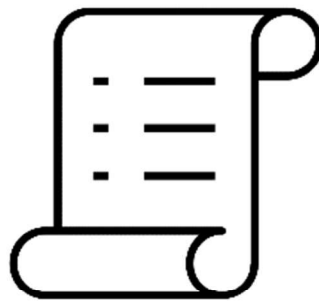


## Unit 2: History of Scientific Research with People and Rules



## Topic 2.1: History of Research with People



### Main Ideas



- **Good things can happen** when we do research.

The good things that can happen are called **benefits**.

- Research benefits can be for the person in the research study or for other people in the future.



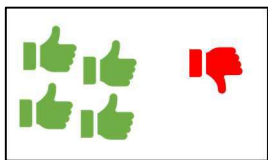
- **Bad things can happen to people in research.**

The bad things that can happen are called **harms** or **risks**.

- Examples include hurting someone's body or feeling sad.



- **Research ethics** are **about making sure people are treated well** and that their **rights are respected** when they are in research.



- **Research ethics** are also about making sure **more good things happen than bad things** when we do research.



## Discussion Questions



1. When you think about research, what pictures or words do you think about? What feelings do you have?



2. How do you think other people with developmental disabilities might feel about research?



## Discussion Questions



3. How do you think people's different experiences with research studies in the past might make them feel about being in research studies now?

## Topic 2.2: Rules for Scientific Research with People

### Topic 2.2.1 Rules for Scientific Research with People



#### Main Ideas

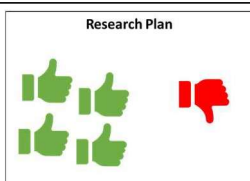
- 
- The **Belmont principles** are the values that help us think about how to treat people when they are in research. They are:
- 



- Respect for persons** is about **believing that everyone can make decisions** with or without support. Respect for persons also means taking extra care of people who have a hard time making decisions.
- 



- Justice** is making sure **all types of people can be in research** and that everyone shares the good and bad things that can happen in research.
- 



- Beneficence** is about making research have **as many good outcomes as possible** and keeping people as safe as possible.
-

## Topic 2.2.2 Institutional Review Boards



## Main Ideas



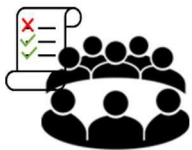
- 
- **Institutional Review Boards (IRB)** are groups of people who make sure researchers **protect people's rights and well-being**.
-



## Discussion Questions



1. Why is it important to have rules for research with people?



2. What does the IRB do?

3. Why is the IRB's job important?



## Putting it into Action: Disability Rights and Research Rules



Talk with your team about how some of the main values in research and disability rights are similar and different.



Check off each research rule that is related to the different disability rights.

You may think of other disability rights—you can talk about those too.

| Disability Rights                                                                                                                                                                                                                                                                         | Research Rules<br>(Belmont Principles)                                                                                                                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> <li>Assuming people can do things and make choices               <ul style="list-style-type: none"> <li>This includes making choices that might not always work out or might be risky. This is sometimes called dignity of risk</li> </ul> </li> </ul> | <input type="checkbox"/> <b>Respect for persons</b><br><br><input type="checkbox"/> <b>Justice</b><br><br><input type="checkbox"/> <b>Beneficence</b> |
| <ul style="list-style-type: none"> <li>Having the same opportunities as everyone else to do things</li> </ul>                                                                                                                                                                             | <input type="checkbox"/> <b>Respect for persons</b><br><br><input type="checkbox"/> <b>Justice</b><br><br><input type="checkbox"/> <b>Beneficence</b> |

## Topic 2.3: Vulnerability



### Main Ideas

- 
- It is important to be **extra careful with people** who are **vulnerable**. 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.

---



## Discussion Questions



1. What helps you understand and make decisions?



2. How can you help someone else with a developmental disability understand a research study?



## Discussion Questions



3. How can you help people who have a hard time making their own decisions make a choice about being in research?

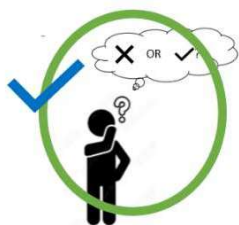
- How can we help people not feel pressured to make a decision?



4. Can you think of a reason we should not include people who are vulnerable in a research study?



## Discussion Questions



5. Why might we want to include people who may be vulnerable in research studies?

- When we do include people who may be vulnerable, what can we do to include them safely?



- How can we make sure that the rights of people who are vulnerable are respected?

## Topic 2.4: Research with Health Records



### Main Ideas



- Healthcare providers keep information about our health and medical history in our **health** or **medical records**.
- Health records can be used for research.



- There is a law called the **Health Insurance Portability and Accountability Act** or **HIPAA** that **protects the confidentiality** of people's **health records**.
- Research with health records needs to follow HIPAA.
- Usually, you need to get permission from people to use their health records for research.



## Discussion Questions



1. Why is it important to keep health information confidential?



2. What are good ways to keep health information confidential?

## Topic 2.5: Research with Educational Records



### Main Ideas



- 
- Schools keep **information about students in educational records**. Educational records include things like grades, test scores, and services.



- 
- The **Family Educational Rights and Privacy Act** or **FERPA** is a law that protects the confidentiality of people's educational records.

- 
- Research with educational records needs to follow FERPA.

- 
- Usually, you need to get permission from people to use their educational records for research.
-

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



### Main Ideas



- The Food and Drug Administration or FDA has rules about doing research on new things that could impact bodies and improve health.



- **FDA rules** are about:
  - what to do in emergency situations
  - what people need to be told about a research study,
  - and what information about the study must be shared with the FDA.
- It is important to follow the rules the FDA has to keep people safe in research.