Good Clinical Practice (GCP) for Social and Behavioral Research *FIELD GUIDE*

Based on NIH's eLearning Course[1]

The goal of this course is to introduce good clinical practice (GCP) principles to clinical and/or community-based research investigations involving human subjects as they specifically apply to social and behavioral research. We have tried to simplify the presentation of GCP as much as possible to make it more accessible to data collectors and study team members for whom the CITI or *MyLearning* GCP courses are not appropriate or not accessible.

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[1] https://obssr.od.nih.gov/training/web-based-learning/good-clinical-practice-for-social-and-behavioral-research-elearning-course/

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I. INTRODUCTION

IRB Approved Research

Before discussing GCP, one must understand the importance of the Institutional Review Board (IRB). Clinical researchers may not conduct research involving human subjects without IRB approval. The IRB approval is not a "general approval" to allow the research to move forward. Rather, it is a "specific" approval, meaning that the terms of that approval are limited to the procedures outlined in the research protocol. When a researcher submits a protocol to the IRB, it's like a contract proposal. The terms of the protocol may be negotiated during the review, but once the IRB approves the protocol, those terms are set in stone. The researchers may not change or deviate from the protocol without prior approval from the IRB.

What is Good Clinical Practice (GCP)?

GCP is a set of 13 principles that help ensure that quality research is being conducted and that participants in research are protected. The principles were established by the International Conference on Harmonization (ICH) in 1990 to define the minimum standards expected for clinical trials involving human subjects. Although these principles were written with drug, device, and biological studies in mind, most of these principles also apply to social and behavioral research. This guide describes key GCP principles and how to implement them in social and behavioral research.

A New, Expanded Definition of "Clinical Trial" Includes Social and Behavioral Research

You may be asking yourself: "If GCP applies to clinical trials, why do I need to learn about them? I'm not conducting a clinical trial to test a drug, device, or biologic."

In 2014, the NIH expanded the definition of a clinical trial to include "any research study in which one or more human subjects are prospectively assigned to one or more interventions to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes." This broader definition includes many social or behavioral interventions and research teams must provide the same assurances for participant safety and quality research that other clinical trials do when following GCP.

GCP represents "Best Practices"

The big question is: Why should you implement what you'll learn through this guide? Studies that are designed and executed in accordance with best practices often run more smoothly, better protect research participants, and reduce study non-compliance. Additionally, data collected and analyzed at the end of a well-run study are often more complete and accurate, resulting in high quality, reproducible study findings.

II. RESEARCH PROTOCOL

What is a Protocol?

There are three documents associated with a research study that often get confused: the *grant proposal* which outlines the science behind a study for the purposes of receiving funding; the *IRB application* for scientific and ethical review that focuses on participant safety; and the *clinical protocol (or more generally, "study protocol", or just "protocol")* that is used to guide the actual conduct of the study from start to finish. The protocol serves as the team's guide for conducting the study and provides operational detail. All researchers, including those conducting social and behavioral research, should always adhere to rigorous standards when developing protocols and processes for their studies.

Common Protocol Elements

There are common elements across IRB protocols, and you should check the templates available at http://www.jhsph.edu/offices-and-services/institutional-review-board/applications-and-forms/research-plans/index.html, for the specific format and content required by the JHSPH IRB. At a minimum, IRB protocols should contain the Objectives, Methods, Quality Control and Assurance, Ethics/Protection of Human Subjects, and Data Handling and Record Keeping. A brief Background and Significance section is also typically included, since an IRB evaluates whether there is a scientific basis to the study that would justify the human participation. The protocol should include a clear description of the study intervention (if applicable) and who is responsible for the study implementation. As all clinical trials involve some level of risk to the participants, the IRB looks at the potential significance of the study to ensure this risk is reasonable, given the potential scientific impact.

Supporting Documents for a Study

There are many documents used by study teams to help support their study efforts:

Standard Operating Procedures (SOP) – step-by-step instructions for all applicable study activities. Helps guarantee tasks are completed in a standard way and ensures all participants receive the same treatment. Other terms for this type of document include "Manual of Operations" or "Manual of Procedures."

Data Safety Monitoring Plan – outlines the steps that will be taken by a study team to ensure the safety of participants and the integrity of a trial's data. All clinical trials require this document.

Finally, there are a few additional resources that can help study teams to demonstrate quality research practices and transparency during a clinical trial. The use of the Consolidated Standard of Reporting Trials or CONSORT checklist and Flow Diagram is a process that is increasingly being adopted in medical publications as a way to evaluate the scientific quality of a study. Specifically, the CONSORT Flow Diagram demonstrates how participants move through the study, when and why dropout is occurring, and whose data remained in the final data set. CONSORT can be particularly helpful in the planning of how to collect data in a study.

III. FOLLOWING THE STUDY PROTOCOL

What is "Study Fidelity"?

"Study fidelity" refers to the consistent adherence to the protocol in carrying out the study procedures. The idea is that you, as a study team member, have a study plan to follow and you're sticking to it. Every study team member should deliver the study intervention(s) in the way the IRB protocol specifies, so that all participants are exposed to the study procedures, as planned.

One method of ensuring study fidelity is to record study team interactions with participants and observe whether or not these interactions are consistent day to day, and participant to participant. It is important to track data back to its source and fully understand the circumstances surrounding its collection. Who collected the data and when? Understanding and recording these details helps ensure rigorous, quality data, and aids in satisfying audit requirements. Ignoring or skipping steps reduces study fidelity and can cost time, money, and the credibility of the study findings.

What are "Protocol Deviations"?

Deviations will likely occur during your study. In general, "protocol deviations" are any departures from your IRB approved study. If you think that your team has completed the study without a single one, it is likely that something has been missed. Deviations may range from missing pages of a survey to missed study visits. Deviations occur when IRB approved procedures are not followed exactly or when events do not go as planned. They also include errors by study team members, such as using the wrong questionnaire or consent form. A deviation from the protocol need not directly involve study participants; for example, a deviation from protocol-indicated data security procedures would also be considered a protocol deviation.

JHSPH policy distinguishes between protocol deviations that are administrative or minor, and those that are more serious and could put the safety of one or more participants at risk or could adversely affect the integrity of the study. The more serious departures may constitute "Serious non-compliance" that requires prompt reporting to the IRB. "Protocol deviations" are "administrative or minor" departures from the protocol that may be reported with your progress report. In general, these reports are accepted so long as there is a corrective action to prevent recurrence. If a study continues over time to report deviations without correction, that pattern may constitute protocol "non-compliance". IRB will consider whether those reports constitute "continuing non-compliance", which if funded by U.S. agencies, could require reporting to the Office of Human Research Protections. Review the IRB's policies on Reporting and Non-Compliance.

Recording and Reporting Protocol Deviations

The study team should record all minor and administrative protocol deviations. You choose the process of recording; you may use an old-school method of tracking, using pen and paper. Or you may use a spreadsheet. Whatever the method, make sure you and everyone else on the study team sticks to it. Tracking deviations may help explain otherwise unexpected data down the road.

Minimizing Protocol Deviations

The best way to minimize deviations is to improve communication about when they occur. Begin by acknowledging that some are inevitable; explain that sharing knowledge about them can help improve the study. Supervisors should react to timely reports of deviations in a positive manner in order to inspire a culture of open communication among team members. Everyone should be on the same page about how to recognize and report a protocol deviation. It's critical that everyone on the study team learn to recognize deviations and be encouraged to report them when discovered.

IV. RECRUITMENT AND RETENTION

Recruitment and retention are the efforts made by a study team to identify, enroll and retain participants for a study. Only people who meet the criteria for being included in a study may participate; they meet study *inclusion criteria*. The exclusion criteria list factors that cause people to be ineligible to participate. People interested in the study but who do not meet the inclusion criteria cannot participate in the study, no matter how much they would like to. You may not enroll someone in the study who does not meet inclusion criteria.

The actual methods used to identify, enroll and engage participants will vary as they are based on the participant population, the study questions/focus, and the overall design/context of the study. For example, if you are hoping to recruit older adults, you are unlikely to focus your efforts on a social media campaign; you may use print materials (letters, flyers, posters, etc.) or identify places for in-person recruitment. When thinking about a recruitment strategy, you should consider using multiple sources. This will help ensure you meet your recruitment goals.

Recruitment and retention should be based on developing informed and respectful relationships with potential participants and those who enroll in the study, throughout the course of the study. Throughout recruitment process, and for the remainder of the study, researchers and other study team members must always be completely open and honest about who they are, and what their involvement in the study is. If you have a good relationship with your participants and they feel valued, they are more likely to continue to participate in your study, which increases the value of the study to all those who participate and society at large. Implementing and adhering to a well-designed recruitment and retention plan also helps to ensure that a diverse population of participants is recruited and retained, which also increases the benefit of the study for a broader range of people, and balances its burden to participants.

Ethical Considerations to Think About in Designing and Carrying out Recruitment and Retention Efforts

- *Standardization:* Develop and use written scripts in staff training that they will use in each planned interaction to recruit and consent participants. This helps ensure that each person is communicated with in a consistent manner, ensuring fairness to all and fostering the success of your study.

- *Process/Recruitment Language:* During recruitment, it is important to avoid statements/actions/incentives that potential or actual participants could interpret as pressure to enter or stay in the study, e.g., pressuring to enroll, stressing payment, offering too much payment, advertising the study as a “treatment” or “cure”. Make sure recruitment materials are appropriate and that they clearly indicate that they are advertisements for a research study. If you are actively contacting potential participants (i.e. in contrast to passive recruitment), let them know how you obtained their contact information, as they have a right to know. Clearly communicate that participation is voluntary and participants can stop participation at any time.

- *Cultural/ethnic/racial considerations*: the design of recruitment materials and training should reflect sensitivity to the likelihood that participants may differ in their cultural, ethnic, gender, and racial backgrounds.

- *Recruitment setting*: Consider the nature of the study and potential participants when determining appropriate recruitment settings. The privacy of the participant must always be protected. Be aware of the participant's current situation. Are your recruitment efforts distracting participants from other things they should be focusing on? Do they have time to be recruited? If you are going into a community or a facility, your IRB protocol should explain how you will work with the local community leaders or get the permission of those who manage the facility for you to do so.

- *IRB approval*: All recruitment materials and methods to foster retention must be reviewed and approved by the IRB before you use them. Any changes to these materials and methods must be submitted as amendments to the IRB for review and approval.

V. INFORMED CONSENT COMMUNICATION

Overview of Informed Consent Process

"Legally effective informed consent" involves providing an individual the opportunity to consider joining a study under circumstances that:

- explain the study purpose and what is expected of participants in language understandable to them
- allow sufficient opportunity to ask questions
- minimize the possibility of coercion or undue influence.

Participants should know exactly what procedures they will undergo (including if/when applicable: drug administrations, monitoring, invasive / non-invasive procedures, observation, interview/discussion, audio/video recording, specimen collection, etc.) as part of participation in a study so they can make an informed, voluntary decision about whether or not to participate. The consent process should make clear that the study involves "research"; and avoid when possible/practical the use of words such as "treatment", "therapy", or "medication", if their usage implies medical benefit. Standard care "treatment" may be described as such; "research" interventions are experimental in nature and should not imply efficacy unless previously shown to be effective. Informed consent in many studies can rightly be considered an ongoing process; for example, in longitudinal studies, or those with multiple contacts, participants should be reminded, at each contact, what procedures/activities are involved and that they have the choice to continue participation. They may need to be re-consented if there are significant changes to the study, new knowledge of greater risk, or in the balance of value to burden. Regardless of how consent is acquired – whether it be through a written document, an oral statement read to the participant, a video, an interactive computer module with comprehension checks, speaking books or patient information sheets – all consent materials must be approved by the IRB in advance of their use. This also includes materials translated into other languages.

The Consent Document

Again, the informed consent document must provide a full disclosure of what the study involves so that study participants know what they are signing up for. It is imperative that you review the entire informed consent document with participants and use best efforts to ensure that they understand exactly what you are telling them before proceeding with any aspect of the study.

- *Begin with your IRB Template*
  Use a consent form template provided by the IRB, as it should include all required elements. Keep in mind that many terms may not be familiar to participants, so keep language simple. A good rule of thumb is to write using a sixth to eighth grade reading level; it should be tailored to the needs of your study population.

- *Elements of Informed Consent:* There are a number of elements that must be included through the process of consent. When developing consent process materials, you might consider using a checklist to ensure all these elements are covered. Elements include:
  - Introduction
  - Purpose
  - Eligibility
  - Design and Duration of study
  - Voluntary Participation
  - Alternative Treatments (if relevant)
  - Possible Risks and Discomforts
  - Benefits
  - Compensation
  - Policy regarding research related injuries (if relevant)
  - Confidentiality
  - Contact Information

Using the Correct Consent Document

The study team member conducting the consent discussion must use the approved, stamped consent document approved by the IRB. If the consent documents originally approved by the IRB change and those changes receive IRB approval, the study team must ensure that its members have access only to the new, revised stamped consent documents and use the correct versions. The study team must adopt SOPs to clarify this process.

The Consent Discussion

The consent discussion should be delivered by a qualified, trained member of the study team, in the potential participant's preferred language, and in a location that protects the participant's privacy and allows a quiet conversation with sufficient time for the potential participant to ask and have questions answered. Even if the potential participant has read the consent document already, you should review the critical sections with the participant and encourage him/her to ask questions along the way.

Be conversational:

You may be conversational in your recitation of the informed consent document. While all the elements must be discussed, the details may be fleshed out in a conversational manner. Show open and inviting body language, and always maintain eye contact to make the participant feel comfortable enough to ask a question. If you ask a question of the participant, try to use open-ended questions to encourage an open dialogue.

Check for participant understanding:

Keep in mind that sometimes it may be difficult to assess how much the study participant understands. Issues like mild cognitive impairment, illiteracy, and hearing or vision disabilities may also affect comprehension. Remember to keep your written and oral language between a 6th and 8th grade reading level. This will keep concepts simple and clear. Remember, just because you've walked through the consent materials, a potential participant may still not fully understand everything. Ask questions surrounding different elements of the form or have the participant explain the study in their own words. Be patient and allow ample time for questions. Use any IRB approved educational materials or comprehension assessment tools if they are approved as part of the recruitment/consent process. Be alert to cues that may indicate that the participant cannot read.

Maintain confidentiality:
The decision to participate must be made by participants on their own, so try to remove all outside influences as appropriate. Clarify that confidentiality (the protection of personal information about the participant) and privacy (respecting the participant's control over her information) are important and valued aspects for participation in the study. Many participants have concerns about confidentiality, and different studies require different types of information to be collected from participants. Even though it is a required part of the informed consent document, explaining privacy and confidentiality to participants in a way they understand can help put them at ease about their participation.

Coercion and Undue Influence:
No matter what, do not pressure the participant. Do use language like "ask for their help" by joining the study as it communicates a need of yours that they can satisfy. Be careful not to push them into participation. Respect any potential reservations and talk through any questions participants might have. If the study team is also provides clinical services to the potential participants, clarify that those services will remain available regardless of whether the individual agrees to participate in the study. You must never use undue influence or coerce anyone into agreeing to participate in a study!

Obtain signatures (as applicable):
If the IRB has approved a consent process that involves a signature, once you believe that the participant understands the material and agrees to join the study, obtain the signature from the participant, guardian, or legally authorized representative. The participant should be given a copy of the informed consent form. If the participant is a minor, you generally must obtain a signed parental or legal guardian permission; if cognitively impaired, from a legally authorized representative (LAR). Study team members must NEVER sign or date documents for the participant.

The original signed and dated consent form should be retained in the study record for as long as the IRB requires. It is also a best practice to document the following information (for example in a study chart, study log or tracking form, or electronically with the participant's study record):

- the informed consent process
- where the consent process occurred
- who was present
- participant questions and the given answers, and
- a confirmation that the participant was given a copy of the signed informed consent document.

These details help substantiate the interaction with the participant if it is ever challenged.

Ensuring ongoing consent at subsequent visits: Allow time before each visit to remind participants what they will be doing, answer any questions they may have and confirm that they want to continue participating in the study.

Things to Think About

Vulnerable Populations
There are special regulations and ethical considerations for vulnerable populations, such as children, teenagers, cognitively impaired individuals, prisoners, and pregnant women. These populations require additional protections because their capacity to consent may be compromised by age, mental capacity, legal status, or considerations for the fetus. These considerations affect the consent and documentation process. Make sure to review the IRB's guidance for vulnerable populations.

Consent vs. Assent

What's the difference between consent and assent? Only adults or legal guardians may provide legally effective informed *consent* to participate in a study. Consent forms may only be signed by adults who have reached the legal age of majority in the study's jurisdiction, or are minors who are otherwise empowered to consent for themselves in the local jurisdiction (e.g., are treated as adults). Since minors may not provide legal consent to participate, IRBs require Parental Permission from the biological parent or legal guardian to allow a child to join a research study. "Assent" is agreement by a minor, typically those 7 years and older, to participate in a study; most studies involving children as participants require assent. The assent process gives minors the opportunity to convey their own independent decision about participation in a study. For younger children, it may mean "cooperation" as opposed to explicit agreement. Assent may be provided with or without a child's signature on a form. Different assent forms may be required for a single study, depending on the ages of the children enrolled. Consult your IRB's Policies and SOPs for more details about assent, informed consent, and parental permission forms.

Undue Influence, Coercion and Payment

Are participants making the decision to participate in the study freely? The risk of undue influence or coercion from family members, friends, faculty advisors, professors and healthcare providers is real. "Undue influence" involves pressure to join a study or promise of an excessive benefit; "coercion" involves the threat of an adverse consequence if you don't join a study. A payment that is inappropriately high may induce an individual into joining a study and taking a risk that he or she would otherwise not take. The payment for participation should be balanced, taking into consideration the participant's time involved and inconvenience as well as the non-financial benefits participants will receive. Payment is not "compensation" in the sense that no one can accurately value the time a participant contributes to a study; it is more akin to a "token of appreciation".

Using the Wrong Consent Form Template

Because informed consent is so important, and we spend a great deal of time developing a process and refining the consent documents, using the wrong form threatens the integrity of the consent. It is important to have procedures in place to ensure that the final approved and stamped version of the informed consent document/material is used. Research staff should be trained to check prior to administering the consent process that they are using the current stamped version of the consent; this is especially important in studies where IRB-approved changes/updates to the consent are made during the conduct of the study.

Plan for participant drop-out

Have a plan in place if a participant drops out or is lost to follow-up. Will you need to recruit another participant to replace the one who dropped out? How will their data be handled going forward? This information should be included in the protocol document.

VI. PRIVACY AND CONFIDENTIALITY

What is Privacy?

Privacy can be defined as an individual's right to control information about themselves. In the context of social and behavioral research, privacy might refer to physical, biological, behavioral, and other psychosocial information. Certain elements of privacy vary from culture to culture. To take these cultural considerations into account, you must fully understand the population to be involved in the study when designing and implementing study procedures.

Here are some examples that raise privacy concerns:

- Environmental privacy concerns involve where the interaction with the study participant occurs:
  - If you are conducting a physical exam of a study participant, is there a curtain or door blocking the view from other people?
  - Are interviews conducted in a space protected from being overheard? If not, do you need to ask family members or other people to leave the area, or provide some sort of "white noise" to protect your conversation?
  - Is the study being conducted at a location that will, in itself, disclose something personal about participants that go there?
- If you are speaking with a minor, have you made clear to the parents or legal guardians that you will not disclose the minor's responses to them?
- If you plan to communicate by text, social media, email, or other electronic platform, how can you make sure that someone no one other than the study participant will see those communications?

What is Confidentiality?

Confidentiality is one aspect of privacy. It refers to how personal information is kept, who can see it, who handles it, and how it is transferred, stored, shared – and protected at all those stages. Confidential information is that which is identifiable, or can be linked to protected information of a participant. Maintaining confidentiality includes ensuring the security of study data as it moves from point of collection, to point of storage and analysis, to point of sharing (if permitted). Consider how you will maintain confidentiality while transferring data or information from the offsite location back to your office. Take a moment to research your own institution's policies and make a note in your study manual.

Privacy and Confidentiality Protection Strategies

Strategies for maintaining privacy and confidentiality are best laid out in the initial design stages of a study but should be remembered throughout the life of a study.

Recruitment and other Participant Interactions

During the recruitment stage, it's necessary to engage potential participants in a way that helps preserve their privacy. Plan ahead and find a private space or room to discuss the study. If you're making phone calls, consider who else is in the room with you and who might answer the phone.

Site Selection
The selection of your physical location(s) where study staff interact with participants is critical in terms of privacy. Sometimes just participating in the study can put a participant at risk, depending on where the study is being conducted. For example, a study that examines gang member-related activities could put a participant in extreme danger if it were obvious he or she was participating in the study. Researchers must choose sites that will provide participants with a safe environment.

Focus groups
Focus groups are not a private setting and all participants should be reminded of this. Every person in the room can hear the information discussed, and the researcher will not be able to guarantee confidentiality.
Also, if a transcript of the group's dialogue is created, all data that could identify a participant should be removed. Remember to frequently remind the group that, what happens in the focus group, stays in the focus group. If topics to be discussed are sensitive, you might invite participants to use a nickname to prevent identification in audio recordings and transcripts.

Group interventions
Group interventions are a common method in social and behavioral research. Many of the concerns of a focus group are also legitimate in a group intervention, as groups are not private and confidentiality cannot be fully guaranteed. Be sure to remove all references to identifiable data and reiterate the importance of keeping what is said in the group within the group setting.

Home visitation
Home visitations may require interactions with members of the household who are not study participants. Consider in advance how you will handle those interactions. For example, a visit to a participant's home may require you to ask any non-participants - such as a spouse, parent, or friend - to leave the room when discussing the study. Sometimes, you'll need to read the participant's body language to see if he or she feels comfortable in this setting.

Recording restrictions
Video and audio recordings can be extremely valuable to a study. However, the intended plans for their use and storage of the recorded data must be described in the IRB protocol and informed consent document. Participants must be fully aware that they will be recorded, and also have a full understanding of how the video or audio will be stored and eventually destroyed. Be sure to remove any identifiable information from a transcription.

Electronic communication
Web-based surveys, social media, video chat, and mobile device applications ("apps") give study teams many methods for collecting data, but their use can put participant data at risk. Internet Protocol (or IP) addresses can reveal someone's identity and collecting digital data often involves the transmission of information over a network which may not be secure. Encryption and other protections may be required. If you are collecting data via portable digital devices using apps, texts, or other communication, provide security scrutiny. Discuss any safety or protection measures for your digital data collection with your IT department.

HIPAA, for U.S. based studies involving Protected Health Information (PHI)
Keep in mind that some health information is considered to be individually identifiable, and must be protected during transfer in accordance with the law and institutional requirements. Visit the federal HIPAA website and your institutional Privacy Office for more specific information.

Data Collection

Participants need to be fully aware of how and when data are collected. However, unless the IRB has approved a waiver of consent, data cannot be collected prior to obtaining consent. Collecting data from a participant who has not consented to the study is a severe invasion of privacy and constitutes serious non-compliance with federal and state law and institutional policies.

Data Security

Data security is critical to maintaining confidentiality. The use of portable electronic devices for data collection and storage should be approved by the IRB and requires encryption. You can check with your own IT department to determine which collection and storage solution (which might include mobile devices, laptop/desktops, servers (physical, virtual, web/cloud based), among others) is the most secure. Additionally, be sure to keep hard copy files in a locked cabinet and encrypted electronic files on password-protected computers. Always follow your institution's polices for proper and secure data storage. Protect confidentiality by keeping any identifier documents separate from participants' data. It might be tempting to store identifiable data on a backup device, but you must never use non-secure data storage methods (for example un-encrypted laptops/flash devices/other) to keep your files.

Study Team Access

Only those individuals who are listed on the IRB application are allowed to see and access identifiable data. This typically includes the PI, coordinator, and research assistants. This information should be handled on a need-to-know basis. Be sure to update this list and the associated permissions whenever a member joins or leaves the study team.

Data Sharing

A good study design lays out who on a study team has access to data. If you are working on a multi-site study, develop a data use agreement, make a plan for how you will share data and have the plan approved by your IRB.

Transcripts

Transcripts must have all names removed and alpha numeric codes should be used to identify participants. It is important to remove all direct identifiers and to maintain code lists and data files in a separate, secure location. If the data come from a U.S. covered entity and are PHI, make certain that the transcription service complies with HIPAA security requirements.

Certificates of Confidentiality (Issued by NIH)

Certificates of Confidentiality may be applied for and issued by the National Institutes of Health (or N.I.H.), the Department of Justice, and a few other federal agencies to protect identifiable research information from forced disclosure by a court or other legal entity. Information that can be protected in a Certificate of Confidentiality includes, but is not limited to, use of illicit substances or other illegal behaviors, sexual attitudes, orientation, or practices, genetic information, and psychological well-being.

Reporting Strategies: Loss of study information or data

Even in the most thorough study, an accident can happen and a breach of privacy or confidentiality may need to be addressed. The typical scenario for a breach of confidentiality is the loss of identifiable information (even if not linked to data). Such loss might occur, to provide just one example, during the transfer or transport of study materials in a vehicle or luggage; the car is broken into or the luggage is lost.

How can you anticipate and plan for such an event? As always, you must begin with a detailed plan that has been communicated with each study team member so that everyone can identify and react to a breach. Be sure to include how to communicate and report breaches in your IRB and clinical protocol documents.

If a privacy or confidentiality breach occurs, you must report the incident, the manner in which it occurred, how it was discovered, and the extent of the breach. The amount or type of compromised data will determine the severity of the breach, and will dictate whether the reporting process extends to entities beyond your institution.

Any breach of confidentiality or privacy is considered a promptly reportable event or occurrence. Regardless of terminology, your institution will have guidelines on the reporting mechanism. Take a moment to visit your IRB's website and note where to find these applicable procedures in your study manual.

VII. PARTICIPANT SAFETY AND ADVERSE EVENT REPORTING

It is critical that all study team members understand the potential risks to participant safety and how to minimize them. All studies involve risks to participants, and may range from physical to psychological to even legal risks. Although social and behavioral trials typically pose lower physical risk to participants compared to those testing drugs or devices, study plans need to anticipate and address any risks of emotional and psychological distress during the study as well as the potential for subsequent experience of depression or anxiety.

What is an "Adverse Event"?

An Adverse Event, or AE, is any "untoward medical occurrence" that can occur during the course of a study, but that may or may not be caused by the study intervention. These events could be expected or unexpected. For example, when studying a population that includes participants with chronic dizziness, it is not unexpected that a participant falls during the course of the study. This event is untoward, but not unexpected, and might not necessarily qualify as a reportable adverse event, depending on how an IRB protocol is written.

Within an IRB protocol document, there should be a section that lists any potential risks a participant might experience. For example, a study requiring an exercise test in a younger population might result in a participant feeling out of breath; in an older population, in addition to feeling out of breath, there could be other side effects, such as dizziness, lightheadedness, angina or elevated blood pressure. A well-prepared PI defines what an adverse event is at the beginning of a study and uses that to help classify events during the study so that study staff will know whether an event is reportable as an AE. This definition must be consistent with institutional guidelines, and also be approved by your IRB.

What is an "Unanticipated Problem"?

Unlike "adverse events" that involve medical occurrences, unanticipated problems include any other development associated with the study that could put participants or others at risk, or could negatively affect study integrity. A loss of study data, contaminated study product, military coup in the country where the research occurs, hurricane, or unavailability of study product all qualify as potential "unanticipated problems" that would require reporting to the IRB.

Reporting Unanticipated Adverse Events or Problems

Methodical approach to defining reportable events/problems

The IRB requires some things to be reported; the Sponsor may have different reporting requirements. Make sure you understand what they are. Let's look at a systematic approach to defining adverse events and determining whether or not they should be reported to the IRB. There are three things to consider:

1. Is the occurrence unanticipated?
2. Is the occurrence related or possibly related to the research in which the participant is taking part?
3. Does the event put participants or others at greater risk of harm?

By answering these questions, you can typically determine if an event meets the definition of a reportable adverse event or unanticipated problem, as well as how it should be reported to your IRB (typically "promptly"). If the answer to any of these questions is "No," then the event does not need to be reported promptly, but may be included in the progress report. If the answers to these questions are "Yes," then this event should be reported as an unanticipated problem.

Classifying "relatedness" of the event/problem to study activities
All study team members should know how to identify and record incidents qualifying as adverse events, but the PI is responsible for *classifying* adverse events according to seriousness, relatedness, and expectedness. A serious "adverse event" as defined by the FDA results in death, life threatening circumstances or long term hospitalization or disability. Within social and behavioral research, "relatedness*"* refers to the possibility that an event is related to a participant's involvement in a study. "Related to study participation" means *to study activities*, not to peripheral activities like being injured in a car on the way to a study appointment. "Expectedness*",* or whether an event is anticipated*,* can be defined by whether or not the event has been observed before or was outlined as a risk in the approved protocol and consent form.

Timeline to reporting
Remember, the timeline for reporting an event will vary. "Serious Adverse Events" and "Unanticipated Problems that pose risk to participants or to others" or that threaten study integrity must be reported *promptly*. At the JHSPH, that means within 10 working days of finding out about the Event or Problem. Other adverse events and unanticipated events may be reported with the Progress Report.

Develop a clear reporting guide for study team members
Make sure that all members have access to a clear *Adverse Event and Unanticipated Problem Reporting Plan* to help guide them through the reporting process. This guide should include the type of event that has occurred and the corresponding timeframe for reporting the issue. This timeline should be based on an event's satisfaction of the three AE considerations: seriousness, relatedness, and expectedness. Also, provide clear procedures for deciding whether a team member should just make note of the event in a study log or whether the event merits an AE/Unanticipated Problem report and IRB notification.

Systematic Strategies to Uncover Events and Problems
Study teams often fall short in identifying adverse events during a study. Not because they mischaracterize an event when it occurs, but because they are unaware an event even happened. To prevent this, develop systematic strategies that can be used by the entire study team.

To ensure that you know of adverse events and unanticipated problems that have occurred with participants, plan for opportunities to ask probing questions. Phrase them so the participant is encouraged to provide more than just simple yes or no responses. If a participant responds with a one-word answer, have a follow up question ready. Good questions to ask can include: Can you tell me about any distress, illnesses or incidents that have occurred since we saw you last? If you've been put on any new medications, what are they? Have you had any medical procedures or accidents? Have you noticed anything out of the ordinary? If so, what happened? To ensure a consistent experience, ask all participants the same set of questions and make note of their responses so that they can be reviewed if needed. In addition to asking questions at regular intervals, consider having participants keep a study diary in which they note anything out of the ordinary. Things are much easier to remember in the moment, rather than two months later at a study visit.

Reporting to the Right People

If a suspected adverse event is encountered, those on the 'front lines' usually are the ones to learn about it. That information needs to get to the right people. It is up to the PI to make the final call on an adverse event and whether or not report it to the IRB and study sponsor.

Open communication is also vital to the reporting process. A dialogue between participants and coordinators alerts the team to a possible issue. Communication among coordinators, research assistants and PIs ensures that suspected AEs are given the attention they deserve.

Institution guidelines on how to report

The way in which adverse events are reported to an IRB can vary based on an institution's requirements. In general, be sure to note the date of an incident, whether or not it was expected, its relationship to the study, a description of what occurred, and what was done to address it. Include any corrective action plans that are put into place to prevent recurrence, if applicable.

Remember, participants should be identified in these reports by their ID number rather than by their full name to protect their privacy. Finally, be sure to note how the issue was resolved. A resolution can range from referring a participant for further medical care, to acquiring the participant's medical records, to simply getting more information. Occasionally, adverse events, such as strained muscles, can resolve on their own over time. Finally, if a pattern of unanticipated adverse events/problems is occurring within a study, there are two possibilities: either the protocol needs to be amended, or the IRB may question whether the study should continue.

Protocol Non-Compliance

Adverse Events and Unanticipated Problems may interfere with study progress, and so can non-compliance on the part of the research team. There are several types of non-compliance, and it is important to be able to distinguish among them:

- An informed (knowing, or intentional) decision to depart from the protocol to protect the health and welfare of study participant(s) without IRB approval
- Inadvertent (unknowing) departure from the protocol
- Knowing (intentional) departure from the protocol without IRB approval and without the justification of participant safety or well being

The first type of non-compliance, e.g. an informed decision to depart from the protocol to protect a participant, is always permitted; protecting the health and welfare of participants is the research team's most important objective. The PI must report this kind of situation to the IRB on a prompt timeline. The second type of non-compliance is the "human error" category. People will make mistakes, and the best protection against this kind of situation is training, tracking and monitoring activities, and supervision. The PI must report incidents of inadvertent noncompliance. The timing on the report depends upon whether the departure constitutes a minor "protocol deviation" which may be reported at the time of the Progress Report, or something more serious, which requires an 'immediate' report to the IRB. If there is a pattern of minor non-compliance, the IRB may view its continuation as "continuing non-compliance"; "continuing non-compliance" is serious itself because it reflects generally poor adherence to the IRB approved protocol. The IRB may have to report the investigator to federal regulatory officials. The third type of non-compliance may have serious repercussions, including report to federal authorities, suspending or stopping the study for safety reasons, etc. The consequences to the study PI and management may be different if the research team itself reports the non-compliance. Self-report shows that a PI is interested in doing things the right way and wants to work with the IRB to address the deficiency.

Data Safety Monitoring

Most clinical trial studies have a data safety and monitoring plan to protect participant safety and data integrity. Some complex or high risk studies may also have a Data Safety Monitoring Board (DSMB). This is a group selected to monitor the data on a regular basis for any signs that a study should be stopped. Members of this Board are experts with knowledge of the study biostatistics and an understanding of the science behind the study. They are recruited to the task by the PI or the study sponsor and are independent from the study.

DSMBs monitor studies by looking for trends, violations, and study milestones. Consider a study that has been unable to recruit the required number of participants. It is the DSMB's job to determine if the study should continue, because failure to recruit an adequate sample size means that the researchers cannot answer the study question. On the other hand, the DSMB may approve the early termination of a study because data/information available at interim analyses indicate the study has either demonstrated a benefit arising from an intervention (i.e. "stopping for efficacy") or that further data collection would be futile (i.e. stopping for futility"). Additionally, if a study has shown a trend of adverse events or deviations, the DSMB may advocate for clinical protocol changes to protect participant safety.

VIII. **RESEARCH MISCONDUCT**

What is Research Misconduct?

Misconduct is a crucial topic that all researchers need to understand and appreciate in order to protect themselves and the integrity of their studies. Just like maintaining the overall quality within a study, all team members are responsible for the checks and balances that can prevent research misconduct. Formally, research misconduct is defined by the NIH as any "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results." Research misconduct does not include moments of real, genuine error or a difference in opinion. For example, if the data for a participant's initial study visit were misplaced by mistake, a team member is not committing misconduct. Additionally, if a Principal Investigator and Research Assistant find that they are interpreting a participant's behavior in two different ways, neither of them is committing research misconduct. While these situations do not rise to the level of misconduct, they still need to be handled, but in the ways discussed under Quality Control and Assurance, above. In cases of misconduct, there are specific steps that must be taken which we will discuss in this section.

Fabrication, Falsification, Plagiarism Definitions

- **Fabrication** refers to the creation of results and data out of thin air - or in other words, "making up" data or results. Perhaps a study coordinator is pressured to enroll 15 participants in a specific time period to meet the study aims, and he is only able to enroll 13 participants in this time period. If the coordinator chooses to make up data for two participants in order to meet the target of 15 participants, this is misconduct. He has fabricated participants and their data.
- **Falsification** refers to the manipulation of materials, equipment or processes of a study. It also includes the omission of data that would result in a discrepancy between data that are recorded and data that are reported at the end of a study. Removing data that do not support your hypothesis - for instance, to make your results look better - is an example of data falsification.
- **Plagiarism** occurs when a researcher borrows or steals the ideas, methods and results of another person, without getting the appropriate permission or properly acknowledging the source of this information. Forgetting to cite your own published work is also a form of plagiarism.

Importance of Intent

Think back to the previous example of misplaced participant data during a study. If this happened due to genuine error, it is not misconduct. It is more likely an incident of protocol non-compliance that must be considered for reporting. However, say a participant is not responding to the intervention as expected, and the inclusion of their results will skew the final data. If this participant was specifically left out in order to make the study's results look better, this situation has just moved from an honest mistake to research misconduct.

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.

While sometimes unintentional things happen that can impact participant safety or data integrity, it's the intent to deceive that matters in whether a particular action is misconduct.

Identifying Misconduct Behaviors

Misconduct can happen at different times during the lifecycle of a study. Some behaviors can have a very real and direct impact on the health and safety of a participant, while others may involve alteration of data that are manipulated after a participant has completed their role in the study.

- Fabrication – examples of fabrication can include "making up" participants, or filling in data or answers for participants that were never recorded.
- Falsification – intentionally leaving out or changing data, manipulating graphs or charts, or intentionally leading participants to the answers you want are all examples of falsification. If bias leads to an intentional manipulation of the data, it can also be considered falsification.
- Plagiarism – plagiarism can occur by not appropriately citing someone else's research, or by copying someone else's work or verbiage.
- Other – other examples of misconduct that may not fall directly under the first three categories could include abuse of a participant's confidentiality, prompting a participant during the informed consent process, failing to report an adverse event, or retaliation against a team member or participant.

Consequences of Misconduct

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. Consider the ramifications of the 1998 study by Andrew Wakefield which falsely linked the MMR vaccine to an increased risk of autism. While this study has now been debunked and the article retracted, many people still believe the research is valid and that the link is real. As a result, some parents are choosing to not vaccinate their children and public health has been put at a greater risk, resulting in outbreaks of once rare diseases, such as measles and mumps.

Beyond the impact of research misconduct on those outside of the research lab, there are real consequences for those on a research team. Careers and credibility can be destroyed. Some members may be reassigned to a new team, fired or even barred from conducting research at all. Additionally, if a researcher has received an award or accolades recognizing their achievements, these can be rescinded. Often times, granting institutions will demand that funds are returned if research they have sponsored is found to be fraudulent.

Finally, and perhaps most embarrassingly, the names of scientists who have been found guilty of research misconduct are listed on the very public website of the Office of Research Integrity (ORI). Anyone can visit this page and read the findings and consequences enacted by the ORI.

Overcome Excuses

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. "It's not my study" or "Someone else will see the problem and report it" are not valid excuses for ignoring misconduct. Even the fear of retaliation must not stop you from reporting a valid misconduct violation, as there are protection measures for whistleblowers.

Remember, it is your duty as a study team member to report potential misconduct. While it's not an easy task - especially if that misconduct is happening within your own team - you must report it. At the end of the day, the consequences resulting from any misconduct will lie with the person who committed the wrongdoing, and not the person reporting it.

If you are afraid to address misconduct directly with the person you suspect of committing it, or even with another individual you trust, many institutions have an anonymous mechanism for reporting suspected misconduct.

Reporting Process

To ensure that you have done your best to assess the facts of the situation, a three-step fact-finding and reporting process is recommended.

Step 1:

Understand the situation.

Any potential misconduct should be approached with an open mind, intent on finding the truth. It is entirely possible, and highly likely, that you may be misunderstanding, or that the situation is the result of an honest error. Start by asking questions to try and understand if a fellow team member is doing something for a scientifically valid reason. Most cases of misconduct are identifiable because someone is doing something that is not scientifically sound.

Step 2:

If, after assessing a situation and asking a few questions, you are still confident that research misconduct has occurred, share this information with someone you trust - a mentor, experienced colleague, or someone else with appropriate experience in social and behavioral research. Discuss the situation and seek their opinion. While reporting research misconduct is your duty, be sure your reasons are valid. Getting a trusted second opinion is crucial to ensuring that your concerns are legitimate, and might help motivate you to action, if necessary.

Step 3:

Once potential misconduct has been identified, understood, and confirmed with a trusted colleague, it's time to report it up the chain. This may involve notifying the PI, who can then report it to the IRB. Alternatively, if the PI is the person suspected of misconduct, the PIs supervisor - usually the chair of the department - should be notified.

After an IRB is made aware of a situation, a preliminary inquiry may be initiated to gather more facts. If suspicions are confirmed, a full investigation may be conducted by the institution to determine the extent and consequences of the misconduct.

If you are concerned about remaining anonymous, a confidential hotline might be the best option for reporting misconduct. However, if anyone along the chain fails to report the event, a team member must report it to the IRB. If you know of a misconduct situation and at any point cover it up, you could be responsible.

Misconduct Prevention

Now that you know the process of reporting misconduct, let's step back, and look at actions the research community can take to prevent misconduct.

Setting up appropriate systems and establishing SOPs for collecting and analyzing data will help team members understand how the study is to be implemented and how data and how data are to be entered. Sound statistical procedures and SOPs must also be implemented for handling missing data and outliers.

At study team meetings, discuss issues openly, as well as strategies to address any problems. Regular lab or study team meetings should also present raw data openly. A team with an established culture of communication that holds its members accountable is less likely to have issues with misconduct.
Be sure to record the designated server location of research data files. You can also institute or improve quality control and quality assurance systems, such as double data entry or secondary data review, to monitor and catch errors that could lead to misconduct. This overseeing of information is critical. The source data should be reviewed, along with final figures and aggregate data.

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 take the three-step method just discussed to assess and report potential misconduct.

Remember, your IRB can be a great resource. In addition to assessing and approving the conduct of research, an IRB can provide guidance on how to manage difficult situations related to research integrity and ethics.

IX. QUALITY CONTROL AND ASSURANCE

Overview of Quality Control and Assurance

"Quality assurance" is defined as "All those planned and systematic actions that are established to ensure that the trial is performed and the data are generated, documented and reported in compliance with Good Clinical Practice and the applicable regulatory requirements." So what does this mean? In general, quality assurance refers to the planned procedures, like your study Standard Operating Procedures (SOPs), determined in advance by your quality assurance plan, that ensure you are doing the right things in the right way.

"Quality control" is defined as "The operational techniques and activities undertaken within the quality assurance system, to verify that the requirement for quality of the trial-related activities have been fulfilled." Quality control includes study monitoring and audits to ensure that the actions of study staff are consistent with the study protocol, that deviations are recorded and explained, and that the study protocol is amended, if appropriate.

Developing and sticking to your procedures manual is key. This helps ensure that the right people are performing each task and that they have been trained to do it. Once quality procedures are put in place, accountability is vital. Every team member has to be held to a high standard.

Everyone's Job

At the end of the day, data quality is everyone's responsibility. It's about being a proactive member of your research team. Consider this Golden Rule of Research: everyone has their own duties, but everyone is responsible for ensuring quality. Typically, the PI and team leaders are responsible for making sure that proper procedures are outlined in the clinical protocol and procedures manual, and that everyone on the study team has access to them. If a study team includes a coordinator, this role can often fall to him or her. Additionally, team members can take actions to ensure quality data are collected. Often times, research assistants collecting data from participants and team members responsible for data entry play this role by checking that the collected and entered data are accurate and complete. Sometimes these roles are performed by the same person.

Importance of Systematic Controls

Systematic controls are a great way to periodically take stock of how well data and processes are being maintained. Here are examples of some study planning and oversight strategies that support good quality data management.

Ensuring Accurate Data Collection

In order to ensure accurate data collection and data handling, clear procedures should be in place for each step in the process and monitoring should be done at frequent, regular intervals with adjustments made and communicated, as needed. Data that are inconsistently collected or handled can contribute to invalidating a study's results or misrepresenting the causal associations, undermining the value of the study, and shifting the benefit/burden relationship for participants, a significant IRB concern.
Although technology can reduce both random and systematic errors, collected data need to be reviewed regularly to ensure that they are complete to the extent expected. Any oddities in the data should also be recorded according to the Procedures Manual and followed up if there is potential for a systematic

problem. Participant-related issues are common. For example, if a participant is physically unable to perform a strength test during the study visit, field/data points related to that test should not be left blank, but rather should be marked appropriately to designate the reason why information is not available. Not Applicable or Not Valid designations can also be used to help explain why data are missing or out of range.

Random and Systematic Error

Errors can be random or systematic. Random errors occur in all research studies and measurements, and are due to implicit and unpredictable variations in the sample or measurement process. When designing research studies and protocols, attempts should be made to minimize random errors as much as possible through training, consistent procedures, etc. However, good research design can address most types of random error.

Systematic error, however, occurs when every data point within a study is exposed to the same set of errant circumstances. This type of error is usually related to imprecise calibration of study equipment, or differences in observations and measurement by either study staff or participants. A good example of this is an uncalibrated scale which affects all participants in the same, consistent way. As a result of this error, all the participants appear to weigh five more pounds than they actually do. This type of error can be mitigated with proper and diligent calibrating processes and continual education of staff.

A common source of systematic error is that of participant self-selection into a study. Although people decide whether to learn about a study, staff need to be vigilant to ensure that they are not contributing to a systematic selection of certain types of participants.

Systematic error may result in the study sample misrepresenting the population to whom the research team wanted to generalize their findings. Although it's difficult to eliminate all errors, in order to minimize them, proper protocols and procedures should be put in place before a study begins.

Measurement Error

One type of error that sometimes can be minimized is measurement error. Measurement errors can affect the quality of the data. For example, say a survey question asks a participant to assess their pain severity. Does this mean pain right now or pain over the course of a day or week? Is it overall pain or pain in a particular area of the body? How participants interpret this question will lead to bias if clarifications aren't made to prevent it.

Influence of Time

For the most part, instances of bias are unintentional and can often stem from practical efforts to manage study resources and logistics. Such efforts must be considered in relation to the overall design and implementation procedures required to answer the scientific question, or may lead to bias. During a participant visit, the highest priority should be placed on the safety of the participant, followed by data collection. For example, if a data collector decides that altering the order of planned activities will make the process more efficient, it wouldn't be surprising that participants asked to complete a strenuous exercise test and then answer a question about fatigue will respond with a higher rating than other participants completing the same activities, but in a different order.

Any situation where the IRB approved protocol is not adhered to - even in the slightest way - should be documented and, depending on reporting requirements, reported to your IRB as a protocol deviation or protocol non-compliance. Additionally, the time of day or year during which data is collected can affect answers provided by participants and should be considered when planning the study.

Transcription Errors

Typing or transcription errors are common. In addition to actively monitoring data quality, it's a good idea to keep all source documents from a study, in case there is a need to verify any possible transcription errors. Your data management plan should include strategies for checking the data for typos, out-of-range data, and logical inconsistencies.

Avoiding Bias

In the Research Protocol section of this course, we discussed the importance of treatment/study fidelity. Remember, study fidelity involves making sure that the actual intervention of a study is conducted as the clinical protocol specifies and that the intervention is received by the participant as intended. As part of this effort, procedures manuals are written to help minimize bias by describing specifically how tasks must be completed. So, it stands to reason that if you deviate from a protocol, you're opening yourself up to bias and potential issues when interpreting data.

To minimize this, provide team members with continual training and communication to help prevent deviations and ensure that everyone understands the importance of data integrity. Also, if frequent clinical protocol deviations, such as repeatedly missed study visits or incomplete assessments occur, this can be an indication that there are problems with the protocol and that an amendment may be needed. All in all, maintaining study fidelity over the course of a study will help minimize the risk of bias that can result from both systematic and random errors.

Quality Control and Assurance Strategies

It's rare that a study will go off without a hitch. The best a research team can do is be proactive and implement controls to prevent and anticipate issues before they arise and learn from them when they occur. Following are some good strategies to assure the highest standards of quality in your study.

Create structured procedures manuals

Begin with a structured procedures manual that outlines the activities of a study. In this document, try to anticipate any unexpected circumstances that might come up and provide a solution.

Develop a data management plan, ensuring data integrity

Data management plans are a part of every study. This document should be readily available to all team members and clarify how data will be selected, collected, analyzed, handled and published. Teams should also have statistical procedures in place to handle any missing or outlying data. Double data entry significantly lowers the error rate in a data set, but it isn't enough to enter data twice without comparing the two sets. It's recommended to audit your data regularly.

Develop standard rules for recording data

Within the procedures manual, there should also be an outline for standard data recording rules. This will help study members understand the data they should be capturing and how it should be recorded. For example, the document should make note of how many decimal places a value should be recorded, what unit of measurement should be used, or how non-response should be noted. These rules should also outline where data is to be stored. A secure, designated server is often the best place.

Have data collectors and staff check their work

Create a checklist to ensure that interventions are carried out as stipulated in the IRB approved protocol document and in as consistent a way as possible. Staff should use these checklists to check data

collected and to make sure that all questions and answers have been received from the participant before he or she leaves.

Have data collectors and staff sign their work
Minimize questionable data by having the team member who is collecting data write their name or initials on any source documents so they can be asked about something later. Similarly, it is critical that all entries be dated in the text or on the form.

Audit data collectors
Plan for, and carry out, periodic checks of procedure adherence and data quality to ensure that study team members are following protocols and maintaining treatment fidelity.

Audit participant files
Routine checks of participant files for completeness and accuracy are always a good idea.

Make Decisions
As part of a double data entry process, there will be discrepancies. In these situations, who gets to decide what is "correct"? This decision should be made by someone who is not actually entering the data - usually the P.I. or data manager. Once a decision is made, it should be documented in a place that is accessible to all team members.

Communicate as a Team
Communication is key. When there is open communication among team members and with participants, everyone is on the same page and better data can be collected. A great time to communicate as a team about potential quality issues is during a regular team meeting. This is also a good time to share raw data with the team.

Learn from every study and from everyone
So how do you implement all these strategies from here on out? Quality control and assurance is a skill that is learned and improved over time. All study teams should prioritize quality control measures, and the entire study team should learn from mistakes and make adjustments for continuous improvement. Throughout the course of a study, make note of lessons learned and how you should do things differently. Also, take advantage of those who have gone before you. Mentors and colleagues are a great resource! You work at an institution with people who likely have encountered the exact same situation. Ask them questions! Two or three brains are always better than one.