
MANAGING LARGE AND COMPLEX FUNDED RESEARCH PROJECTS

PRC Research Guide

Congratulations! If you're reading this, you are about to launch a substantial research project with external funding. Over the years, we have learned a lot about the complexities and problems that often emerge for PIs managing large and complex projects, especially those involving data collection. These problems usually emerge from issues with documentation, transparency, compliance problems, and management and oversight of large research teams. Such obstacles impede the success of research projects and sometimes lead to serious complications with funding agencies (including the possibility of losing funding) and with the IRB. This guide is designed to ensure the success of your project and to protect you and the PRC throughout the life of your project.

COMMUNICATION—RESEARCH TEAM, ADMIN TEAM, FUNDING AGENCY

- A. PRC advisory group.** The advisory group will include faculty members with significant large project management experience, strong NIH (or other relevant funding agency) experience, IRB knowledge and experience, and large project budget management experience.
- a. The group will meet at least quarterly with the PI and research team to review progress and help address any problems along the way. The advisory group will meet with the PI/research team immediately after funding occurs and prior to project launch.
 - b. Admin staff will also attend quarterly meetings
 - i. Meghan Thomson—as PRC compliance officer
 - ii. Sylvia Celedon—as PRC accounting expert
- B. The research team.** Good communication among team members is essential to the success of a large research project. These projects include co-investigators, graduate students, postdocs, and outside contractors. The following will help with communication among team members.
- a. A project manager (described below) will play an essential role in helping with communication.
 - b. Having clear and transparent expectations about the role of each team member. Put those in writing and discuss them at project meetings.
 - c. Have regularly scheduled project meetings. Most large projects should meet at least weekly with all team members. The PRC admin and computing teams can easily help you set up a regularly scheduled ZOOM/Skype meeting with your team members.
 - d. If there are any differences of opinion among team members concerning compliance requirements, authorship, data dissemination, or (among multi-PI projects) management of resources, you should immediately involve your chair of the advisory group, your advisory committee, or the PRC director. You can usually avoid these differences with clear expectations and good communication—which we hope this plan will you with.

COMMUNICATION—RESEARCH TEAM, ADMIN TEAM, FUNDING AGENCY (cont.)

C. Funding agency. When communicating with the funding agency, it is important to know who to speak with in regard to specific items for your project.

NIH

- Grants Management Specialist – this person is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions.
- Program Official – this person is responsible for the scientific, programmatic and technical aspects of the project
- The Grants Management Specialist and the Program Official work together in overall project administration. [Prior approval requests](#) should be submitted in writing to the Grants Management Specialist (signed by the authorized organizational representative).

NSF

- Questions regarding grant management issues (e.g., allowable costs) should be directed to the Cognizant NSF Grants Official named on the award letter, not the Program Officer. Questions about changes in an award's scope of work or direction should be directed to the Program Officer. Some changes (e.g., remove/add a PI or Co-PI; change in Participant support Costs) require official NSF approval via a Notification and Request in FastLane/Research.gov.

PROJECT MANAGEMENT

- A. Project manager.** Your budget should include a project manager to handle all the documentation needs and to oversee data collection and management tasks on a daily basis. This is essential to proper documentation and assuring the quality of data collection efforts.
- B. PRC finances, budget—**Sylvia as point person.
- C. IRB, funding agency compliance—**Meghan as point person.
- D. Senior PRC faculty member—**will be assigned to chair the advisory panel. The PI/research team will work with the chair of the advisory group to immediately address problems or concerns that arise and to help devise a plan to resolve those concerns. Problems inevitably arise on this kind of project. It is extremely important to identify those problems as early as possible and come up with a strategy to respond to those problems.

DOCUMENTATION. It is very easy to postpone documentation and, the longer you wait, the more difficult it is to adequately provide documentation. This is one of the reasons you need a project manager—to help keep up with the vast amount of documentation that is needed in at least the 4 following areas.

- A. Communication with funding agency.**
- B. Human subjects and IRB.**
- C. Budget, finances.**
- D. Data collection, data quality.**
- E. Data analysis and results.**

TRANSPARENCY. Good communication, clear policies and plans, regularly scheduled research meetings, and great documentation all facilitate transparency. Make it easy for your team to figure out what the rules are, what the game plan is, and each person's role on the team. Make it easy for the PRC admin team to keep up with your project.

COMPLIANCE. In the excitement of launching a new research project, it is easy to overlook the many details that ensure your project is in compliance with the many rules and regulations REQUIRED by the university and by funding agencies. The importance of compliance cannot be overstated! **Of all the things that can go wrong in a research project, falling out of compliance is among the most serious.** If you are not in compliance, you put your own scientific reputation and funding at risk. You also put the PRC and UT at risk.

- Compliance refers to a broad set of guidelines ranging from general guidelines to contractual agreements to regulations governing a type of research like human subjects research.
- Meghan Thomson is the official compliance officer for the PRC. She will help you develop a general compliance plan. This plan must be in place prior to your project launch. This plan will then be shared with the advisory team for your project. This plan focuses on compliance with university and federal rules and regulations.
- IRB and human subjects
 - You must stay up to date with IRB requirements and approvals in order to collect or analyze data. Copies of these documents must be kept on file with the PRC admin team.
 - Any change in protocol must be reported to and approved by the UT IRB before it can be implemented.
 - You must report any unanticipated problems to the UT IRB as soon as you are aware of them.
 - All project staff must be current on CITI human subjects training and conflict of interest.
 - Add Meghan Thomson (EID: meghant) to the list of team members (under "Other") submitted to IRB for your project. You do not want to be the only person receiving important notices about deadlines, renewals, etc.
 - See additional links in the following section on “professional standards.”
- The University of Texas at Austin (University) requires faculty, staff, and students who are or will be involved in the conduct of human subjects research to complete human subjects research training, financial conflicts of interest training, and to submit a financial interest disclosure form. IRB approval will not be provided if these requirements are not met. Both training and the form can be accessed here: [CITI Human Subjects Research Training](#) every three years as well as the [Financial Conflicts of Interest \(FCOI\) Training/Financial Interest Disclosure \(FID\) form](#).

Records Retention. The [UT Records Retention Schedule](#) provides detailed guidance on the retention requirements for records created, received, used, and stored at the University of Texas at Austin. Specific records retention information as it relates to sponsored projects are below:

- Protocols for Research Projects involving Human and animal subjects - 3 years after closed, terminated, completed, expired or settled
- Protocols for research projects - 3 years after closed, terminated, completed, expired or settled
- Research files – proposal, contract, fiscal reports – 5 years after closed, terminated, completed, expired or settled

COMPLIANCE (cont.)

Publications.

- For NIH awards, all publications must comply with the [NIH Public Access Policy](#). Upon acceptance to a journal all publications must be submitted to PubMed Central and must be assigned a PMCID within three months of publication.
- Texas law ([H.B. No. 1295](#)) requires that all publications resulting from sponsored research acknowledge the sponsor.
- NSF requires that either the version of record or the final accepted manuscript in peer-reviewed scholarly journals and papers in juried conference proceedings or transactions (also known as “juried conference papers”) be deposited in a public access compliant repository designated by NSF; be available for download, reading and analysis free of charge no later than 12 months after initial publication; possess a minimum set of machine-readable metadata elements in a metadata record to be made available free of charge upon initial publication; be managed to ensure long-term preservation; and be reported in annual and final reports during the period of the award with a persistent identifier that provides links to the full text of the publication as well as other metadata elements.

PROFESSIONAL STANDARDS FOR RESEARCH. You can avoid many of the problems that most commonly arise on big research projects by following basic professional guidelines. Please read and follow guidelines offered through these links:

- The National Institutes of Health (NIH) offers an online tutorial, "Human Participants Protections Education for Research Teams," at <http://cme.nci.nih.gov>.
- The Department of Health and Human Services' (DHHS) Office of Research Integrity Website: www.ori.hhs.gov.
- DHHS Office of Human Research Protections Website: <http://ohrp.osophs.dhhs.gov>.
- “Five principles for research ethics: **Cover your bases** with these ethical strategies.”
- <http://www.apa.org/monitor/jan03/principles.aspx>
- Responsible Conduct of Research Workshops offered through the Office of the Vice President for Research: <https://research.utexas.edu/postdoc/events/responsible-conduct-of-research-workshops-031119/>.

COLLABORATIONS, COAUTHORSHIP. Large research teams will inevitably juggle multiple publications and collaborations among team members (co-investigators, faculty members, postdocs, graduate students).

- It is important that all team members are aware of each other’s papers and presentations (which should be tracked by the project manager).
- In addition, it is essential to be completely clear with team members about expectations, roles, and co-authorship on collaborative papers.
 - Written agreements on these collaborations will ensure a smooth operation, minimal misunderstanding, and greater productivity. Below, we provide a link concerning best practices for publication and co-authorship: <http://www.apa.org/research/responsible/publication/>
 - “Determining and negotiating authorship.” APA (includes agreement forms and contracts) <http://www.apa.org/science/about/psa/2015/06/determining-authorship.aspx>

WHERE TO GO FOR HELP. If you have any questions or concerns at any point, please ask for advice right away. It is always best to address concerns as soon as possible and to include others in your decision making. This strategy helps to protect you and your project. The PRC is here to help you. We have lots of experience and have probably dealt with similar issues in the past. We will help you figure out whether you need to be concerned and come up with strategies and solutions. The first step is to talk to the PRC director, associate director, or development director. When in the fog of a large project, it can be difficult to see all the possible pathways—we can help you find them!