Module 8: Research Misconduct

Introduction to Research Misconduct

Welcome to the eighth module in the Social and Behavioral Research Best Practices for Clinical Research course. In the next few minutes, we'll cover what research misconduct is as well as how to report it. Let's begin by hearing from Amy, a study coordinator, who found herself in a bit of an uncomfortable situation.

A Case of Missing Data

I've been a research coordinator for quite a few years now. I've worked with a lot of different teams and I know that everyone has their own way of doing things. Most recently I was assigned to a study that would assess the impact of a self-management program on maintaining functional ability in older adults with heart failure. The study was longitudinal, and was going to last for several years.

Elena was our research assistant for this study and this was her first job out of school, so she was really excited to get started. Elena's role was to conduct study visits where she met with participants to collect survey information and then she entered data into the study database.

Unfortunately, a few weeks into the study I was checking the study database and noticed that not all the participant demographic data and survey information were complete. Many of them had missing survey data.

Suspicious Participant Data

After I noticed the missing data, I pulled Elena into my office to have a conversation. She said that she was having trouble getting participants to return her calls to set up study

visits. I encouraged her to reach out to participants with both an email and a phone call and give them several different options for times to meet.

A few weeks later we were doing much better, and Elena was having more success with our participants. All the data were in the system and things were looking good. Maybe a little too good. Not one question was missed and many answers were identical, and there were also no adverse events reported. I started to have a few suspicions that not all the participant data were real.

Fabrication of Participant Data

After some thought, I asked Elena to walk me through several participant files. I could immediately see that she was nervous to answer my questions, and it didn't take long for her to confess that when there had been missing data, she had filled in answers so that the surveys would be complete. It really was an unfortunate situation, but I knew that I had to report this to our study P.I.

Course Study Manual

Take a minute to explore the Resources section in the top right corner of your screen. Here you'll find your Social and Behavioral Research Course Study Manual for this module, Research Misconduct. Be sure to print this before you continue.

Throughout this module you'll be able to pause the course and take notes specific to your institution. In the end, you'll have a roadmap to a successful social and behavioral research study.

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 National Institutes of Health 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 not committing research misconduct.

While these situations do not rise to the level of misconduct, still need to be handled through different channels.

In cases of misconduct, there are specific steps that must be taken. These steps will be covered later in this module.

Fabrication, Falsification, Plagiarism

There are three ways to commit misconduct.

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 may also be 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. 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.

Keep in mind however, that even if a situation lacks intent, there can still be serious consequences. In the instance of the misplaced participant data, a potentially serious confidentiality breach may have occurred. Appropriate action steps must be taken to correct any lack of training or missed steps in the established standard operating procedures.

Take a moment to write down your own questions about research misconduct in your course study manual. This will remind you to address these questions with your I.R.B. at a later date.

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 are cases of data that is manipulated after a participant has completed their role in the study. Click on each area of research misconduct to identify realistic behaviors that you should be aware of.

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 measles, mumps, and rubella 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 (or O.R.I.). Anyone can visit this page and read the findings and consequences enacted by the O.R.I.

Overcome Excuses

Everyone, from a P.I. 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.

Take a moment now to pause this module and make a note in your course study manual of the research misconduct resources at your institution.

Reporting Process: Step 1

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

Your first step is to 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. Think back to Amy, who believed that a few participant files were falsified. She began by asking Elena questions to fully understand what was going on, rather than immediately reporting her to the study P.I.

Reporting Process: 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.

Reporting Process: Step 3

Once 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 P.I., who can then report it to the I.R.B. Alternatively, if the P.I. is the person suspected of misconduct, the P.I.'s supervisor - usually the chair of the department - should be notified.

After an I.R.B. is made aware of a situation, a preliminary investigation is often launched to gather more facts. If suspicions are confirmed, a full investigation may be conducted by the I.R.B., department, or 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 I.R.B. 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.

Appropriate systems and established S.O.P.s 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 S.O.P.s 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 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.

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

Course Study Manual Check-In

By now you should have filled in the Research Misconduct section of your Course Study Manual. If you haven't, take some time to complete this job aid. And don't forget to check out the Resources section for additional information and links, as well. When you're ready, click Next to move to the final assessment for this module.

Lessons Learned

After I let our P.I. know what was going on, an initial investigation into the data of our heart failure study was launched. Unfortunately, my suspicions were confirmed and the few incidences of fabrication turned out to be much more frequent.

A formal panel was convened to determine how to handle the situation and our sponsor was notified. As a result, the study was shut down during the investigation and Elena was fired.

Our team determined that we had several lessons to learn. First, we had assigned this study to a novice who we had failed to train adequately. The P.I. was busy and we were all conducting a number of research projects with a limited staff.

While Elena was responsible for her actions, the system was flawed. And although the P.I. may have assumed delegation was being managed well, ultimately, she was still responsible.

The months that followed haven't been a picnic, but I'm really glad I spoke up. I know I made the right call. Scientific research demands a high ethical standard. The research community must make ethical, scientifically accurate conclusions and we can't conduct fraudulent research.