

Unit 2: History of Scientific Research with People and Rules



Topic 2.1: History of Scientific Research with People and Rules

In this topic you will learn about the history of scientific research. This history helps us understand why we have rules for research.

Now that you know more about what research with people can look like, you need to also learn about how to treat people well in research and keep them safe. First, you will learn about the history of research with people.



We already talked about some of the really good things that can happen when you do research. It is also important to talk about **harms or risks**. Harm or risks are some of the bad things that can happen in research.

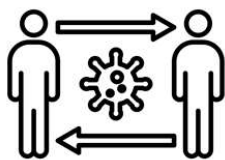
Sometimes we know bad things might happen, but they won't happen often or hurt people really badly.

Sometimes we are surprised at the bad things that happen. Sometimes we can stop bad things from happening. Learning how to stop bad things from happening is one of the reasons you are doing this training.

Unfortunately, there have been times when researchers have hurt people. We now have rules so that people in research will be treated well. You'll read more about that later, but first, you will learn about two examples of researchers hurting people many years ago.



One happened at an institution for kids with disabilities in the 1950's—Willowbrook in New York. Back then, most people thought it was a good idea to have people with disabilities live in institutions. At Willowbrook, the researchers gave the kids a virus that could make them sick. The researchers sometimes told family members that their kid could only live at the institution if they were in the research study. The researchers didn't think it was bad to make the kids sick because they would probably get sick anyway living in an institution.



Another example of people getting hurt in research happened in Alabama starting in the 1930's. The researchers were interested in learning about a sexually transmitted infection called syphilis. The researchers didn't ask the Black men if they wanted to be in the study, lied to them about parts of the research, and offered them things they really needed, like food and medical insurance, so it was hard for them to say no to being in the research study.



While the study was still going on, we learned about a treatment for syphilis, but the researchers didn't give it to the Black men or tell them about it because they wanted to keep doing research about syphilis.

People agree that the things these researchers did were not right. So bad things like this don't happen again, we now have rules to help make sure people are treated well when they are in research. These rules are all about ethics.



Ethics is about making sure we take care of people.

There are ethical rules for all types of research. In this training, you will learn about ethical rules for doing research with people.

Because people with disabilities have been hurt by researchers, some people with disabilities have a hard time trusting researchers. When people don't trust researchers, they often don't want to be in a research study. You'll learn about this later. It is important to be extra careful to not hurt or take advantage of people with disabilities when they are in research.

Topic 2.2: Rules for Scientific Research with People

Topic 2.2.1 Rules for Scientific Research with People

In this topic you will learn about rules for scientific research with people.

You will learn about rules for research with people. Now that we have rules about taking care of people who are in research, people in research have rights.

Their rights include:



1. The right to know all the information about a research study



2. The right to not be hurt when they are in a research study



3. The right to say no to being in a research study



Research Participant Rights

The 3 Belmont principles are the values that help us think about how to treat people when they are in research. They are:

Respect for Persons	Justice	Beneficence
Believing that everyone can make decisions with or without support. Treating people who can not make decisions with extra care.	Making sure all types of people can be in research and that everyone shares the good and bad things that happen in research.	Making research have as many good outcomes as possible and keeping people as safe as possible.

You also have rights as a researcher.

When you are a researcher, you have the right to be safe and respected during research. Talk to your project leader if you have questions about rights during research.

Check out the handout on these rights on the Research Ethics for All website.



As a part of a research team, it is important for you to understand these rules and know how to follow them. Doing this is your responsibility. There is a US law that helps make sure we take care of research participants. People call this law **The Common Rule**. This law is based on 3 big ideas about how you should make sure to take care of people in research. This law only applies to some types of research but the ideas in it are important in all research with people.

The Common Rule is based on the **Belmont principles**.

The three big ideas in the Belmont principles are:

1. Respect for Persons
2. Beneficence
3. Justice

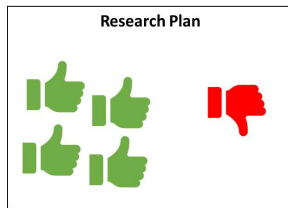


Respect for persons means believing that everyone can make their own decisions on their own or with support.

Respect for persons also means we take extra care of people who may have trouble making their own decisions.

Researchers need to make sure that people get the opportunity to decide if they want to be in research or not. Researchers must give people the support and accommodations they need to make their own choice or make a choice with support and/or with their legally authorized representative or guardian.

Respect for persons is related to disability rights and self-determination, because people are in charge of their research decisions. You should make sure people always get the support they need to be in charge of their decisions.

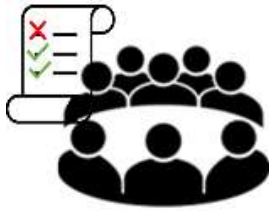


Beneficence is about making sure the research leads to more good things than bad things. Like in the rest of your life, there are always bad things that can happen. In research you can do your best to stop them from happening. Or you can try to make them hurt people as little as possible. You can also try to make as many good things happen as possible.



Justice is making sure all types of people can be in research. It also means that everyone shares the good and bad things that can happen in research. Your team will try to find lots of different types of people to be in research studies.

Topic 2.2.2 Institutional Review Boards



In this topic you will learn about Institutional Review Boards and how they help keep people safe in research.

There are groups of people that make sure researchers follow these rules. These groups are called **Institutional Review Boards** or **IRBs** and they are made up of people who are not part of the research team. IRBs check how researchers do research to make sure their plans follow the rules and will keep people safe and treat them with respect.

IRBs also check that the things researchers use follow the rules to keep people safe. They might look at the materials you use to find people to be in a study (like flyers), or the things you use to help people make a decision about being in a study (like consent forms), and the materials you use to collect information from participants (like surveys).



Getting approval from the IRB is something your team must do before you find people to be in your study and gather information from them to answer your question.

One way you can make sure to follow the rules is by following the plan the IRB approved. This means using the forms they approved and following the plans for how you do each step of research.

The person who is in charge of the research project, the project leader, is the person who is responsible for making sure your research project follows the rules. If you're not sure about something, it's always best to ask your project leader.

There are other laws or policies that your research team may need to follow. Your project leader will talk to you about them.

Topic 2.3: Vulnerability

In this unit you will learn about supporting people who may have a hard time making decisions or need extra help understanding.



When you do research, you have to think about how different people may need to be included in research in different ways. Researchers think a lot about giving extra support to help people who are or who may be more easily hurt in research. This can include people who have a hard time making a decision.



Vulnerable is a big word. People who are vulnerable may not be able to make their own decision because:

- They can't understand the information
- They might not be able to tell someone their decision
- Other people might influence their decisions

They also might get hurt by research more easily than other people.

Lots of people wonder whether adults with developmental disabilities are vulnerable, and people don't always agree. If it doesn't seem right to just say that all people with disabilities are vulnerable, there are many people who agree with you. We don't want to say that all people with a certain label like developmental disability are vulnerable in all situations.

Instead, researchers should think about what bad things might happen if someone agrees to be in a research study and whether other people can influence their decision too much.

It is important to think about how you can help people understand the good and bad things about research and help them use their strengths to make their own decision.

It is also important to make sure everyone has the dignity of risk, or chances to make their own decisions even if they may not turn out well. It is also important that you set up your research in a way that isn't ableist, or discriminatory against people with disabilities.

You will keep learning about how to balance keeping people safe, while also making sure people have the right to make their own choices.



Mental Health for All Team Talks about the Belmont Principles



Micah: Our team talked a lot about how we could do our research project in a way that followed the ideas in the Belmont Principles.



Katie: That's right, we thought about how we would find people to be in our study, help them make their own decision about being in our study, and take care of people who agreed to be in our study. We knew it would be hard to balance taking care of everyone and giving everyone a chance to make their own decisions.

Micah: Brendan and I helped a lot because we know thinking about disability rights means balancing our worries about people getting hurt with their rights to make their own choices.



Brendan: First, we talked about how we could make sure people were making their own decision. This is the principle of respect for persons.

We agreed we would make sure that all the information was easy to understand or accessible. We talked about what words and pictures would be easy to understand.

We also talked about how to help people feel comfortable asking questions. We also talked about how to make sure they felt ok saying no.

Micah: We decided to give people lots of time to think about their decision and a chance to talk to someone they trust. We also let them know we wouldn't be upset if they didn't want to be in our study.

Brendan: We agreed we would remind the people who work in the group homes that it is the person's choice about whether to agree to be in our study.



Ariel: We also knew some people might have a guardian appointed by a judge or court. We knew we would need to work with their guardian and with the person to follow the rules and respect everyone. We will share more about this later.

Micah: We also talked about how to make sure our study would help make communities better and not hurt the people who agreed to be in the study. This is the principle of beneficence—that's a big word but see how it looks a lot like benefit?

Ariel: We also tried to imagine what bad things might happen in the study. We thought the worst thing that would happen is that some people might get upset answering our questions about their experiences with mental health services. So, we made a plan for what to do if that happened.

Katie: The last principle or big idea we talked about was justice or how we work to give everyone a chance to be in research. We wanted to make sure we recruited people from all different kinds of backgrounds. We wanted people from a lot of different backgrounds and experiences so that our findings can apply to a lot of people.

Micah: We thought about only including our friends in the study because that would make doing the research a lot easier. But, we decided not to do this because we wouldn't be able to learn about all types of people with disabilities if we only included our friends.

Brendan: We'll talk more about how these 3 big ideas can help you make decisions about how to set up your research project. Remember, anytime you aren't sure about something, talk to your project leader.

Topic 2.4: Research with Health Records



In this topic you will learn about research with **health records**.

Sometimes researchers use information about people that has been collected for other reasons.

For example, doctors keep records of information about conditions, and test results—like blood pressure. **Health records** also have people's contact information like their phone number and home address.

Doctors keep this information in health or medical records.

Researchers can use health records in research. Health records are information a doctor keeps about a patient's health. Health records include information like a patient's height, weight, health condition, and test results. Health records are also called medical records. Health records can be used to find people to invite to be in a study. For example, if you want to study a new treatment for diabetes, you can send out an invitation to people who are getting treated for diabetes at a health center.

Health records can also help answer research questions. For example, some people with cerebral palsy might get shots to relax their muscles. Researchers can use health records to study the most common age people start getting shots, how often they get the shots, and if the shots helped.



There is a law in the United States about health records.

The law is called **HIPAA**.

HIPAA stands for the **Health Insurance Portability and Accountability Act**. That's really long! People usually just say HIPAA.

HIPAA is about keeping people's health records confidential. HIPAA has rules for who is allowed to see health records and how health records can be used. HIPAA is all about protecting people's confidentiality.

Confidential means that only people with permission can see the information.

Sometimes researchers can look at information in health records without getting permission from individuals.

If people need to give permission to have their health records used for research, it's called HIPAA

Authorization. If you ever asked your doctor to share your health records with another doctor, you probably gave HIPAA authorization.

It is very important to follow HIPAA and to keep people's private health information confidential. Talk to your project leader about HIPAA rules and your study.

Topic 2.5: Research with Educational Records



In this topic you will learn about research with educational records.

There are also rules that researchers need to follow if they want to use information that schools collect about students.

Educational records are information that schools keep about students. This can include their grades, test scores, and the services they get.



There is a law in the United States about keeping educational records confidential. The law is called **FERPA**. FERPA stands for **The Family Educational Rights and Privacy Act**.

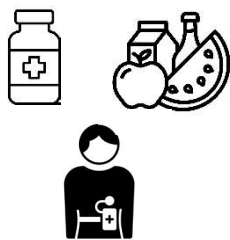
FERPA says we have to protect students' records and information.

FERPA has rules about what schools can or can't share from students' educational records.

FERPA also says that sometimes the student must give permission for their school records to be used for research. If the person is a child under the age of 18, then their parent must give permission for the records to be used.

If your study includes educational records, your project leader will help you learn more about what FERPA means for your study.

Topic 2.6: Research with Food, Dietary Supplements, Medications, and Medical Devices



In this topic you will learn about research with things that impact people's bodies.

Sometimes research is done with things that impact people's bodies—like food; dietary supplements like vitamins; medications; or medical devices used inside or outside people's bodies. In these types of studies, researchers have to follow rules from the U.S. Food and Drug Administration or FDA for short.

FDA rules help make sure people are safe when they are in research with things that might impact their bodies.

FDA rules include things like:

- What people have to be told when they are deciding if they want to be in a research study
- How to handle emergency situations like if a person's life is in danger or if a person has a serious reaction to a medication
- What must be reported to the FDA about the research

FDA rules are complicated.

If FDA rules need to be followed in your study, you will have someone on your team with special training to make sure your study follows the FDA rules.