

## Unit 4: Written Training

### Unit 4: Keeping Research Participants Safe

#### Topic 4.1: Risks and Safeguards

Now that you know a lot about finding people to be in studies and working with them to make decisions, let's talk about the other responsibilities you have as a community research partner to keep people safe when they are in research.

#### Topic 4.1.1: Introduction to risks: Learning about psychological and physical risks



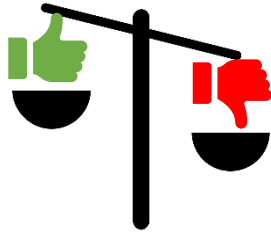
First, let's talk about some of the bad things or risks that can happen in research. We will start with bad feelings and ways bodies can be hurt. We talked earlier about how important it is to not hurt people when they are in research. This is the Belmont Principle called beneficence.



There are a few different ways people can be hurt in research. We call these **risks** or possible **harms**. Some of these things can hurt a lot, some things can hurt just a little bit. Some can hurt for a short time and some can hurt for a long time. Some harms happen to only a few people. Just because there are things that may hurt people who are in research doesn't mean everyone will get hurt!



Researchers try to keep bad things from happening when people are in research studies. You have an important role on your research team. You can share your ideas about what bad things may happen and what you can do to stop them from happening or make it so they don't hurt people too much.



Keeping people safe when they are in research studies is very important. There are always risks, or possible harms in research. Researchers have to make sure they balance the possible good things and the possible bad things. That means if there are going to be a lot of bad things, you have to do as much as you can to make sure the study helps participants and other people in the future. It also means you have to do more to make sure participants stay safe.

When you do research, you should always ask:

- “How can this project protect the people in this study from getting hurt?”
- “How can we make it as safe and easy as possible to be in this study?”

You should think carefully about the people who you ask to be in your study. Something that is hurtful to you might not feel hurtful to someone else. That’s because everyone has different comfort levels with different things.

For example, if a study is about experiences with healthcare providers, and someone recently was treated badly by a doctor, it might be more upsetting for them to talk about their healthcare experiences.

You want to keep in mind that different people might need different things to be safe in a research study. For example, people who have an aid who comes to research with them, might need different things to keep their information private than people who do not have an aid who comes with them to research.

There are different types of bad things that can happen to people in research. Remember, we call the possible bad things that can happen risks.

We will talk about the different types of risks in research and examples of how to reduce those risks.



**Physical risks** are about your physical health or how your body feels.



For example, someone could get hurt in a research study if they fall doing new exercises. To reduce the chances of falls happening, you might have people who want to be in the research study check with their healthcare providers to make sure it is safe for them to do the exercises. You could also have someone next to them or bars they can grab onto so they don't fall.



A more common physical risk might be feeling tired if you have to do research activities that take a long time. To help people not feel so tired, you might be able to give people breaks or have things they can fidget with.



**Psychological risks** are about how people feel.

An example might be feeling anxious during the research activities because you aren't sure what to do or because you are in a new place.

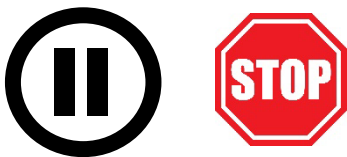
You might have good ideas about how to make people feel more comfortable—like sending pictures of where the research activities will be to people.



Sometimes you might do research about topics that are hard for people to talk about. Like we mentioned, different topics will be hard for different people. When we say hard, we mean a few things. Hard could mean that you are talking about or doing something that frustrates participants or is really confusing and it ends up making participants feel like they can't do it. Hard could also mean that it is upsetting to talk about the topic.

It is important to only ask questions about what you need to know to answer the research question. This way, no one has to talk about anything that is upsetting and not related to the research.

Another way to reduce psychological risks is to only ask about general topics if you don't need to know people's personal experiences to answer the research question.



You can plan breaks, let people skip part of the research activities, or stop if someone is too upset.

It is important to have a plan in case someone gets too upset. You can give them resources like hotline numbers or a local Center for Independent Living or Self-Advocacy group.

You can also have someone ready who knows how to help people who are feeling really upset, like a counselor, and call them when you need them. In the next unit we will talk about different kinds of risks.

## Topic 4.1.2: Social, economic, and legal risks

In the last unit we talked about physical and psychological risks. In this unit, we will talk about a few other types of risks-- social, economic, and legal risks.



**Social risks** are bad things that can happen related to other people.

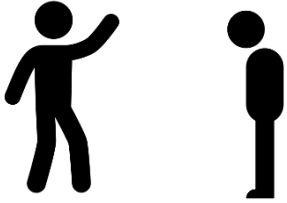


For example, if other people find out personal information related to the research, they might treat the person differently. To reduce this risk, we don't tell other people if someone is in our research study or what they shared with us.

Another social risk is if the research makes other people think badly about people with disabilities. To reduce this risk, researchers should be careful about how they share what they learned and make sure they talk about disability respectfully—we'll talk more about this later.



It is also important to think about the relationship between researchers and research participants.



You usually meet new people when you do research. Sometimes this is a part of research that makes people nervous. Other times it is a part of research that makes people excited. In some types of research, you will get to know the participants well and they get to know you.

For some people, it can be hard when research ends, because they won't get to spend time with the new people they met anymore. They might feel sad about the relationship ending, or feel like it is another person who came into their life and then left, just like having lots of different support staff come and go.

We can do things to help people feel better when research ends. For example, you can talk about the research relationship at the beginning and at the end. This means you can explain how long the relationship will last and what it will be like. It is important to make sure participants know what will happen when they are done being in the study.

If you have been spending lots of time with people in research, near the end you might add more time in between research visits to help people prepare for the study ending. You might have more ideas about how to handle research relationships ending—be sure to talk to your team and share your ideas!

It can also be hard to do research when you already know the person who wants to be in the research study. Maybe they are in your self-advocacy group or are someone you know from your Synagogue or Temple. When you have a research relationship and another type of relationship with participants, it is important to make sure everyone understands the different relationships. You can talk about the different responsibilities you have in each of these relationships.

Micah and Brendan will share more about this! It might also be hard for you to keep information private when you know someone from another part of your life. Be sure to talk with your research team about how to handle this—having someone else on the research team gather the information from the person might be a good idea.



**Legal risks** are about the law.

For example, a research participant might share a story about a time they did something illegal. If someone finds out about it, they might get in trouble.

Researchers sometimes decide not to collect information on things that are illegal. When you do need to collect this information, you work really hard to make sure no one else finds out. You might decide to never collect people's names when you need to ask about illegal activities.



**Economic risks** are related to money.

For example, if a participant's supervisor found out they shared negative things about their work and fired them from their job.

Just like with information about illegal activities, research teams work really hard to make sure no one else finds out information that could hurt them financially.

You also might need to figure out if anyone on your team has something called a conflict of interest. A conflict of interest in research is when someone doing the research has circumstances that might change how they do the research in bad ways.

For example, if the research study has good findings for their organization, they may earn more money at their job.

Or a researcher who made a new healthcare app might want the research to say the app really helps people so they can sell the app and make money.

This would be a conflict of interest. You might worry that the person with a conflict of interest might make up information, only share the information that makes them look good, or pressure people to be in the study.

When someone has a conflict of interest, your teams need to work together so the conflicts of interest don't cause problems. If you think you might have a conflict of interest, talk to your project leader.

### Topic 4.1.3: More information about risks and safeguards



There are also a few other things you need to know about risks and safeguards. There are some situations where something really stressful happens during research. Or, sometimes, researchers want to learn about how people think or act, and they can't tell participants everything about their research right away.

When researchers don't tell participants everything about the study, it is called deception.

If something really stressful happened or there was deception, it can be important to **debrief**, or talk about what happened after the research study. This can help make sure participants feel better and they know the truth.

Doing the debrief can help participants understand what they did as a research participant. During a debrief, you or someone on your research team can help participants feel better if they were stressed out or confused.

Your team will talk more with you if your study involves deception or think you will need to debrief.



If there are reasons to worry that people in your study might get really hurt—like they are trying a new treatment—your study might have a Data Safety Monitoring Board or DSMB. Your project leader will talk to you about this if your project has one.



Even though you will work hard to keep people safe in research, people can get hurt and unexpected things can happen.



An **adverse event** is when someone is hurt in research. This can be expected or unexpected. For example, someone could get really angry about something during the research. Or, someone could get hurt trying a new activity in research.

It is important to have a plan to make sure you help people in your research study if there is an adverse event. You also need to pay careful attention to how people are feeling and acting during research, so you can stop research activities before something bad happens.

If you think an adverse event happened, talk to your project leader right away.



## Mental Health for All Team Talks About Risks



**Brendan:** One of the main things we were worried about in our study was that people would feel upset talking about bad experiences they had using mental health services. We were also worried that people may be upset talking about how hard it can sometimes be to have depression. I remember being interviewed once and it was so hard to talk about the help I needed that I wasn't getting—it made me sad and angry to remember when I had a counselor who just didn't get how to work with me.



**Micah:** We talked a lot about how to handle these situations. We needed to talk to people about mental health, but we also wanted to keep them feeling good. One thing we decided was that when we talked to people about their experiences, we would always do it one-on-one and never in a group.

**Brendan:** We talked a lot about each question we wanted to ask to make sure they were the important ones —we decided not to use a few questions that might be too personal or upsetting and weren't important to answer our research question.

We also decided some people might like to have someone they know and trust nearby in case they got really upset. So, we let all the people in our study know they could invite someone to come with them and stay in another room while they answered our questions.

**Micah:** I also work at our local Center for Independent Living. I talked with Katie, and we agreed that if anyone got services from us, I would not interview them. I also let them know I wouldn't talk to them about the research study.



**Katie:** I also reminded Micah and Brendan that lots of people with developmental disabilities don't get the mental health services that they need. So, we created a handout with local organizations and hotline numbers that we could share with everyone in our study.

I also made sure that when we did our project training for how to do our interviews that everyone on the team learned some tips for what to do when someone was upset. This included reminding participants that they could take a break and knowing that I could also call another team member for help.



**Ariel:** We also practiced talking to people about the relationship they would have with the researchers, including how it would end.