**Managing Human Subjects Research Projects:**
**A Tool Kit for Project Managers**


*Written by*
*The Project Managers Working Group of*
*The Centers for Population Health and Health Disparities*

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# Introduction

## Background

*Managing Human Subjects Research Projects: A Tool Kit for Project Managers* was written by seasoned project managers from more than eight institutions nationwide. The authors came together to document their experiences operationalizing multidisciplinary research programs in order to assist other project managers involved in nationwide research initiatives focused on reducing health disparities. The authors' institutions and research projects differ with respect to research emphasis, organization and structure In addition authors are from diverse educational cultural,and ethnic backgrounds and represent professionals with varying years of experience in both academic and community settings. Managers pooled their resources, individual practices and guiding principles, critically analyzed the resulting data and selected overarching practices common to the coordination and management of research at any large academic institution. The resulting document is a work in progress which has proven to be an invaluable( and not often available) learning opportunity for participating research-based administrative personnel .

## Purpose

This tool kit was designed for project managers of all levels of experience to guide the coordination and management of research projects at academic institutions. The tool kit provides practical tips for project managers, spanning the research process from beginning to end to enhance effective functioning both within and external to the university and promote maximum collaboration among all. This resource is focused on research involving in-person and telephone interviews with human subjects and outlines useful ways to involve community organizations, recruit research participants and staff from minority and underserved populations.

### How to Use the Toolkit

This toolkit is available in three different formats, HTML, Word, and PDF. Choose the format with which you are most comfortable using. In the HTML format, you can navigate the document by clicking on the section link to which you need to refer. Use the PDF format if you are most comfortable printing the entire document, then perusing to find the sections that you are in need of or to read the whole document. Use the Word format to save it to your hard drive and make notes in the document itself. This tool kit contains generalized information, so the Word format may be especially useful if you want to make the information provided more specific to your needs.

It is also important to note that the authors' intent is for this toolkit to be a "living" document to which others can contribute. If, as you are using the toolkit, you find that you can contribute personal experiences to use as examples in certain sections, please complete the suggestion form. Links to the suggestion form can be found throughout the

document.  Also, please complete an evaluation form so that we can make improvements where needed.

# 1. Staffing Research Projects

In order to successfully implement a research study, it is imperative to hire staff capable of achieving the desired outcomes. The following sections will address staffing issues, including hiring and training staff and building good staff relationships.

## 1.1 Hiring Staff

When starting a project, it is important to define the project's staffing needs. The project manager must translate the project's goals into tasks and positions needed to complete the tasks. This entails thinking about the process of determining what is necessary to meet the goals of the project (e.g., recruitment, interviews, data entry, etc.). It is important to think about key qualities and strengths that are crucial to the effectiveness of the project. The project manager needs to ensure that the number of employees matches the estimated workload while remaining within the budgetary limits for hiring staff.

In order to adequately staff the project, it is necessary to write detailed job descriptions for each specific role in the study. Job descriptions should be clear and concise so that expectations are comprehensible. The job description should include, but not be limited to, the following:

- Position overview
- Position requirements
- Position responsibilities
- Performance expectations
- Physical and mental demands
- Work schedule
- Salary and benefits
- Supervision

Once the job descriptions are written, they should be posted with the institution's human resources office, on the Web and/or in local newspapers. When potential candidates have been identified, the project manager must interview them to ensure that the most appropriate candidate is hired. It is also essential to consider how different qualities and personalities will work within the research team. The team should be balanced so that each individual brings a key quality or qualities to the group.

When conducting position interviews, it is advisable to prepare a comfortable environment to put the interviewee at ease. Begin by providing a brief explanation of the general details of the research project. Questions should be prepared in advance and should be open-ended so that the interviewee does most of the talking. Probe the resume to clarify any unclear points, and conclude the interview by giving the interviewee the opportunity to ask questions.

## 1.2 Orienting and Training Staff

Orientation is the process for welcoming new employees and providing general administrative information about the institution. New employee orientation is, for the most part, conducted by the institution's human resources office and generally contains information about the work environment, safety, benefits and benefit eligibility criteria. A separate orientation to the center or department should include the following:

- History, mission and goals of the larger institution
- History, mission and goals of the Center/department
- Current Center/department status
- Daily operations of the Center/department (e.g., staff meetings, work hours, lunch hours, leaves of absence, etc.)
- Trainings
  - Human subjects training
  - Adverse event reporting
  - Roles and responsibilities
- Performance planning and evaluation process
- Institution policies and procedures
- Introduction to staff, their responsibilities and chain of command
- Workplace tour (restroom and kitchen facilities, cafeteria, etc.)

It is important to establish a clear chain of command so that new employees know who the project managers are. An ideal new employee orientation:

- Has targeted goals and meets them.
- Makes new hires productive on the first day.
- Is not boring, rushed or ineffective.
- Makes the new employee feel a part of the team (may use ice breakers and/or have a lunch outing).
- Uses feedback to improve subsequent orientations.

## 1.3 Supervising Staff

Components pertinent to effective supervision are described below.

### Clearly Define Expectations

The key to effective supervision is clear and reasonable expectations. In order to achieve a desired task related to the research study (e.g., five interviews per week, complete delivery of the intervention as instructed, etc.), the staff member needs to know what the goal is and how best to achieve it.

Expectations should be outlined in writing so that there is no question about the details of particular tasks and outcomes. Expectations should be clear and specific and can pertain to any or all of the following:

- Hours
- Quality of work
- Completeness of work
- Timeliness of work
- Appropriate dress
- Level of professionalism and conduct
- On-going training

Once expectations are known, the PI, project manager, and employee must all be accountable for those expectations. If a staff member is not meeting expectations necessary to achieve the project goals, it may be that he/she is unable to meet the expectations. To correct this, additional training or extra encouragement may be needed to raise his/her level of proficiency. Not meeting expectations may also suggest that a staff member is unwilling to do so, which may require either exercises to increase motivation or reassignment. Probation and/or termination should be explored if the previous options are not possible or do not produce the desired result.

**Communication**

Communication is critical to effective supervision. It must work in both directions (i.e., from project manager to staff member and from staff member to project manager). Honest communication requires good listening skills (which may need to be taught and/or reviewed) and a supportive, non-judgmental environment in which each party feels comfortable sharing his/her feelings without concern for negative consequences.

Several factors contribute significantly to effective communication, including, but not limited to:

- *Availability*: All parties should have adequate availability in order to facilitate effective two-way communication. Availability will be determined by the nature of the work to be performed and other responsibilities. It is helpful to know the best days and times to reach one another, and times when one person may be unavailable for contact (e.g., vacation, professional leave, family leave, etc.). If a project manager will be unavailable, it is imperative that an alternate contact be identified in the event that there is an urgent matter.

- *Responsiveness*: Prompt response enhances effective communication; expectations for response times should be established at the start of employment. Responsiveness applies to phone and email as well as in-person contact.

**Conflict Resolution**

Conflict situations are those in which the concerns of two or more people do not seem to be compatible. In research project settings, conflict is almost inevitable, but does not have to be negative if managed properly. Project managers should establish a creative

and innovative environment that encourages the completion of the project goals, despite staff conflicts.

Aspects to consider when there is conflict in the workplace include:

- *Detecting conflict*: The first step is to acknowledge the conflict and take responsibility for dealing with it in a comprehensive and open way.

- *Creating a communication plan*: Project managers should create a work environment that is conducive to openly communicating about and resolving conflicts. Staff members should know the appropriate channels through which to communicate about conflicts and feel comfortable expressing concerns directly with other staff members and the project manager.

- *Understanding cultural differences*: When there are projects that include employees from diverse backgrounds, especially projects that involve employees from different racial and ethnic groups, project managers should have a strong understanding and sensibility about the values, beliefs, and practices of the different cultures represented in the Center.

**Follow-up**

Without follow-up, expectations and communication have little value, and involved parties may lose interest and sight of the goal. Follow-up can occur in several forms, including individual or group meetings. Depending on the study environment, follow-up may occur in-person or via conference calls or email. Follow-up arrangements can be established by the project manager and/or by the staff members, depending on the purpose, need and urgency. For more consistent contact, progress reports on tasks completed during the week and tasks scheduled for the following week can be submitted to project managers for review. This may be especially helpful if staff members have a heavy workload or if project managers manage multiple staff on multiple projects. Weekly staff meetings are also an effective strategy for follow-up.

If field work (i.e., interviews, intervention delivery) is a task for staff members, observation of those staff members conducting interviews or delivering intervention components should be conducted by a project manager at intervals appropriate for the project. This contributes to process evaluation and, in turn, enables the project manager to give specific, timely feedback to the staff member regarding accuracy and quality.

It is important that regular follow-up be established early in the supervisory process so that it becomes an integral part of the relationship. Feedback to staff members should be prompt and specific so that changes can be made immediately, if necessary. Once specific feedback is given to the individual, it may benefit other staff members to hear the same message.

Opportunities for staff members to provide feedback to project managers is also recommended so that project managers may best meet the needs of their staff members.

**Long-distance Supervision**

It can be challenging to supervise staff members who are not always in the office. It is necessary to have an organized opportunity for communication among staff, with clear expectations and a regular schedule of follow-up and feedback. Some aspects to consider when dealing with long-distance supervision are establishing and conveying a clear understanding of the project's priorities and the responsibilities and deadlines of each staff member.

## 1.4 Delegating Responsibilities

One of the primary tasks of a manager is to delegate responsibilities and tasks to achieve the project goals. It is important to have a clear idea of those tasks and relevant timelines for completion before delegation begins.

**Maximize Efficiency**

- Evaluate potential candidates on the basis of their strengths and weaknesses in relation to what tasks they will be hired to perform (interview/pre-hire phase).
- Know the strengths and limitations of staff members and delegate considering those strengths and limitations.
- Know what tasks staff enjoy doing to achieve higher quality work and willingness to volunteer for future opportunities.
- Avoid delegating only those tasks you do not like to do or are not willing to do. Perceived fairness and balance from the perspective of the staff member may help minimize staff turn-over and may contribute positively to staff morale and the ultimate success of the project.
- Know when to stop delegating. Overloading staff members, especially those with a strong sense of responsibility, may lead to job dissatisfaction, burn-out and a higher rate of staff turn-over.

## 1.5 Increasing Staff Motivation

Staff motivation is an important staffing issue, and it is helpful to know what specifically motivates individual staff members at the beginning of the supervisory process.

- *Feedback*: Feedback of any kind is helpful to increase staff motivation; however, positive feedback is more readily accepted than negative feedback. Feedback can come from either project managers or research participants. Positive feedback from research participants is especially helpful at annual reviews. Feedback can be written or verbal.

- *Recognition*: Staff may be motivated by public or private recognition of their efforts, depending on their preferences and personalities. Recognition can be written or verbal.

- *Gift incentives*: Staff may be motivated by monetary or gift incentives either for achieving a specific milestone (e.g., 100 interviews) or for going above and beyond basic position requirements.

- *Small words of encouragement*: Small words of encouragement, either in-person, over the telephone or at the end of an email, can go a long way to let staff members know they are valued and appreciated.

# 2. Involving Community Members in Health Research

In addition to the strategies outlined previously, the PI and project manager may need to involve community members in implementing some or all of the research project endeavors. This section highlights information to consider when involving community members in health research.

## 2.1 Involving Community Members in the Research Process

Community based participatory research (CBPR) is a type of research that intricately involves community stakeholders in all aspects of the research process, from planning the study design through implementing and finalizing the study. As the project manager of a community based participatory research project, you may be asked to develop ways to identify and/or work with community stakeholders. In most cases, the principal investigator will identify key individuals in the target community who have similar goals and who can mutually benefit from working together in partnership; however, the PI may also ask the project manager to come up with ways to identify these stakeholders and to approach them.

Community stakeholders should be invited and made to feel like a welcome addition to the research team. *Roles of community members should be discussed when invitations to participate are extended. It should be clear to all parties (research team/committee members) that community members are not only expected to attend research meetings,* but should be included in making decisions about how to approach the research question in the target community. The project manager can ensure that community stakeholders are active participants in the research process by:

- *Setting up a plan for alternating between the institution and community for regular research meetings, ensuring that meeting times remain convenient and verifying periodically that the operating procedures are still mutually agreed upon*
- Brainstorming ideas about the research questions and how to approach them within the community.

- Assessing barriers and facilitators to developing and implementing interventions for the target community.
- *Including a "Community Report/Update as a regular agenda item*

## 2.2 Recruiting Community Advisors

Community advisors are typically members of the target community who accept the responsibility of communicating the goals of a research intervention and eligibility requirements to other community members who may participate. Community advisors play an integral role in the implementation of research programs in the target community and often themselves disseminate the intervention to research participants. They may also advise researchers on how to communicate the goals and objectives of the research study. Because community advisors act as liaisons to the rest of the community, it is essential that the project manager remain in regular contact with them to assess anything that may prove problematic to the success of the program. Community advisors should:

- Be selected based on their status in the community
- Be provided information about basic research principals
- Be provided with whatever they need to accurately communicate the information that is a part of the intervention and to reach the outcome goals of the program
- Provide researchers with the basic principals for working in the community

As a project manager working on a new study that will involve community partners, you should consider the following questions as you embark on your search for key community stakeholders:

- What are the criteria for defining a key stakeholder within my institution, according to the principal investigator of the study?
- What individuals are most respected as leaders in the community? (This can be assessed using a brief survey question that can be asked of various individuals in the target community. For example: To whom do you go in the community for help and advice about community or other issues?)
- What does the PI feel is the most important issue to deal with in the community? What key community stakeholders share the same priority?
- Of the community stakeholders who share the same priorities about important community issues, who is willing to play a leadership role in organizing the community around this set of issues?

When key community stakeholders have been identified and grant preparation or funded grant activities begin, the project manager may be responsible for continued rapport building with community members. There are several ways to build rapport with key stakeholders in the community:

- Attend community meetings to get a personal view of what is important to community members.

- Invite community members to research meetings to allow them a full view of the research process.
- Avoid using a condescending tone in communications with community members.
- Acknowledge community members' expertise.
- Avoid making assumptions about community members' knowledge, or lack thereof, about research.

## 2.3 Interacting with Community Partners

It is often the case that communication with community partners ebbs and flows, with the most intense involvement occurring at critical points as dictated by the grant application and project deadlines. There is much discussion as the application is being prepared, soon after news of the award is received, when progress reports are due, and when new applications (e.g., pilot projects) are in development. Regular communication with community partners varies with each project and can reflect the philosophy and expectations not only of the investigators, but also of the community partners. In many cases, community partners are actively involved in regularly scheduled meetings and sub-committee tasks.

Project managers can play an important liaison role to the community and be perceived as a trusted communication source by:

- Ensuring that notices of meetings are disseminated in a timely manner, particularly to community partners who may have to travel distances and work around less flexible schedules.
- Facilitating input and arranging conference calls if members are not able to attend in person.
- Maintaining consistent, purposeful contact with partners via telephone, newsletters, and e-mail.
- Obtaining feedback from partners regarding previous meetings, particularly from individuals who may have been silent or in instances when dialogue had to be curtailed because of time constraints.
- Attending community-sponsored events related to the Center program.
- Objectively representing the articulated community point of view to academic partners while conveying the investigator/university point of view to community collaborators.

## 2.4 Promoting Your Research Study

Due consideration should be given to the methods by which the research team will promote participation in the research study. Recruitment methods, as well as relevant exclusion criteria and incentives, should be discussed early and often, and should benefit from the wisdom of the community partners. Community partners often have insight about how best to reach members of the target community. In addition, there are several

communication strategies that have proven effective at promoting community-based research. Paid television, newspaper, and radio advertisements can be useful if it is within the project budget to use such methods. Free placements, such as public service announcements via local media and local newsletters, also can be worthwhile to pursue.

Working with community advisors to schedule meetings and presentations with community leaders and residents about the research project and its goals may help to build rapport between the academic institution and the community, and get the word out about your study. Further, if it is feasible to do so, hiring local community members as surveyors may help to build trust.

## 2.5 Linking the Community with Resources

Project managers have access to a myriad of university resources that community partners may find useful and beneficial. To increase the likelihood that relevant information is shared, project managers should familiarize themselves not only with the Center-related resources that may be available, but also with resources that support the overarching mission, goals and programs of participating community organizations. Information should be shared equally among all community partners. The project manager can facilitate a relationship that ensures support for the community organizations by:

- Creating a master e-mail and mailing list for key community partners.
- Incorporating information about community partners and organizations on a study Web site (including links to organization Web sites, if applicable).
- Forwarding information on possible funding opportunities (new grants, requests for applications) that focus on areas in which partners have expertise.
- Providing fliers and information on new research studies that are opening on campus in which they or members of their community may be interested.
- Inviting partners to attend university seminars, educational programs and workshops.
- Developing an extended database that includes contact information for other community agencies and organizations to provide updates on study progress, new developments and other major studies that may be initiated in the community.

## 2.6 Disseminating Research Findings to the Community

As is the case with determining the best methods by which to recruit participants for a research study, the community advisors can help to inform which dissemination mechanism will work best to communicate research findings in a particular community. Toward the end of a study, the project manager may either spearhead or oversee the process for disseminating important information about study findings to the study participants and to the community from which the data were collected. Not only is it

important to share the research findings with the community, it is equally as important to convene a forum in which community members can voice their opinions about the findings and how they were presented. One mechanism by which both reporting research findings and obtaining community feedback can be accomplished is through a community forum or symposium.

**Planning a Community Forum**

There are several steps to consider when planning a community symposium.

*Before the event:*

- Review the budget for a symposium with the study PI. If funds are low, consider partnering with a community organization or academic institution that serves the same community and shares the same health-related concerns.
- Meet with your community advisors to determine the agenda and date for the event and to get an estimate of the number of attendees.
- Determine a location. A community forum should be held in the heart of the target community, or someplace that is easily accessible by the majority of its residents.
- Send "Save the Date" fliers to community organizations (e.g., faith based organizations, community health, etc.) so that the information can be included in event calendars.
- Advertise the event in local print media (community newsletter, city newsletter, etc.) and radio, as the budget permits.
- Develop an expanded agenda that gives a step-by-step description of everything that should take place during the forum, and the time slots in which those tasks should take place.
- Explain to all staff and volunteers who will work during the event what their job will be (e.g., register participants, usher participants to a seat, provide materials, etc.).

*During the event:*

- Make sure all helpers arrive 45 minutes to an hour prior to the start of the event.
- Talk with community members; ensure their comfort.
- Allow room for flexibility in the agenda.
- Allow adequate time for community members to provide feedback.

*After the event:*

- Debrief about the event, soliciting feedback from community members.
- Schedule a meeting with the research team and community advisors to discuss feedback in more detail.

- Assess how to act on feedback, if needed, in a way that community members know that their suggestions are valued.

**Obtaining Community Feedback**

There are a few ways to receive community feedback on the research and research findings:

- *Focus/discussion group*: Break off into discussion groups after the presentation of research findings during a community symposium, and obtain feedback in a structured way.
- *Evaluation survey*: Encourage members to complete an evaluation survey at the end of the symposium.
- *One-on-one feedback*: Interview individual members in a structured way. The project manger can take qualitative notes about discussions with individual community members during or after the event.

## 2.7 Establishing and Maintaining University/Community Subcontracts

Investigators were required to demonstrate existing linkages with community-based organizations and to design, conduct and evaluate a community-based research initiative related to and consistent with the theme of the CPHHD. Thus, in most instances, budgets for subcontracts and corresponding budget justifications were prepared, agreed upon and incorporated into a corresponding letter of collaboration when the grant was submitted. This section provides guiding principles for project managers at different stages in the subcontracting process.

**Developing the Sub-contractual Budget Justification (for Inclusion in the Initial Application*)***

Project managers can provide support and technical assistance to the principal investigator and facilitate the budget justification by:

- Participating in planning meetings that address key proposal components as well as focusing on community relationships and collaborations.
- Providing recommendations regarding funding options for community involvement (consultancy, stipends/fees for meeting participation, subcontracts).
- Working with the principal investigator and the community agency collaborator to outline areas of responsibility and extent of involvement, and develop the related budget justification.
- Establishing contact with the business manager at the collaborating organization to verify salaries and confirm final figures (as required).

- Developing draft letters of cooperation for community partners that include intent to participate and subcontract terms, i.e. services to be performed and/or designated work for the agreed upon dollar amount.
- Ensuring that all required documents have been submitted (e.g., organization description, curriculum vitae of community co-investigators/collaborators, letters of collaboration, etc.).
- Disseminating full copies of the proposal to all collaborators, including community partners.

**Facilitating the Sub-contractual Agreement (Post Award)**

Once the notice of award has been received and the formal sub-contractual agreement is being entered, project managers play a critical role by:

- Assisting the principal investigator in transforming the budget justification into a work scope and plan for inclusion in the sub-contractual agreement.
- Circulating the proposed work plan to community partners for focused review and revision.
- Coordinating a meeting to revisit the proposed agreement prior to submitting the sub-contractual document. (While the dollar amounts may not change, the specifics regarding project activities may change as grants are being implemented almost a year after the grant proposal was submitted.)
- Verifying that community partners have participated in the required IRB training or have completed the Individual Investigator Assurance.
- Establishing realistic expectations by providing an orientation to the university procedures, time frames for processing paper work, etc. (**Do not avoid this step even if the partners are not new.)**
- Addressing and reaching an agreement regarding payment plan (e.g., advance funds, monthly reimbursement, quarterly, etc.).
- Monitoring/expediting sub-contractual signing.

**Initiating a New Sub-Contract (once the Center programs are underway)**

- Participating in the initial discussions regarding work scope and projected budget (arrange to have face-to-face meetings for individuals who are new partners).
- Identifying steps in the sub-contracting process with the university (focusing on general time frames).

# 3. Regulatory Guidelines for Human Subjects Research

Prior to the initiation of research, the project manager should review the federal regulatory guidelines and procedures that govern all human subjects research in the

United States. Additionally, the project manager should contact the institution's Office of Protection for Research Subjects and attend research ethics training prior to the initiation of any research activities. This section provides an introduction and overview to federal regulations for human subjects research. All project managers should contact their organization's Office of Protection for Research Subjects for institution-specific guidance on interpreting federal human subjects research guidelines, attending training and submitting and maintaining Institutional Review Board (IRB) approval.

## 3.1 The Federal Institutional Review Board (IRB) Guidebook

Federal regulations for the protection of human subjects are available on the United States Department of Health and Human Services web site. See the Office for Human Research Protections for a detailed list of documents that may help tailor the research for IRB approval that is specific to an institution (http://www.hhs.gov/ohrp/).

The federal IRB Guidebook (http://www.hhs.gov/ohrp/irb/irb_guidebook.htm) will assist you in understanding how members of the IRB make decisions about initial submissions, continuing review and amendments.

## 3.2 The Office for Human Research Protections (OHRP) Policy Guidance

The OHRP is the oversight office for federally-sponsored research studies. Many institutions also apply these policies to non-federally funded research. Therefore, it is important to understand the regulations under which specific institutions operate, in order to know which of the resources provided in this section are relevant to any non-federally funded research conducted at your institution. Listed in this section is a brief sample of topics included on the OHRP Web site.

### Databases and Data Storage

This is a link to guidelines that will assist in the acquisition and storage of paper and electronic data and biological samples.

- Repositories, Tissue Storage Activities, Data Banks

### Decision Charts

This is a great tool for understanding whether the activity being planned is considered human subjects research. Be sure to seek confirmation from your IRB before moving forward.

- Human Subject Regulations Decision Charts

### Engagement in Research

This link will assist you in determining whether partnering institutions, agencies or organizations are actually "engaged" in research. The OHRP has detailed guidelines on which activities are considered "engagement." This determination will be the factor in

deciding whether that institution, agency or organization needs a Federal Wide Assurance (FWA) number. To obtain a FWA, institutions, agencies and organizations must apply to the OHRP.

- Engagement of Institutions in Research
- Engagement of Pharmaceutical Companies in HHS-Supported Research

**Common Rule**

The Common Rule is a code of federal regulations concerning the public's welfare and the uses of personal health information. It is one of the primary rules that governs human subjects research. Understanding the Common Rule will ensure proper conduct of human subjects research.

- Federal Policy for the Protection of Human Subjects
- 45 CFR 46
  - 45 CFR 46 FAQs
- Federal Register Notice announcing the final rule
- Portions of the Federal Register Notice announcing the final rule:
  - Common Rule 1
  - Common Rule 2
  - Common Rule 3
  - Common Rule 4

**Institutional Review Board (IRB)**

The Institutional Review Board (IRB) is the governing body of human subjects research within an institution. The IRB typically consists of members of the scientific community, as well as individuals from other fields and lay individuals. The IRB meets on a regular basis and decides what protocols will be allowed to be implemented at the institution. The IRB also decides annually what protocols will be allowed to continue, using a process called "Continuing Review." Below are links to information about various research activities for which the IRB provides oversight.

- AIDS Research, Guidance for IRBs
- Clinical Trial Websites
- Designation of an Independent IRB
- Expedited Review--1998 Revised Categories
- Knowledge of Local Research Context
- Meetings Convened via Telephone Conference Call
- Multicenter Clinical Trials, Local IRB Review
- Multicenter Clinical Trials, Local IRB Review, DAIDS, NIAID
- Reliance on Another Institution's IRB
- Review of Applications for HHS Support
- Written Institutional Review Board (IRB) Procedures [PDF - 132KB]

**Informed Consent**

Informed consent is not simply a form to be filled out by research participants, but an important process to be completed for every research project. Information must be presented to enable persons to voluntarily decide whether or not to participate as a research subject. It is a fundamental mechanism to ensure respect for persons through provision of thoughtful consent for a voluntary act. The procedures used in obtaining informed consent should be designed to educate potential research subjects in language that they can understand. Therefore, informed consent language and its documentation (especially explanation of the study's purpose, duration, experimental procedures, alternatives, risks, and benefits) must be written in "lay language" (i.e., language that is understandable to the people being asked to participate). Written information is used to document the basis for consent and is provided to subjects for future reference. The informed consent document should be revised when deficiencies are noted or when additional information will improve the consent process. For more details, see (www.hhs.gov/ohrp/humansubjects/guidance/ictips.htm).

- Emergency Research Informed Consent Requirements
- Exculpatory Language in Informed Consent Documents
- Informed Consent Tips
- Informed Consent Checklist
- Informed Consent, Legally Effective and Prospectively Obtained
- Informed Consent, Non-English Speakers

**Repositories** (see also Tissue Storage/Repositories)
This is a link to guidelines that will assist in the acquisition and storage of paper and electronic data and biological samples. (This link is the same as that provided previously under *Databases and Data Storage*.)

- Repositories, Tissue Storage Activities, Data Banks

## 3.3 Health Insurance Portability and Accountability Act of 1996 (HIPAA)

Researchers in medical and health-related disciplines require access to many sources of health information – from archived medical records and epidemiological databases to disease registries, tissue repositories, hospital discharge records, and government compilations of vital statistics and health records. The HIPAA Privacy Rule was implemented to further protect participants' personal health information. The U.S. Department of Health and Human Services and the National Institutes of Health maintain a web site devoted to the explanation and documentation of HIPAA. A 93-page document (45 CRF Parts 160 and 164: Standards for Privacy of Individually Identifiable Health Information, Final Rule) entitled *The Privacy Rule - Final Modification* is located at http://privacyruleandresearch.nih.gov/. Also located on the web site are links to:

- Office for Civil Rights HIPAA Information (Medical Privacy Home Page)

- Office for Civil Rights HIPAA Guidance (PDF/RTF)
- Office for Civil Rights Summary of the HIPAA Privacy Rule (PDF/RTF)
- Center for Medicare & Medicaid Services HIPAA Information (Covered Entity Decision Tool)
- Final HIPAA Enforcement Rule (PDF/TXT)

The link to the Center for Medicare & Medicaid Services HIPAA information (provided above) is a great resource that provides a decision tree to assist organizations in determining if they are considered a covered entity as defined by the Privacy Rule. Importantly, not all researchers have to comply with the Privacy Rule. It is best to consult with the IRB at your institution to determine their rules and regulations regarding researchers and the Privacy Rule. Federal information for researchers on how to interpret the privacy rule is available at: http://privacyruleandresearch.nih.gov/pr_02.asp

**Research Repositories, Databases, and the HIPAA Privacy Rule**

This web site provides detailed information about HIPAA Privacy Rule and its use when working within research repositories and databases (http://privacyruleandresearch.nih.gov/research_repositories.asp).

## 3.4 Working with the Office of Protection for Research Subjects at Your Institution

Most research institutions have offices for research subject protection or regulatory affairs. These groups are responsible for upholding the rights of research subjects and participants. They also are responsible for reviewing protocols regularly and providing oversight to ensure that participants are being treated ethically and that the research is being conducted responsibly. Project managers work closely with these offices to make sure that the research is being conducted in accordance with regulatory guidelines that govern human subjects research. Project managers should become very familiar with the rules and regulations set forth by this office within their own institution.

## 3.5 Attending Ethics and Human Subjects Training

One way for the project manager to ensure that he or she is familiar with the rules and regulations that govern human subjects research is by attending human subjects trainings offered at his or her respective institution. Most research institutions offer on-line training.

## 3.6 Submitting and Maintaining IRB Approval

IRB approval must be renewed annually. Most research institutions have standard procedures for submitting and maintaining IRB approval for a study, including forms that

should be completed and the number of copies of the application that must be submitted based on the study's review status (i.e., full or expedited review; see IRB section).

### Identifying and Reporting Adverse Events

Identifying and reporting adverse events is very important. An adverse event is broadly defined as any unfavorable or unintended sign (including an abnormal laboratory finding, symptom, or disease temporally associated with the use of an investigational product or participation in the study), whether or not it is considered related to participation in the research. In a survey study, an example of an adverse event is if a person mentions he or she has had thoughts of committing suicide, or a person is unusually agitated by a line of questioning. These should be reported to the IRB within the time-frame specified by the institution at which the adverse event has occurred. Most research institutions have an Internet-based adverse event submission form.

# 4. Fielding Research Projects

This section focuses on the day-to-day tasks involved in research project implementation.

## 4.1 Managing Data Collection

Effective data management is crucial to the validity and reliability of the data collected. Project managers should ensure that all data are collected and entered in a standard format and that the data quality assurance checks are conducted on a regular basis. The following describes techniques that are useful when collecting data using an in-person or telephone interview approach:

### Distribution of work to interviewers

The smaller the workload, the better the quality of work performed by project interviewers. This rule applies to assigning the number of homes that the interviewers need to approach or calls they need to make to collect data for the study. Interviewers are more likely to follow a sampling scheme and specific instructions for home-based interviews if a list of homes by blocks is assigned. This is possible when the project manager conducts a pre-visit to the study area to document the specific characteristics of the area and homes and prepares unique instructions for the interviewers. For telephone interviewers, the project manager should assign calls by equally dividing the sample among interviewers.

### Ways to avoid "cherry picking" among interviewers

When the interviewer does not apply the sampling procedure and deliberately selects participants that are to his or her liking, they are "cherry picking" participants. This act of selectively choosing whom to interview will eventually skew the data to a preferred outcome, therefore resulting in an unrepresentative sample of the study population. Possible ways to avoid cherry picking are to:

- Assign the interviewer a previously screened list of homes to approach.
- Make sure the list of homes is by the block level or equivalent.
- Keep track of the total number of homes, not to exceed 50 to 100 per assignment.
- Conduct periodic quality control checks. This can be accomplished by calling or visiting 10 percent of a random sample of the interviews submitted per interviewer and increasing the percentage by 5 for each discrepancy found.
- For telephone and in-person interviews, the project manager can review hard copies of a random sample of interviews and compare the captured data to those entered into the database.

## 4.2 Recruiting and Retaining Respondents

While research studies might differ with regard to institutional preferences and target populations from which to recruit, there are certain key aspects to recruitment that apply to all research institutions and populations. Below we have outlined eight key strategies that were written for recruitment of African-Americans to cancer prevention and control studies; however, the basic concepts can be used to recruit individuals from any population and for any type of research study. Project managers should review Section 2 of this document (*Involving Community Members in Health Research*) for additional information on how community advisors can assist in recruiting research participants.

**Adequately characterize the target population**
Project managers should fully understand the study's target population.

**Involve members of the target population in planning efforts**
Members of the target population will have insight into the community or population that is vital to the conduct of the study and to successful recruitment. Not soliciting some input from the community can alienate the community from the research team and hamper research efforts.

**Take the message to the target population**
Those involved in communicating with target population should clearly define the purpose of the research. Having a full understanding of the research study will afford individuals the opportunity to make an informed decision about participating. If the message or intent of the research is clearly stated to the research population, this may help to alleviate any rumors or negative press about the study.

**Give something back to the community**
Assure the community that at the end of the study, results will be disseminated to them.

**Enhance credibility of study by using a community spokesperson**
If possible, recruit community advisors who are recognizable in the community to assist the research team with promotion and recruitment efforts. This individual or group of individuals should be intricately involved with the study from inception to final data collection and analysis. Working with members of the target community will enhance the validity of the research efforts.

**Identify and remove barriers to participation**
Each community or population group has its own barriers to participating in research. It is important not to make general statements about a population, but rather to assess the specific needs of the target community and address them in a way that is respectful and conducive to effective research. For example, project managers should think about the differential transportation needs of potential participants in rural and urban areas, as well as possible literacy and language barriers in all settings.

**Improve staff sensitivity**
Respect for individuals and communities should be the primary factor involved in all recruitment activities. Ensure that all study staff have been provided cultural competency training. Training should include a component on the appropriate manner in which to recruit people of various ages, genders, incomes, etc.

**Educate the target population about the importance of prevention and early detection**
This statement is true for all types of research. It is important to educate the population about the health concern being studied. It is important for the target population to understand how the disease may affect them on a personal level.

In addition to the aforementioned community recruitment strategies, clinic/hospital-based studies have unique recruitment issues. The buy-in of the clinic administrators and other personnel is imperative to the successful recruitment of patients from clinic/hospital settings. Project managers should consider involving key staff members as community advisors.

## 4.4 Reviewing Data Quality

Managing incoming interviews can become an overwhelming task if a quality check is not performed periodically. Project managers should conduct quality checks on 10% of the incoming data per interviewer and increase the percentage by 5% for each discrepancy encountered. An initial *visual* check is recommended before deeming the data as acceptable. Currently, electronic data are commonly used among primary data collectors because they facilitate simple queries/analyses to detect discrepancies at any given moment. Hard copy data collection is limited to visual checks and quality control checks via telephone for verification purposes before it is used in simple analyses to detect more detailed discrepancies.

## 4.5 Collecting Biological Samples

Research studies may involve the collection of biological samples for use in the analysis of specific biomarkers of interest. Examples of commonly used biological samples include blood, saliva, and hair. It is important to establish detailed protocols for the collection and storage of biological samples in the research proposal and to hire and train staff accordingly.

# 5. Preparing for Data Collection

The role of the project manager may vary in the early phases of data collection depending on several factors, including the scope of work, the investigator's knowledge and familiarity with the research process, and the structure of the research institution. Because project managers often serve as collaborators on some or all of the design and budget phases, helpful strategies for the preparation of research and communication with investigators are outlined in this section.

## 5.1 Establishing the Study Design, Timeline and Budget

Typically, investigators have ideas about the type of study they would like to conduct initiate most research projects. The role of the project manager in the study design phase may be limited, but often investigators work closely with project managers to adjust the design, timeline and budget as financial support is allocated. In any case, it is useful for the project manager to prepare complete budget estimates for the study and to review budgets with investigators at the beginning of the study and periodically throughout the project. Many project managers specify the project timeline and budget in a formal proposal letter that is reviewed and signed by investigators.

Research budgets and timelines often are influenced by many factors in the study design – primarily by the interview mode (e.g., telephone or in-person), questionnaire length, and sample size. Project timelines often are useful for keeping track of projected goals for both the entire grant period and each fiscal grant year. Project Timeline Example for toolkit HTML.mht Important milestones should be noted in the timeline for future reference. Periodic reviews of the timeline should be included as a standard procedure for all research projects.

## 5.2 Designing the Study Questionnaire and Qualitative Data Guides

The instrument design process will vary depending on the type of study, the length of the questionnaire and the number of questionnaire revisions. In particular, there are three main survey modes: mail (self-administered), in-person interviews, and telephone interviews. Data from both self-administered questionnaires and those administered by an interviewer can be collected using a paper and pencil method or computer assisted method. The questionnaire types and instrument design will vary depending on the mode of administration and data collection. Common procedures used for the development of various types of data collection instruments are outlined in this section.

### Creating a Measures Binder for Quantitative Survey Instruments

As questionnaires are developed, the project manager can assist the PI by developing a Measures Binder. A Measures Binder is useful to document each scale and individual item considered for use in the study. The project manager can help track in-house and

existing scales and items by collecting hard copies to include in the binder, labeled with the author's name and citations for validation studies. This documentation will be helpful to investigators as they begin to develop publications and need to describe the scoring and psychometric properties of each scale and individual item.

The project manager may also help to obtain approval from researchers to use the existing, published scales and/or individual items, and document the permissions in the Measures Binder. A hard copy and an electronic copy of permissions and relevant scales and items should be kept on file.

Upon selecting a final survey instrument, the project manager may develop a data codebook consisting of all study variables and values along with a description of each variable. The final survey instrument and associated codebook should be kept in the Measures Binder, along with labeled and date-stamped copies of all previous versions of the data collection instruments.

**Quantitative Data Entry Software Systems**

There are many software systems available for data entry and analysis, as well as survey development. Common software programs utilized for programming research questionnaires include:

- Blaise: Blaise is powerful and flexible software available for Windows-based systems. The software is designed to support telephone interviewing, face-to-face interviewing and data entry. The system includes methods and utilities for conditional question routing, using multiple languages, coding, looking up data in external files, data manipulation, weighing data, data documentation and exporting data to external statistical packages or databases. See http://www.cbs.nl/en-GB/menu/informatie/onderzoekers/blaise-software/default.htm for more information.
- CASES: CASES (Computer-Assisted Survey Execution System) is a software package used for computer assisted telephone interviewing (CATI). It is useful for collecting survey data based on structured questionnaires, using telephone or face-to-face interviewing as well as self-administered procedures. It also contains built-in quality assurance and scheduling features. See http://www.centerforhealthstudies.org/sciresc/surv_cases.html.
- Surveycraft: Surveycraft is software that allows researchers to create questionnaires and administer questions in any format (using pen and paper, CATI, CAPI, Web or any combination of these). The software also helps to manage the revision process and is capable of producing questionnaires and analyses in Asian languages such as Chinese, Japanese and Korean. See http://www.spss.com/surveycraft/.
- Access: Access is a data management program useful for data entry and subsequent analysis using various programs such as SAS, SPSS, and EXCEL. It is also useful for the development of spreadsheets. See http://www.microsoft.com/office/access/prodinfo/overview.mspx.

**Qualitative Data Collection**

In addition to collecting and analyzing quantitative data, many investigators also collect qualitative data via focus groups and/or key informant interviews. The project manager may play a role in developing the question guide for the facilitator or interviewer to use during focus groups and key informant interviews. Similar to a questionnaire, the guide consists of important questions to ask research participants. The difference between qualitative and quantitative data collection is that, while quantitative data mostly requires concrete answers to questions using a scale, qualitative data provides an in-depth explanation for the concrete answers given during quantitative data collection. Focus groups and key informant interviews are tape recorded and transcribed. Often, project managers summarize the qualitative data analysis using various software programs, including NUDIST (N6), NVivo, and Snap Survey software. These programs allow focus group and interview transcripts to be coded on screen and examined across multiple transcripts. www.qsrinternational.com

SNAP survey software allows researchers to design questionnaires and conduct analysis using two different models. The snap Internet Model provides five different ways of creating questionnaires for publication on internet and/or intranet web sites, as e-mail attachments and plain text e-mails. The PDA interviewer model uses snap professional software using pocket personal computers as interviewing devices. See http://www.snapsurveys.com

## 5.3 Drafting and Documenting Research Procedures

Data collection process and management are conducted simultaneously. Maintaining quality control is an important management function that is helpful in obtaining reliable and valid study data. As such, it is necessary and useful to develop study procedures for the various forms and manuals that will be used during the data collection process. This will maintain continuity and reliability for future researchers.

**Management Forms**

- *Tracking Forms*: Tracking forms are used by recruiters and interviewers to track daily contact with research participants. The interviewer should note the time and date for every encounter, whether in person or by telephone. Click here for example of tracking form Interview Tracking #1 html.htm

- *Data Quality Assurance Forms:* After data are collected and entered into a study database, it is necessary to examine for accuracy. Staff should use a standard form for citing corrections that were made in the database, including the instrument name, the question number of the answer that was corrected, and the date the correction was made. Both the person making the correction and the project manager should sign the

form indicating responsibility for making the change in the database. Access to the database should be limited.

**Consent Forms**

All research participants must sign consent forms before data collection begins. The grantor's required consent form template should be used and modified according to the project's needs and specifications. To protect the personal information of the research participant in the event that private parties, such as attorneys or representatives of the federal government, would ask for the data information to be released, a request for a Certificate of Confidentiality granted by the National Institutes of Health should be sought and added to the original consent form(s). In some cases, this form is called a Research Subject Authorization Confidentiality and Privacy Rights Form Research Subject Authorization form example.mht

## 5.4 Developing a Study Procedures Manual

Developing standard procedures for implementing various aspects of the study is integral to the scientific rigor, and therefore the validity and reliability, of the research findings. Project managers often are responsible for making sure that all study activities are conducted in a standard way. One way to ensure standardization of study activities is to develop a manual of study procedures for all staff to follow. Examples include protocols for recruitment and consent procedures, interviewer guides, incentive payment procedures, etc. The investigators and research staff members should have access to the study procedures manual at all times.

## 5.5 Effective Communication and Meeting Facilitation Strategies

Effective communication skills are crucial to successful project management. The project manager is the key person responsible for demonstrating effective communication. Effective communication skills incorporate the following strategies:

- Paying attention/active listening
- Clarification/questioning
- Follow-up/documentation
- Comprehension/review of expectations.

Clear and detailed expectations should be communicated to project staff with respect to the project timeline and goals that should be reached within the specified time. To ensure that all team members have an adequate understanding of roles/expectations: 1) communicate them effectively and consistently; 2) review guidelines/expectations as needed; and 3) provide written documentation of expectations with verbal follow up (or vice-versa).

One of the most challenging elements of effective communication is choosing the best method of communication (email, phone, in-person). Academic research environments

often rely heavily on email as a form of communication. Although email is convenient, it does not allow you to understand the extent to which the involved staff member(s) have read and/or understood the communication. The preferred method of communication, especially for important guidelines and/or expectations, is verbal communication (telephone or in-person meetings) with written follow-up (meeting minutes or email). This way, all parties involved may engage in a dynamic conversation about expectations and duties, allowing for conversational nuances and details to be more clearly communicated.

**Tips for Facilitating Research Meetings**

An essential element of managing complex projects is effective communication throughout the entire implementation of the project. This would involve all members of the project, including field surveyors or interviewers, project coordinators, data managers, research assistants, project advisors, co-investigators, principal investigators, and funding agents. All study personnel must be held accountable for effective processing and dissemination of information. A primary mechanism for the distribution and dissemination of information is the staff meeting. A meeting is an indispensable venue for presenting and distributing information and, if used effectively, can be a strategic tool for productive decision-making.

**Meeting Elements**

Some basic elements of a productive meeting include the following:

- Meeting objective(s)
- Meeting facilitator
- Meeting participants
- Agenda
- Active participation
- Time management
- Meeting minutes

**Meeting Objectives**

*What is the reason for the meeting and what should the meeting accomplish?* Some of the primary reasons for meetings are to 1) share information, 2) make decisions, and 3) accomplish tasks. Establishing meeting objectives sets the tone and format for the meeting. Meeting objectives should be clear.

**Meeting Participants**

*Who should attend the meeting and what are their roles and expectations?* Inviting the right attendees to the meeting is essential. Meeting attendees should be able to offer input on the meeting objectives. (For example, requesting the presence of a data manager at a recruitment strategy meeting would probably be unproductive because he or she is not

directly involved with the recruitment process; however, requesting the attendance of a community advisor would be useful because such a person would have a clear understanding about community nuances that can make or break study recruitment efforts.)

**Meeting Facilitator**

*Who conducts the meeting?* Typically, the project manager and/or study PI facilitate team meetings because they are directly responsible for making sure that all study procedures are being implemented correctly. The facilitator should ensure that all items on the agenda are covered sufficiently within the allotted time for the meeting.

**Agenda**

*What items will be discussed during the meeting?* The agenda should tie into the overall objectives of the meeting. Each item listed on the agenda should be able to be openly addressed during the designated timeframe of the meeting. Prior circulation of the agenda is extremely helpful.

**Active Participation**

*How can the facilitator maximize attendees' input?* The meeting facilitator should make sure all attendees have adequate opportunities to speak during the meeting. It is important to establish up front that everyone's input is not only valued and respected, but also essential to the successful implementation of the project or study.

**Time Management**

*How long will the meeting last?* It is very important to be considerate of meeting participants' time. Having the meeting start and end on time shows consideration to those participating. If the meeting is stated to last 1 hour, try to keep the meeting on schedule. If it appears that discussion on particular topics is running over, the meeting facilitator may consider postponing additional discussion until the next meeting.

**Meeting Minutes**

*How should meeting items and resolutions be formally documented?* All meetings should be documented through meeting minutes that are disseminated to all meeting attendees. Meeting minutes should include a list of attendees, agenda items and their resolution and/or action. Incorporating an "Action Item" list in the meeting minutes is useful to ensure timely follow up. Generally, meeting minutes should be reviewed and approved during the next scheduled meeting. This process shows that all meeting attendees are in agreement as to the items discussed during the previous meeting.

**Meeting Formats**

A productive meeting can have different formats, such as face-to-face, conference call, or web conferencing. The format or combination of formats chosen for your grant meetings will depend primarily upon attendee geography and available funding and resources, including meeting space and information technology.

*Face-to-Face Meetings*

The benefits of a traditional face-to-face meeting are that all attendees are in the same location, which allows for multi-faceted communication, including body language. The use of body language in a meeting, either conscious or subconscious, can effectively stimulate additional input and discussion and possibly minimize miscommunication.

*Conference Calls*

Conference calls allow people from various locations to participate in the meeting without traveling. A conference call can be extremely convenient, as people can interact individually or as a group from their home or office. Conference calls organized through central conferencing centers offer the added advantage of meeting recordings, which can help tremendously when taking meeting minutes.

*Web Conferences*

Web conferencing is a relatively new meeting format where participants log in to a specified location on the World Wide Web. It can serve as a forum to present data or reports and generate discussion in real-time to online meeting attendees. Web conferencing can be a true complement to face-to-face or conference call meetings by allowing presenters at different locations to communicate with a live audience and share immediate feedback.

# 6. Finalizing Data Collection

## 6.1 Collecting Post-Interview Data

For some projects, there is a need for post-interview data collection; data that have been previously obtained (secondary data) are needed to answer the proposed research questions. A few notable differences for using secondary data are described here.

- **Budgeting** for secondary data collection should always be considered. Secondary data collection is not always less expensive than primary data collection. Project managers should plan ahead for the possible use of secondary data and budget appropriately for purchasing or accessing the data, as well as for preparing the data to be compatible with the current study.

- **Terms and Conditions** for purchasing and using secondary data vary widely. It is important to clarify whether the data are free, can be purchased and owned by

the project, or are allowed to be used only for specified purposes dictated by the contract.

- **Access** to the data is also a consideration. Some secondary data are easily accessible in multiple formats and can either be directly downloaded by or sent to the research team. Other datasets require a programmer or researcher to obtain permission and travel to a secured site. This person may be able to perform analyses on the data only within the secured site. Consequently, the results of the analysis belong to the project, but the data used to obtain the results remain secured. In other cases, the researchers are not allowed direct access to the data but make their request to the source and are charged for the analysis. Most places with large datasets that obtain personal identifiers and personal information have a method for restricting access that is intended to guard the confidentiality of the information. The method that is used has associated costs and time considerations for the project.

- **Documentation** that describes how the secondary data were obtained and cleaned, whether any variables were created, and the method used to create those variables should be provided by the project manager. The research team will need to provide additional documentation that describes their review of the dataset, as well as decisions that were made regarding inclusion, exclusion, and aggregation of the data in creating variables. This process can be extremely time consuming but is vital in describing how the analyses were conducted.

When budget and timeline decisions about the use of secondary data are being made, they should be conducted in consultation with the programmer or researcher who has the most in-depth understanding of the data variables and analysis of the project. The project manager's role is to reflect these needs in the budget and timeline. In addition, the data acquisition process and obtaining the correct forms, signatures, payments, etc. may be the responsibility of the project manager.

### 6.2 Preparing Final Deliverables (Data File Preparation)

The objectives of a research project will be defined early in the study's creation and development. These research objectives will be translated into database creation and maintenance, where the structure and format of the data collection and entry will be consistent with the research objectives and statistical analysis. (For example, if one of the research objectives of a project is to analyze the health perceptions and behaviors of minority males, the data collection instruments used in the project will capture the sex, race or ethnicity of the subject, and include questions involving the health status and opinions of the individual.)

Once data have been collected according to the study criterion, the data will need to be prepared for analysis and interpretation. For the purposes of this section, it will be presumed that data have been collected in a consistent and uniform manner, and once

entered or transcribed into a database package, have been subject to a basic level of consistency and verification.

There are three primary areas of data analysis preparation: 1) developing a comprehensive data dictionary or codebook; 2) performing rigorous data quality checks to ensure data accuracy and consistency; and 3) performing summary statistics on the data to document the data content and structure.

### 6.3 Preparing a Final Methodological Report

A final methodological report will provide investigators and project managers with detailed information about management of the project. The methodological report should include an overview of the study, study design, sampling plan, questionnaire and data collection protocol. In addition, the methodological report may include details about the pretest, main study, data cleaning and processing, a final disposition of samples and sample rates and study limitations. Methodological reports often include all final forms and/or questionnaires used in the fielding of the research study.

### 6.4 Reporting Study Outcomes

Typically, outcome data are reported by the project PI; however, in some cases, project managers may be allowed to report on some aspects of the study findings via scientific conferences, community symposia, and published manuscripts. Regardless of the mechanism through which study outcomes are reported, it is important to portray the target audience in a way that reports the data accurately, and not offensively. Ultimately, the PI makes the decision about when, where, and how to report the study outcomes. The project manager can be an integral part of this process. Be sure to review Section 2 of this document for tips on reporting research findings to the community.