorities of the two projects conflicted, the researcher gave priority to the other project.
- Despite assurances from senior managers at community agencies that their agencies will comply with research protocols, compliance is spotty. Inadequate staff and limited resources can often make it hard for staff to participate fully in research projects.
- When research involves randomly assigning participants to receive either enhanced services or services as usual, front-line staff find it troubling to withhold services for research purposes. In one program aimed at improving services to children at risk of criminal activity, project staff stated they would rather live with research findings that the intervention had no effect than deny services to some children assigned to the control group.
- Practice drifts away from the program model that is being researched. Despite program manuals and training, people resort to past practices. At times staff may disagree with elements of the program model and feel uncomfortable using those elements.
- Key staff members leave their jobs during the project and vacancies are not filled in a timely manner.
- Tensions between staff or organizations arise, mistrust develops and people begin to "circle the wagons" to protect their turf. In one situation, researchers and program staff disagreed over who would be responsible for securing consent agreements from program participants and for locating participants for interviews. Researchers felt that program staff had easier access to participants and program staff felt uncomfortable pursuing already stressed people for research interviews. Researchers cited confidentiality barriers to approaching participants and program staff refused to change internal procedures to make participants more accessible. Neither focused on developing creative solutions to the problem.
- The project has more than one funder and the priorities, oversight style, reporting requirements and program interests of these funders differ or even conflict.

- Attention to research products such as interim qualitative reports, preliminary findings or articles for peer-reviewed journals gets diverted to other project priorities, and anticipated products are either late or are not completed at all.

Managing Research Projects to Address These Problems

While analyzing data and writing journal articles are important activities to researchers and a major reason they apply for grants in the first place, once they receive their grants experienced researchers often find themselves spending their time managing staff, securing equipment, navigating differences of opinion and writing status reports.

Following are some suggestions to help researchers manage grants:

- **Set a mission and a vision for the project, and create a work environment that motivates and inspires staff.** Principal investigators have a responsibility to translate research interests into human terms that have meaning for staff. Rashi Fein, Ph.D., a prominent health researcher, commented: "Think not only of hunger, think also of people who are hungry." When employees feel inspired by the mission of their work, realize that they are integral to its success and understand their role in advancing knowledge or improving society, they are more likely to buckle down and do the hard, frustrating or unrewarding parts of the job.

  People involved in RWJF's *Active for Life* national program commented: "We have come to understand that the *Active for Life* management team is able to demonstrate… the very behavior we expect the grantee coalitions to employ in managing efficient and effective partnerships, focused on accomplishing their mission."

  In one project aimed at improving employment and health outcomes for welfare recipients, junior researchers and staff in community-based organizations serving recipients reported that they felt inspired by the words and tone set by the principal investigator. Program staff said: "He makes us feel like we are really making a difference in the lives of poor people." Researchers reported that "going to his meetings is like having a master class in research techniques."

- **Lead and manage all aspects of the project.** In addition to the activities described in Section 2, leading and managing projects include the following:

  - Early in the grant, **finalize formal work plans, communication protocols and internal reporting requirements**. Set clear lines of authority for the project. If you need information from researchers, subcontractors, government agencies or community agencies, create a written document specifying what each is expected to do. Manage and monitor those relationships according to that document.

  - **Establish clear procedures for the resolution of misunderstandings** or conflict among the various partners with the research project, such as the national program office or subcontractors.

    Also from RWJF's *Active for Life* program: "What seems to work for us is regular and open communications—we have biweekly calls with the management committee and similar regular communications with our grantees. . . .This sharing gives everyone an early heads-up on program activities and an opportunity to participate in joint sharing and problem solving."

    Frank Chaloupka, Ph.D., Lloyd Johnston, Ph.D., and colleagues created a *Data-Sharing Agreement and Project Management Guidelines* as part of the RWJF *Bridging the Gap* national program. The agreement took a long time to develop but serves as the fundamental framework through which this complicated project is managed. **Appendix 3** provides a short description of *Bridging the Gap* and the full *Data-Sharing Agreement and Project Management Guidelines* is available as a separate document.

- **Give staff and program participants timely and practical feedback regarding their work.** People are more likely to help provide data if they know they will learn the results. Although it takes time to gather, analyze and report on data, it is important for researchers to find a mechanism to tell agency staff what they are learning, and how those lessons affect program participants.

  For community agencies in particular, little is more frustrating than providing information to researchers who then disappear for a few years to prepare reports or journal articles.

- **Visit program sites at every stage of the project**—start-up, early operations, full implementation and closeout. One program included personal discussions between researchers and program participants as part of each site visit. These discussions allowed researchers to learn ways the program could be improved and they allowed participants to ask questions about how research findings would be used. Participants said they felt important and valued knowing that their personal experiences would be used to help others.

- **See both the forest and the trees**—the big picture and the details. Notwithstanding the need for principal investigators to set a vision and mission, they also need to know specifically what is going on within the project. They have to fill in or have others on hand to fill in if staff leaves. One well-established researcher said: "I am always amazed at how detail-oriented I have to be. I have never run a research project where I did not have to go back personally and go over all the measures to be sure that staff got them right. I thought I would not have to do this, but I always do."

- If the project is supported by more than one funder, **specify how you communicate with and relate to each funder**. Indicate clearly if one funder is the lead and specify how you will resolve conflicts between funders if they arise. Avoid becoming the messenger between funders who disagree about project activities or goals.

■ **Do the heavy lifting. If information is incomplete or unreliable, look more deeply, find other sources and track down whatever is there.** In one situation, data expected from data-entry documents had many missing or confusing elements. The researcher flew to Ohio where the original case records were warehoused in boxes, opened the boxes and reviewed the records herself.

■ **Communicate with your program officer.** The relationship between a principal investigator and the RWJF program officer or national program office staff is reciprocal. Program officers like to know they can call grantees for general information about an issue or for guidance on questions. Similarly, they like to know that grantees will keep them informed about progress, successes and problems. RWJF program officers are interested in learning from the grants they make. They want to know what is happening and they want to help when they can.

Although RWJF requires annual grant reports, principal investigators should call or e-mail their program officers when any of the following occurs:

- The project achieves an important or unexpected result.
- A paper has been accepted for publication.
- The project is releasing a product, hosting a conference or issuing a news release.
- The project has deviated from what was proposed (such as problems with enrollment or disenrollment), needs a no-cost extension or is running into problems. In these cases, ask:
  - Why do I need an extension and what might I have done to avoid it?
  - Are the delays due to inadequacies in the data or are there underlying problems among staff and partners?
  - What strategies do I have for resolving the problem and what are implications for the project schedule, budget and findings?

Section 4: After the Grant

RWJF and grantees want to strike a balance between sharing knowledge gained through research projects and respecting the propriety of the investments researchers have made in their work. RWJF's policy is to encourage researchers to disseminate knowledge gained with RWJF funds and to acknowledge RWJF's support and guidance. This includes sharing not only research findings but also information regarding data challenges and methods. If there are questions regarding who owns the data, these should be raised with the program officer or national program office staff before the grant begins.

RWJF may require grantees to submit data to the Inter-University Consortium for Political and Social Research at the University of Michigan ***www.icpsr.umich.edu***. (Grantees should refer to their grant agreements for requirements.) ICPSR staff is available to help researchers prepare their data for archiving. All researchers proposing grants to RWJF should be familiar with ICPSR and use its *Guide to Social Science Data Preparation and Archiving.*

Researchers should think through publications and other products that they can produce throughout the course of the research, and not solely after the grant has ended. Proposals should include mention of these products and the timeline for when they are likely to be available. While publication in peer-reviewed journals and final project reports generally follow project completion, it is possible to produce interim reports at specified intervals during the project. Producing interim reports reduces the likelihood that the grant will end before data analysis is complete, leaving researchers to absorb the costs involved in finalizing their analysis.

RWJF program officers are interested in interim reports and publications, and researchers should inform program officers when they are about to be issued. In addition, because RWJF is committed to ensuring that research findings are easy to understand and widely shared, RWJF staff may work with researchers in producing information or creating materials to be posted on the RWJF Web site. In these cases, RWJF will work with researchers to be sure that publication does not jeopardize subsequent acceptance or publication by peer-reviewed journals.

Section 5: Conclusion

RWJF staff members have enjoyed and benefited from working with some of the most talented and committed researchers in the country. We have learned and grown from working with you. Your struggles, innovations and successes informed this report and continue to inform our grantmaking in general.

RWJF wants to be as helpful as possible in making it easier for researchers to get grants and to manage those grants effectively. We hope this resource is useful to you. We welcome your comments, feedback and suggestions about anything included here by using the "Contact Us" form on ***www.rwjf.org***.

Appendix 1: Institutional Review Boards

Social science and health research often involves examining sensitive personal behaviors among vulnerable people. Researchers ask people about their sexual practices, drug use or criminal activity. It is imperative that such studies be executed only with the informed consent of participants, in a manner that respects their privacy and integrity, and assures complete confidentiality.

The purpose of an institutional review board (IRB) is to protect the rights and welfare of human research subjects recruited to participate in research activities of the institution with which it is affiliated. An IRB has the authority to approve, require modifications in or disapprove all research activities that fall within its jurisdiction as specified by both the federal regulations and local institutional policy

The Office for Human Research Protections (OHRP) ***www.hhs.gov/ohrp/related.html*** at the U.S. Department of Health and Human Services provides clarification and guidance to research institutions, develops educational programs, and promotes innovative approaches to enhancing human subject protections.

OHRP prepared an Institutional Review Board Guidebook ***www.hhs.gov/ohrp/irb/irb_introduction.htm*** to help researchers understand and comply with regulations regarding research involving human subjects. The following short history of human subjects protections comes from the guidebook.

Summary of Information From the Institutional Review Board Guidebook

Human subjects protections begins with the *Nuremberg Code*, developed for the Nuremberg Military Tribunal as standards by which to judge the human experimentation conducted by the Nazis. That code captures many of what are now basic principles governing the ethical conduct of research involving human subjects. Freely given consent to participation in research is the cornerstone of research involving human subjects.

The Declaration of Helsinki: Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects included recommendations similar to those incorporated in the *Nuremberg Code*, and also distinguished therapeutic from nontherapeutic research.

In the United States, regulations protecting human subjects first became effective on May 30, 1974. Promulgated by the then Department of Health, Education and Welfare (DHEW), those regulations raised to regulatory status the National Institutes of Health Policies for the Protection of Human Subjects, which were first issued in 1966. The regulations established the IRB as one mechanism through which human subjects would be protected.

In 1981, the Department of Health and Human Services (DHHS, formerly DHEW) and the Food and Drug Administration (FDA) promulgated significant revisions of their human subjects regulations. The DHHS regulations are codified at Title 45 Part 46 of the Code of Federal Regulations. HHS also developed protections for particularly vulnerable populations including pregnant women, fetuses, prisoners and children.

IRBs generally meet at specified intervals and are composed of people with diverse backgrounds from within and outside of the institution conducting the research. Principal investigators must submit documentation of the research design, methods, and all interview and survey forms to the IRB for review and approval before they can begin their research. Research projects involving more than one institution generally must be approved by the IRB of each institution.

Researchers must take the IRB process seriously and allow adequate time for IRB review and approval of projects. IRBs are not rubber stamps for the institutional priorities and many research projects do not receive approval at the first submission. IRBs often require that researchers change elements of the research design or modify their survey and interview instruments. These changes must be made and the documents resubmitted to the IRB before approval is secured and work can begin. Periodically, an institution's IRB is caught up in a controversy over its approval of a research project. When this happens, the institution may put a hold on all IRB activity until the controversy is resolved.

Before submitting a proposal, researchers should thoroughly understand their institution's IRB protocols and timetables. If more than one institution is involved, researchers should understand the IRB processes for all institutions. Proposals should include realistic timetables for projects to be submitted to IRBs, revised to meet IRB standards and resubmitted for final approval.

Appendix 2: The Health Insurance Portability and Accountability Act

Revisions to the Health Insurance Portability and Accountability Act (HIPAA) included provisions for protecting health information of patients and research subjects. Some of these provisions have confused patients, researchers and community agencies. Agencies such as health clinics or drug treatment programs have found these provisions hard to understand, and in response, some have become extremely reluctant to share any information even if doing so would not violate HIPAA standards. Researchers working with community organizations should be prepared to work intensively with agency managers and staff to explain HIPAA rules, help them become comfortable with the requirements, and negotiate mechanisms by which information can be released.

If staff is uncomfortable sharing information about clients, projects will not enroll participants and activities will quickly get behind schedule. Researchers proposing projects involving agencies subject to HIPAA provisions should include adequate time to help agencies understand HIPAA and become comfortable sharing information within HIPAA standards.

The Office for Civil Rights at the U.S. Department of Health and Human Services ***www.hhs.gov/ocr/hipaa/*** offers fact sheets for consumers and educational information for researchers.

The National Institutes of Health of the U.S. Department of Health and Human Services published a guide to HIPAA ***http://privacyruleandresearch.nih.gov/pr_02.asp***. This extensive guide includes information about HIPAA and IRBs and about how HIPAA applies to research activities. Information on the next pages are from this guide.

Summary of Information From Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule

The Privacy Rule section of HIPAA introduces new standards for protecting the privacy of health information held by a covered entity or its business associates. The rule sets minimum standards for how health information may be used and disclosed and how individuals can have control of their health information, including for research purposes.

HIPAA was not intended to impede research. Rather, it provides ways to access vital information needed for research in a manner that protects the privacy of the research subject. The Privacy Rule describes methods that health information can be separated from individual names or other identifiers so that it can be shared. If de-identified health information cannot be used for research, the Privacy Rule includes provisions under which researchers can obtain the individual's written authorization for the research. When obtaining authorization is not practicable, an IRB or privacy board could waive or alter the requirement. The Privacy Rule also provides alternatives to obtaining an authorization or a waiver or an alteration of this requirement, such as limited data sets or with representations provided for certain research activities.

Many researchers are accustomed to complying with federal and state regulations that protect participants from research risks; some of these regulations even require, as applicable, a researcher to describe privacy and confidentiality protections in an informed consent. While the Privacy Rule may add to these privacy protections, researchers are aware of the importance of protecting research subjects from foreseeable research risks, including risks to privacy. Understanding how and why the Privacy Rule protects the privacy of identifiable health information is an important step in understanding how covered entities implement the rule's standards.

Appendix 3: Data Sharing Agreement and Project Management Guidelines

Frank Chaloupka, Ph.D., and Lloyd Johnston, Ph.D., and colleagues have developed a *Data Sharing Agreement and Project Management Guidelines* to guide data collection and analysis in RWJF's *Bridging the Gap* national program. The data sharing agreement is available in a separate file.

Bridging the Gap examines the role of policy and environmental factors in youth alcohol, illicit drug and tobacco use, diet and physical activity, to evaluate their effectiveness in reducing substance use and obesity among youth.

Bridging the Gap involves mail surveys of school administrators and students, observations in schools, on-site observation of communities where schools are located, telephone interviews of community members, and collection of state-level policy information regarding alcohol, illegal drugs, tobacco, physical activity, diet and obesity-related outcomes. It also involves gathering and analyzing archived data from a variety of sources.

For additional information about *Bridging the Gap*, see ***www.impacteen.org*** and ***www.yesresearch.org***.

For more information about the *Data Sharing Agreement and the Project Management Guidelines*, contact Frank Chaloupka at:

Frank J. Chaloupka
fjc@uic.edu
(312) 413-2287
University of Illinois at Chicago
Institute for Health Research and Policy
Room 558, M/C 275
1747 West Roosevelt Road
Chicago, IL 60608

Bibliography and Resources

Guidelines Published by RWJF and Its Grantees

Planning and Using Survey Research Projects: A Guide for Grantees of the Robert Wood Johnson Foundation
Prepared by Diane Colasanto, Ph.D., Princeton Survey Research Associates
www.rwjf.org/files/publications/RWJF_SurveyGuide_0804.pdf
This guide is designed to help RWJF grantees make better decisions about their survey research projects, know what questions to ask of survey experts they hire, recognize the circumstances when it may be acceptable to use various data-collection methods and understand the consequences of decisions regarding different kinds of survey design.

A Guide to Evaluation Primers
Prepared by the Association for the Study and Development of Community for RWJF
www.rwjf.org/files/publications/RWJF_ResearchPrimer_0804.pdf
This report is an orientation guide to handbooks and basic primers on program evaluation. Primers described in the report are not academic texts, but are directed towards non-experts. The report summarizes several widely used primers or tools and provides information regarding how to obtain each one.

Health Plan Data: A Rich Resource Ripe with Challenges
Anne Gauthier, Program Director, RWJF *Changes in Health Care Financing and Organization* national program
Published by Academy Health
Washington, DC
202-292-67600
www.academyhealth.org
This report provides information to help researchers utilize data available from managed care health plans. It describes the kind of data collected by health plans, outlines steps to take in working with health plans to secure their cooperation in providing data, and highlights some of the technical problems likely to arise in analyzing this data. This report provides guidance to new and experienced researchers.

Bridging the Gap Data-Sharing Agreement and Project Management Guidelines
Frank J. Chaloupka
University of Illinois at Chicago
Institute for Health Research and Policy
Chicago, IL
(312) 413-2287
fjc@uic.edu
This data-sharing agreement and project management guidelines are included in full here. It sets forth the framework for many aspects of the research conducted as part of RWJF's *Bridging the Gap* national program. The agreement represents more than a year's worth of work by several researchers and is a good template/tool for other researchers to use in designing their projects. This agreement will be helpful to all researchers, but especially those who are undertaking large and complex projects.

Inter-University Consortium for Political and Social Research
Guide to Social Science Data Preparation and Archiving
University of Michigan
Institute for Social Research
Ann Arbor, MI
Peter Granda
Assistant Archival Director
(734) 615-2977
peterg@umich.edu
www.icpsr.umich.edu
RWJF requires grantees to submit data to ICPSR. This guide compiles best practices in preparing data for archiving, documenting data for outside use and submitting data to ICPSR. ICPSR staff is also available to help researchers use the guide or to answer questions regarding archiving requirements. This guide is aimed at more experienced researchers.

Guidelines Published by Other Foundations

Grantcraft: Practical Information for Grantmakers
The Ford Foundation
New York, NY
www.grantcraft.org
Grantcraft is a project of the Ford Foundation. Although Grantcraft is aimed at grantmakers rather than grantees, new researchers in particular may find these short reports helpful in understanding how their grants may be perceived. Grantcraft materials have been used in college courses in philanthropy. One Grantcraft report is entitled *Outcomes and Evaluation*.

Government Web Sites

Institutional Review Boards

www.hhs.gov/ohrp/irb/irb_introduction.htm
This Web site links directly to the guidebook for IRBs prepared by the U.S. Department of Health and Human Services Office of Human Research Protections.

www.hhs.gov/ohrp/related.html
This Web site links to the Office of Human Research Protections, which features an extensive discussion of all federal regulations and procedures related to IRBs.

Health Insurance Portability and Accountability Act

www.hhs.gov/ocr/hippa/
This Web site for the Office for Civil Rights at the U.S. Department of Health and Human Services provides simple but clear fact sheets for consumers and educational information for researchers subject to HIPAA rules.

http://privacyruleandresearch.nih.gov/pr_02.asp
This Web site includes an extensive guide to HIPAA, including the relationship between HIPAA and IRBs. It also includes information about how HIPAA applies to research.

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Frank Chaloupka, Ph.D.
University of Illinois at Chicago
Institute for Health Research and Policy
Chicago, IL 60608
fjc@uic.edu
312-413-2287

Peter Granda
Assistant Archival Director
Inter-University Consortium for Political and Social Research (ICPSR)
University of Michigan
peterg@umich.edu
734-615-2977

Sandra Newman, Ph.D.
Director, Johns Hopkins Institute for Policy Studies
Johns Hopkins University
Baltimore, MD
sjn@jhu.edu
410-516-4614

Beth Stevens, Ph.D.
Senior Health Researcher
Mathematica Policy Research
Washington, D.C.
bstevens@mathematica-mpr.org
609-716-4542

Thanks also go to these five researchers and the following additional researchers who read and commented on draft versions of the paper:

David Altman, Ph.D.
National Program Director
Substance Abuse Policy Research Program
One Leadership Place
Greensboro, N.C. 27410
altmand@leaders.ccl.org
336-286-4548

Sharon B. Arnold, Ph.D.
Vice President, AcademyHealth
1801 K Street NW, Suite 701-L
Washington, D.C. 20006
Sharon.Arnold@academyhealth.org
202-292-6700

Earl Babbie, Ph.D.
Campbell Professor Emeritus in Behavioral Sciences
Department of Sociology
Chapman University
One University Drive
Orange, Calif. 92866
babbie@chapman.edu
www.chapman.edu/~Babbie
714-997-6565

Maribel Cifuentes, R.N.
Deputy Director, Prescription for Health
University of Colorado Department of Family Medicine
12474 East 19th Avenue, Building 402
Aurora, Co. 80045
maribel.cifuentes@uchsc.edu
303-724-9772

Marjorie A. Gutman, Ph.D.
National Program Co-Director
Substance Abuse Policy Research Program
Gutman Research Associates
42 North Main Street
Cranbury, NJ 08512
magutman1@aol.com
609-655-3524

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