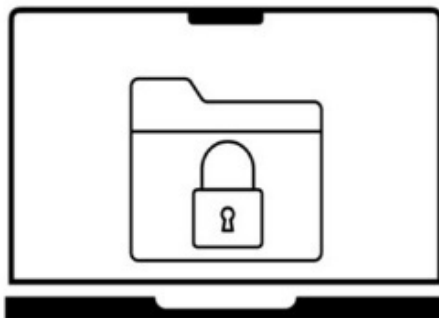


Unit 4: Keeping Research Participants Safe

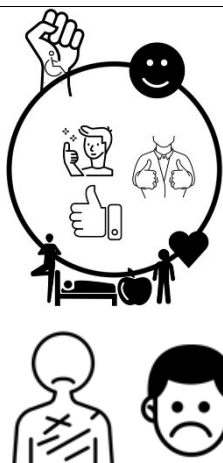


Topic 4.1: Risks and Safeguards

Topic 4.1.1: Introduction to Risks



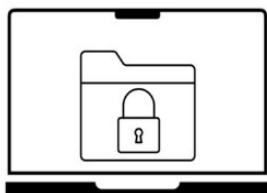
Main ideas



- It is **important to keep people safe** in research.
- Researchers have to **balance the good (benefits)** and **bad (harms or risks)** things that can happen to people when they are in research.



- Every research study has **different good and bad things** that can happen.
- The **good and bad things might also be different for different people** in a research study



- **Safeguards** are the things researchers do or use to **keep people safe** when they are in research.



Discussion Questions

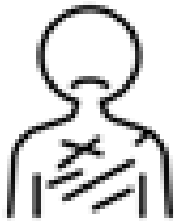


1. What are some risks that you think could happen in research?

Topic 4.1.2: Physical and Psychological Risks and Safeguards



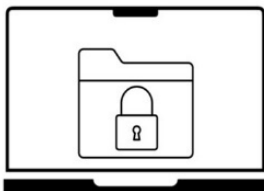
Main idea



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



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



- **Safeguards** are the things researchers do or use to **keep people safe** when they are in research.
-



Discussion Questions



1. **Who** may have a hard time talking about mental health with the Mental Health for All team?

- What **experiences** or **feelings** might be hard to talk about?
- **How** can you **help** someone who has a **hard time talking** about their **feelings** or **experiences**?

Topic 4.1.3: Social Risks and Safeguards



Main idea



-
- **Social risks** are bad things that can happen related to other people.
 - Social risks can include how people think about and treat you. They can also include changes in how you feel about other people.
-



Putting it into Action: Being Clear

You are doing a research study that will ask people to do

4 interviews over 4 months. You **worry** some **people will be sad** about the **study ending** and not getting to talk to you anymore.

Practice explaining how many times you will see participants during the study and **what will happen when the study ends.**

Write a script to help you talk to the participant. Explain:

- **How many times** you will **see each** other while you are doing the interviews
- **What will happen when** you are **done** doing the interviews:
 - You will **probably not see each** other after the interviews end.
 - What will you do with the information they shared with you?
- Think about **how** you will **say goodbye** in a way that makes them feel like you will not forget about them.
- Explain what will happen if you see each other in the community. Remember everything you learned about keeping people's information private and confidential.



Putting it into Action: Being Clear

Write your script to talk to the participant about the study ending.

Topic 4.1.4: Legal and Economic Risks



Main ideas



- **Legal risks** are about the law.



- **Economic risks** are related to money.
-

Topic 4.1.5: More information about risks and safeguards



Main ideas



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- If something very stressful happens during research, it may be important to **debrief**.
 - **Debriefing** means talking about what happened and why.



-
- An **adverse event** is when someone is hurt in research in a way you weren't expecting them to be hurt.
-



Discussion Questions



Risks and Safeguards for the Mental Health for All team's study



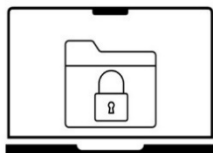
1. What are some possible **risks** or **harms** in the Mental Health for All team's study?

- What can they do to **make sure people stay safe** in research?

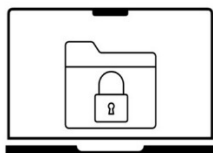
Topic 4.2.1: Privacy and Confidentiality



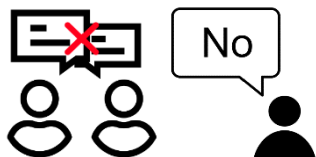
Main Ideas



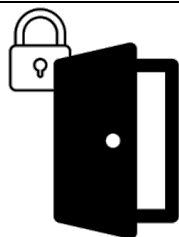
Privacy and confidentiality is about keeping research participants' information (data) safe so other people don't have research participants' information.



- Keeping people's **information private** and **confidential** is important in research.
- Researchers keep people's **information private** and **confidential before, during, and after** people are in a **research study**.



- You cannot **share information** you learn about research participants **with anyone who isn't on the research team**.



- We usually **do research in private places** to make sure information stays private and confidential.



Putting it into Action: “That’s confidential!”



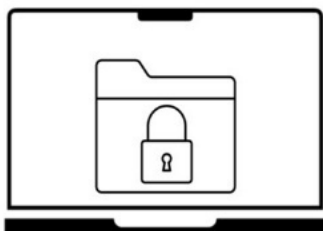
Practice **explaining** to a family member or a friend **what** you **can** and **can not share about** the **research** study and the people in it.

You can write a script to help you **explain what** you **can** and **can not** share about the study. Then, act it out.

Topic 4.2.2: Privacy and Confidentiality when Other People are Present



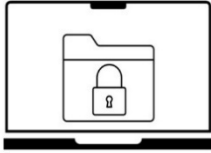
Main Ideas



-
- Researchers also need to **think about privacy and confidentiality** when **participants bring someone** with them.
 - Other people do not have a right to know research participants' information.
-
- You can **ask your project leader for help** when you are **not sure what to do** about something the person the research participant brought with them says or does.
-



Discussion Questions

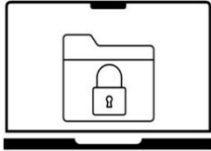


1. What are some **concerns** or **challenges** the Mental Health for All team might have about **how** they will **keep** research participants' **information private** and **confidential**?

- **How** can they **keep** research participants' **information private** and **confidential**?



Putting it into Action: What does Privacy and Confidentiality Look Like?



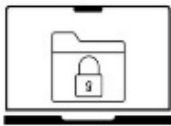
Describe, write, draw, or act out what **privacy** and **confidentiality looks like** when you are collecting information from participants in a research study.

- **What** would the **room look** like where you are collecting data?
- **Who** would be there?
- **What** could **you do** or **use** to keep research participants' information private and confidential?

Topic 4.2.3: Privacy and Confidentiality when Sharing about Research



Main Ideas



- Researchers need to keep information private and confidential when they **share about research**.
 - It is important to not share research participants' names or other information that could let someone figure out who they are.
-

Topic 4.3: Breaking Confidentiality and Mandatory Reporting



Main Ideas



- **Mandatory reporting** means if researchers learn that a research participant is being hurt or abused, they have to share the information with authorities (people who can stop other people from being hurt). Researchers also have to share information if they found out a research participant is hurting or abusing someone else.



- Mandatory reporting means you **cannot keep information private and confidential** if you find out **someone is being hurt or hurting someone else**.



- Mandatory reporting **helps people be safe**.
- **Mandatory reporting can be hard**. Your **project leader can help** you learn more about mandatory reporting.