Social and Behavioral Research:

Best Practices for Research Course Manual

Tool/Resource:	Course manual for the Social and Behavioral Research Best Practices for Research online training (fulfills NIH requirement for GCP training)
Purpose:	To serve as a workbook companion to the online training modules and to aid study team members in applying research best practices to their won studies
Audience:	Study team members interested in learning applying research best practices and those responsible for training study team members on the principles of good clinical practice
Best Practice Recommendations:	• Use the manual as a review tool while taking the course • Use the manual during the study design and/or startup phase to support consideration and adoption of research best practices • Use the manual during study team onboarding or training of new study team members

RESOURCE REVISION HISTORY

VERSION NO.	DATE	SUMMARY OF REVISIONS
V1.0	---	Original
V2.0	Sept2022	Added SBR course branding and introduction; updated each module to reflect current course content and removed resource links from each module and included them in a separate document
V3.0	10Oct2022	Added copyright information to footer
V4.0	10Oct2023	Updated copyright information in footer; updated version number in footer

SOCIAL AND BEHAVIORAL RESEARCH

Best Practices for Research Course Manual

Protocol Title	
Protocol Number:	
Version Number:	
Principal Investigator:	
Key Study Team Members:	
Special Considerations:	

Contents

Module 1: Introduction

This course is designed to familiarize study team members with research best practices as they related to social and behavioral research. This resource manual can be used as study aid during the course itself to help you pass the end-of-module assessments. It can also be used during all phases of a study life cycle, from inception and study design to study close out, to help you and your team integrate research best practices into you daily workflow.

List of Course Modules

Foundations of Research Best Practices

Research best practices for social and behavioral research stem from the international research standard of Good Clinical Practice (GCP) enacted by the International Conference on Harmonization in 1990. GCP is a set of principles designed to support and enable quality research and participant safety; the best practices described in this course represent these principles from the perspective of the study designs, interventions, data, and participant safety concerns more commonly associated with social and behavioral research. It is expected that all study team members will successfully complete GCP or research best practices training prior to working NIH-funded studies (a requirement of funding). **Review your study training logs, is your team up to date on their protection of human subjects and research practices training?**

Definition of Clinical Trial

The 2014 NIH definition of clinical trial is any research study in which "human participants are prospectively assigned to one or more interventions to evaluate the effect of those interventions on health-related biomedical or behavioral outcomes." **Think about your current portfolio of studies. Which ones meet the definition of a clinical trial?**

Study Team Roles and Responsibilities

Social and behavioral research studies may many different roles to fill. Roles and responsibilities are often assigned based on experienced, education and study logistics. It is not uncommon for one person to fill more than one role and have multiple responsibilities. Use the list below to **review how roles and responsibilities are divvied up among your team to help estimate workload and plan for study implementation.**

Study Role and Responsibility	Team Member
Advisory Board	
IRB	
Research Assistant	
Data and Safety Monitoring Board	
Statistician	
Co-Investigator	
Data Manager	
Research Nurse	
Monitor/Auditor	

Study Role and Responsibility	Team Member
Principal Investigator	
Coordinator	
Interventionist	
Sponsor	

Other Notes

Module 2: Research Protocol

After completing this module, you should be able to differentiate the protocol document from other study documents and list the key elements of a social and behavioral research protocol document.

Protocol Document: Defined

The protocol document is the central study document. It describes the WHAT, WHERE, WHO, WHEN and HOW of your study. Contrast your study protocol document with other documents sometimes used instead of a protocol, e.g., grant proposal, IRB application, or manual of operations. **Will the content and level of detail in your protocol document support study conduct in alignment with best research practices and research regulations?**

Protocol Document Content

The organization and content of a protocol document may vary based on study design, and sponsor and institutional requirements. Many institutions and sponsors have protocol templates that outline the key elements. The NIH has a template for social and behavioral research studies. **Compare your study protocol document with the NIH template or other required template. Is your study protocol document complete? Does it include sufficient detail to support conduct under international standards for Good Clinical Practice? Is it written clearly to support scientific rigor and reproducibility and participant safety?**

Challenges to Protocol Accuracy: Inconsistency

Though not recommended, people often copy and paste from other documents when drafting protocol documents. This contributes to inconsistencies within the document that can impact study conduct and lead to protocol deviations and potentially impact participant safety. **Review your protocol document for inconsistencies between sections, and against the original proposal to ensure accuracy.**

Other Supporting Documents

While the protocol document is the central study document, there are several other documents that support study conduct and that are usually designed for a specific audience and/or purpose. **Review the list below of other common supporting study documents. Which ones are relevant to your study? Is the information consistent with and an extension of protocol document?**

- Grant proposal
- Manual of Operations
- Data & Safety Monitoring Plan
- Data Management Plan
- Informed Consent Document
- Publications

Other Notes

Module 3: Recruitment and Retention

After completing this module, you should be able to recognize the importance of reviewing your protocol document for key participant characteristics and begin to develop a recruitment and retention plan for your study.

Recruitment and Retention Process

Recruitment and retention describe your plan and efforts to enroll and retain participants. The participant qualifications should be clearly defined in your protocol document. **Review your study materials and note any confusing criteria or inconsistencies between study documents.**

Successful recruitment and retention are about nurturing relationships with repeat interactions over the course of study. If you have a good relationship with the participant and they feel valued and trusted, they are more likely to complete the study. **Think about how you engage with potential participants. What study team actions or behaviors contribute to a successful enrollment? Which ones are not as successful?**

Once someone is enrolled, **how do you retain them in your study? Are there different strategies for different groups of participants?**

What strategies or resources does your institution offer to help with recruiting and retaining participants?

Recruitment Strategies

There are many strategies when it comes to recruiting participants. These should be appropriate and relevant to your desired study population. Using multiple strategies for the same study will increase your chances of recruiting and enrolling a diverse and representative study sample. **List strategies that have worked for you in the past. What new strategies might be worth a try?**

Which of these strategies could you apply to your current study? Which new ones might be worth trying? Are there any unlisted strategies to consider? Add them to the appropriate box.

In-person	Print	Online
• Advocacy groups • Community events • Clinics • Promotional items (swag) • • •	• Letters • Flyers • Brochures • Print ads in newsletters, etc. • • •	• Website postings • Clincaltrials.gov • Search engine advertising • Social media • • •

Retention Strategies

A comprehensive recruitment plan also includes retention strategies, or those actions and behaviors you undertake to keep participants enrolled through the designated end of their participation. Retention strategies should be thoughtfully planned and tailored to your study population. **How do you accomplish each of the following? How do you ensure your participants feel valued?**

- Build trust with your participants
- Check-in (should be outlined in your protocol document)
- Be sociable

Review your recruitment and retention plan and practices. **Are there practices that might come across as coercive or applying undue pressure?**

Recruitment and Retention Considerations

There are multiple considerations to keep in mind when recruiting and retaining participants. It will be important to weave these considerations into practice from the start. **Develop or review your current recruitment and retention plan from the following perspectives.**

- Ethical considerations
- Cultural/ethnic/racial considerations
- Characteristics of the recruitment setting
- IRB approval
- Plan if a participant drops out
- How did you hear about us?

Other Notes

Module 4: Informed Consent

After completing this module, you should be able to identify the required elements of informed consent, have a set of tools to use to prepare for and conduct informed consent, and be aware of special situations that may have different consent requirements (e.g., children or legally authorized representatives, etc.).

The Informed Consent Process

Informed consent ensures that participants know exactly what is going to happen within a study, so they can make an educated decision about their participation. Below is a list of critical elements for the informed consent process that were outlined in this module. **Are there any other elements you should, or would like to, include? Based on your study design and population, are there any accommodations you will want to make during the consent process to ensure understanding and informed decision-making?**

Element	Discussion Tips
Introduction (Study title, names, credentials)	• Highlight voluntary nature of research and reiterate the importance of understanding the information presented during the informed consent process • Explain that the project is a research study, and if necessary, how it may differ from clinical care
Key Information (Summary of essential information to support informed decision making)	• Reiterate the importance of understanding what the study is about and what participation entails
Purpose (Study goals)	• Use plain language and ask participant to paraphrase for you to gauge understanding
Qualifications to Participate (Eligibility and exclusion criteria)	• Highlight key criteria • You do not need include the exhaustive list of eligibility criteria
Design and Duration of Study (Study expectations, procedures, assessments, timeframes)	• Present study activities in chronological order • Use tables, charts, and figures to convey information

Element	Discussion Tips
Statement of Voluntary Participation (Highlights voluntary nature of research)	• Explain what a participant should do if they want to withdraw from the study • Tell them how to contact the study team
Alternative Treatments (Options to participation)	• Sometimes the option is simply to decline to participation
Possible Risks and Discomforts (Known and expected risks of participation)	• Use plain language to describe the risks and the study's approach to minimizing them • Acknowledge there may be unknown risks
Benefits (Direct benefits to participant, benefits to society)	• Avoid overstating the benefits of participation • Remember that incentive payments and token gifts are not considered benefits
Incentives or Payments (Financial or other gifts)	• Explain the incentive structure and outline what the participant must do to receive an incentive • Distinguish between what is paid for by the study and what is the responsibility of the participant
Research-related Injuries (Process for reporting)	• Explain what a participant should do if they experience a change in health during the study • Tell them how to contact the study team and ask them to paraphrase for you to gauge understanding
Confidentiality (Privacy protections and limits)	• List the ways you will protect a participant's information, including specimens • Explain what happens to the information after the study is over and the implications (e.g., data in a repository, future research, data stored in 3rd party applications, etc.)
Contact Information (For PI, study team, IRB)	• Include full address, including email and phone; let participants know the best way to contact the study team • May want to note the participant's preferred contact method as well

Think about your planned informed consent process. **Will you use elements of e-consenting, traditional paper document with a signature, will the consent dialog take place in person or virtually? Jot down any special considerations and how you will support information sharing and informed decision making.**

Take a moment to find and **review your IRB's or Sponsor's version of an informed consent template. Consider whether a specialty template, if available, makes sense for your study. Make note of the website address. Write down any questions or comments you have in the space below. Confer with your peers or mentors and connect with your IRB to get the answers.**

One of the most important things to convey is the difference between research and clinical care and what that means for the participant. **What things can you say to explain this difference?**

Preparation

Whoever is conducting the informed consent process must be able to explain every element. This will help ensure that participant questions can be addressed. Remember, the informed consent process is a dialogue. Preparing for your first potential participant visit is critical to the informed consent process. **What are some ways you can prepare yourself and your environment for a successful conversation? Consider the differences in your approach for phone or video-based consenting, and for e-consenting.**

Participant Conversations

The first encounter with potential participants sets the stage for the entire study. **What are some key phrases or wording that will be important for you to include in your own studies?** We have given you a general checklist below of the items you will need to cover:

- ✓ Ensure privacy during the conversation and protect privacy and confidential data
- ✓ Review all of sections of the consent document in full with participants and translate any legalese or medical terms into plain language
- ✓ Use a checklist to help ensure that all critical elements are covered
- ✓ Use open-ended questions and paraphrasing methods to ensure participant comprehension
- ✓ Make sure you use the most current informed consent document
- ✓ Make sure you document that consent was provided in a manner suited to your study (i.e., signature vs. verbal consent and documentation by study team vs. electronic signature, etc.)
- ✓ Provide a copy of the consent to the participant and document that the process is complete according to your institutional or sponsor requirements
- ✓ Use culturally and linguistically appropriate consent materials for your study population

Other Considerations

Be mindful of individuals and populations at risk for coercion including children, teenagers, cognitively impaired individuals, prisoners, and pregnant women. **Does your study include any vulnerable populations? What adaptations to your consent process might be needed? What other questions do you have?** Review your IRB's guidelines surrounding precautions and protections for these individuals for answers.

Will your study include participants who may have a legally authorized representative (LAR)? How might this impact your consent process?

What can you do to protect against coercion and undue influence to participate? What are the possible sources of coercion and undue influence in your study?

Other Notes

Module 5: Privacy and Confidentiality

After completing this module, you should be able to define privacy and confidentiality, list strategies to protect participants privacy and confidentiality, and know how to identify and report breaches in privacy and confidentiality.

Privacy and Confidentiality Overview

Privacy is as an individual's right to control information about themselves. Confidentiality is considered an extension of privacy. It refers to how you keep the actual information that is gathered: who can see it, who handles it, and how it is stored. **What are potential privacy and confidentiality concerns related to your study?**

What ideas do you have to address them?

Protection Strategies – Privacy and Confidentiality

Strategies for maintaining privacy and confidentiality are best laid out in the initial design stages of the study, as it will take careful planning to anticipate privacy needs. **How can you be sure to protect participant privacy needs in the following situations?** Choose one or more that might apply to your own study.

- Environment
- Focus Groups and Group Interventions
- Digital Communication
- Sites outside the lab or clinic
- Home visits
- Wearables

Data security is imperative to maintaining confidentiality. Never store information on a flash drive or other type of portable storage device and be sure to keep all file cabinets locked and computers password-protected. Below are the privacy and confidentiality protection strategies discussed within this module. **Which one could you improve in your own study?**

- Data collection
- Data security
- Certificates of Confidentiality (issued by the NIH)
- Password protection
- Study team access
- Electronic backup
- Recording restrictions
- Transcripts
- Data sharing

Does your institution have any policies regarding data security when data is being transferred using a portable storage device? What about cloud-based storage? What about data stored on a third-party's site (e.g., Fitbit® or continuous glucose monitors, etc.)?

Documenting and Reporting

You must begin with a detailed plan that has been communicated with each study team member. Every person on the staff must know how to identify a breach in privacy and confidentiality and what to do when it happens. **Visit your IRB's website and note any documentation and reporting guidelines in the event of a breach in privacy or confidentiality.**

What questions do you still need to discuss with your study team, IRB or IT team regarding privacy and confidentiality?

Other Notes

Module 6: Participant Safety and Adverse Event Reporting

After completing this module, you should understand how to apply the definition of adverse event to your study, and know how to identify, document and report adverse events and harms in social and behavioral research.

Participant Safety and Adverse Events Overview

In this course, an Adverse Event, or AE, is defined as any untoward medical occurrence that happens during the study, but that may or may not be caused by the treatment intervention. Note that your sponsor or IRB may use a slightly different definition. Visit your own IRB's website. **How does your institution or sponsor define an AE?**

Note some potential adverse events for your study and the processes you have in place to identify them.

Reporting Adverse Events

How and when you report adverse events to the IRB will depend on both your institutional and sponsor guidelines. In general, be sure to note the date of an incident, whether it was expected, its relation to the study, a description of what occurred, what was done to address it, and how it was resolved. Use the space below to **make notes about an adverse event you have encountered in one of your own studies.**

Data and Safety Monitoring Plans

All studies should outline how participant safety and data integrity will be upheld. The nature of the monitoring and oversight for a study depends on the risk level and complexity, and any applicable institutional or sponsor guidance. Some studies require a full Data and Safety Monitoring Board whereas others may rely on a one or two independent safety monitors or the PI to provide participant safety oversight. **Use the space below to list key elements of your data and safety monitoring plan.**

Other Notes

Module 7: Quality Control and Assurance

After completing this module, you will be able to articulate the importance of quality control and assurance in social and behavioral research studies. You will be able to identify potential bias and implement strategies geared toward upholding data integrity.

Defining Quality Control and Assurance

Quality Assurance or QA reflects the planned and systematic actions established to ensure that the research is performed, and the data are generated, documented, and reported in compliance with Good Clinical Practice and regulatory requirements. Quality Control refers to the implementation of the techniques and activities within the Quality Assurance plan. **Does your study have a Quality Assurance plan? What quality control measures are included in your QA plan?**

Importance of Quality

Data quality and control is everyone's responsibility. Besides recording study outcome data, it is important to note information about how the data were collected, especially if there was something different about the collection or recording process. **What is your study team's process for recording and reporting anomalies?**

How does your team systematically check the quality of your data? If you do not have any methods in place, what strategies can you suggest?

Bias

Bias in research studies may influence raw data or the interpretation of data. Whether in the study design, data collection, or analysis phase, bias can lead to errors, which makes it harder to evaluate the true association between an intervention and study outcomes. **What are sources of potential bias in your study?**

Strategies

Throughout the course of a study, make note of lessons learned and how you should do things differently. Take advantage of those who have gone before you. **Pick one of the Quality Control and Assurance strategies highlighted in this module and outline how you could implement it in a study you are involved with now.**

- Create structured procedure manuals – anticipate potential challenges to study integrity and provide recommendations
- Develop a data management plan – describe how data will be sampled, collected, handled, analyzed, and published

- Develop standard rules for recording data – whether in a procedure manual or a data management plan, include instructions for data documentation and entry
- Check your work – use checklists and audit tools to monitor for incomplete or incorrect data
- Sign your work – documenting who did the work provides accountability
- Audit data collectors – regularly review study team members and processes for data collection
- Audit participant files – regularly review files for incomplete or aberrant data and for compliance with Good Clinical Practice and regulations
- Make decisions – stipulate who will make decisions about data conflicts or questions related to study implementation
- Communicate as a team – use regular meetings and study logs to share information

What resources are available to you if you have questions? Are there electronic tools or platforms available at your institution? Think about which colleagues you can approach for mentorship in QA/QC.

Other Notes

Module 8: Research Misconduct

After completing this module, you will be able to define, recognize, and understand how to report research misconduct.

Misconduct Overview

Research misconduct is defined by the NIH as any "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results." The intent to falsify, fabricate or plagiarize is pivotal to determining if someone has committed misconduct. For an official finding of misconduct, the act must be committed intentionally, knowingly, or recklessly. Use the space below to **describe situations in your own research where instances of misconduct might arise. Describe instances of honest mistakes that may be confused with misconduct.**

Fabrication
Falsification
Plagiarism

What questions do you have about research misconduct? Note any items you would like to address with your IRB.

Misconduct Behaviors

Falsified research is not something that exists in a vacuum. Research results have the potential to become widely known and have a real, tangible impact on the public. Examples include:

Fabrication

- "Making up" participants
- Filling in or making up data or answers for participants that were never recorded

Falsification

- Intentionally leaving out or changing data
- Manipulating graphs or charts
- Intentionally leading participants to answers

Plagiarism

- Copying someone else's work or verbiage
- Not appropriately citing someone else's research

Are there any other behaviors that might be helpful for you to note?

Reporting Misconduct

Everyone, from a PI to a part-time research assistant, must be held accountable when it comes to reporting suspected misconduct. If you see something, say something. Take a moment to **research and note the research misconduct resources at your own institution. For instance, does your institution have an office of research integrity?**

Use the space below to **make notes about the three-step fact-finding and reporting process for research misconduct as it relates to your own study.**

Understand the situation
Bring it to someone you trust
Report up the chain

Preventing Misconduct

While research misconduct is rare, it does happen. Make sure all team members understand what is expected of them and what to do if they see something that might be misconduct. Upholding the study integrity is the entire team's responsibility. Use common sense and use the three-step method just discussed to assess and report potential misconduct.

Below are several best practices to help prevent misconduct. Be sure to **note any others that you feel would be useful to implement in your own environment.**

- Establish appropriate systems to help team members understand how the study is to be implemented and how data is to be entered
- Discuss issues and solutions openly at staff meetings
- Implement quality improvement systems (i.e., double data entry, secondary data review) to monitor and catch errors

Other Notes

Module 9: Community and Stakeholder Engagement

After completing this module, you should understand why it is important to engage communities in research, ways to engage members of the communities of interest to your research into your research planning.

Understanding Context

In this course, you learned about underlying root causes of health inequities that shape what are called the "social determinants of health". These are the conditions in which people are born, live, learn, work, play, worship, and age. Negative social determinants can impact someone's health, functioning, and overall quality of life.

Social determinants of health (neighborhood and built environment, social and community context, education access and quality, economic stability, and health care access and quality) are important factors to consider when designing research studies. These factors affect how relevant the research is to your community of interest as well as the ability for your research to translate into practice in real-world settings. **What social determinants are most relevant to your research or to a current study you are working on?**

Defining Community and Stakeholder Engagement

While it is important to consider the social determinants of health in early stages of planning research, it is essential to engage community members and stakeholders who will be affected by your research. Communities may be defined by geographical proximity, but more broadly, can also be defined as people who have common interests, identities, or health conditions. Community partners may be at community-based organizations, agencies, or institutions, but may also be individuals. Stakeholders can include patients living with a particular condition, family members, or others, such as health care providers or payers. **What types of communities, community partners, and stakeholders are important to consider when designing and planning your research study?**

What resources are available at your institution that support community and stakeholder engaged research?

Frameworks of Engagement

Community-Based Participatory Research (CBPR) and Patient Centered Research are two frameworks used to engage community members in research. CBPR engages community members and stakeholders in all aspects of the research process in an equitable way with shared responsibility. The focus is on action to promote change and typically focuses on historically excluded communities. Patient-Centered Research focuses on patient and stakeholder-identified priorities and is a little more flexible than CBPR in how it is applied. **Think about how CBPR or Patient Centered Research can be applied to your research. Articulate a strategy for engaging community members/stakeholders in your research below.**

Benefits of Community and Stakeholder Engagement in Research

Benefits of engaging communities and stakeholders include the ability to reduce health inequities, to enhance relevance of the research, have more sustainable interventions over time, and to build capacity in the organization and by enhancing knowledge and skills for both academic and community members. **Describe what benefits you have seen or can foresee in engaging communities and stakeholders in your research.**

Community and Stakeholder Advisory Boards

Community and Stakeholder Advisory Boards are an option for engagement of these groups in the plan, execution, and dissemination of study findings in a research study. Boards can be study-specific or work across several studies. Several strategies are suggested to ensure that engagement is optimal. Strategies include identifying diverse members, co-creating governance (rules), providing fair compensation, training board members, and ensuring accessibility of the meetings. **Do you have a community or Stakeholder Advisory Board you work with on research initiatives? If so, describe how these strategies are applied in your situation. If not, list a few strategies that you think are especially important to consider and apply to your research when creating a Board.**

Practical Strategies and Tips

Good practices for community engaged research include attention to planning, logistics, approach, and resources and results. The table below outlines ways in which you can address these areas.

Focus Area	Good Practices
Planning	• Ask the community to identify needs and priorities • Consider community perceptions • Identify opportunities for co-learning • Acknowledge diversity within communities
Logistics	• Consider accessible meeting locations • Provide fair financial consideration • Communicate clearly
Approach	• Engage with humility and a willingness to learn • Ensure a diverse study team • Consider implicit bias training • Build and nurture long term relationships
Resources and Results	• Build community capacity • Share access to materials, training, and university resources • Engage partners in creating a dissemination plan

Think about your own research or research in which you are part of the team. Choose a focus area that you may not attend to as much as the other areas and list some ways in which the good practices from that focus area could be applied to the research.

Other Notes

Module 10: Conclusion

In this course, you viewed modules that discussed research best practices from the perspective of social and behavioral research. Use the space below to **list any lingering questions or plans for incorporating the practices and strategies outline in the course.**