



*Research Ethics for All:
Accessible Research Ethics Education for Community
Research Partners*

Topic 3.3: Consent: Working with people as they make decisions about being in research

Once you have invited people to be in your study and figured out that they are eligible to be in it, you need to work with them on making a decision about being in your research study. This unit is all about how to treat people well when they are making decisions about being in research.

Topic 3.3.1: Main ideas of consent: informed, voluntary, and ongoing.

Like we talked about before, people have the right to know information about a study, make their own choice about being in a research study without pressure from other people, and, if they want, get support when making decisions about being in a research study. We call this decision-making process **consent**.

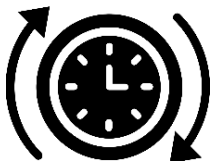
Consent to research participation means a person making an **informed, voluntary, and ongoing choice**.



- **Informed** means that people have all of the information they need to be in a study.



- **Voluntary** means making your own choice without pressure from others.



- **Ongoing** means that researchers check for consent from the beginning to the end of the study.

One of your roles in your research team may be to help plan how your team will ask for consent. You can share your ideas about:

- how to make information easy to understand,
- how to make sure people can make their own choices, and
- what to look for to see if people have changed their mind about being in the study.

This is an important responsibility!



Consent can happen in different ways. Sometimes people will learn about a study on their own (like from a website) and make a decision. Sometimes, researchers give people the choice to be in a study during a consent meeting—a meeting where someone learns more about the research and decides if they want to be in it or not. Sometimes these meetings are one-on-one, and other times they are in a group.

After the meeting, a person may say they want more time to think about their decision. They can:

- Say “yes, I want to be in the study”
- Sign their name to a consent document
- Click “yes I agree to be in the study”
- They may make their “mark” to sign their name. Sometimes not signing a full name is an accommodation for participants.
- They may also decide that they do not want to be in the study and say “no.”



Dissent is when someone decides they do not want to be in a research study.

Remember, we mentioned 3 ideas about consent-informed, voluntary, and ongoing? Let’s talk about those now.

The first big idea is that in research, researchers make sure there is **informed consent**.



Informed means that people have all of the information they need to be in a study. This includes knowing why the study is being done and what will happen if they are in the study, including good and bad things that can happen. It also means that they know how their information will be used and know their rights and the choices they have about the study.



The second big idea is that consent is **voluntary**.

Voluntary means making your own choice without pressure from other people. People in research have the right to say no to any or all parts of a research study. Remember, when people say no, that is called dissent.

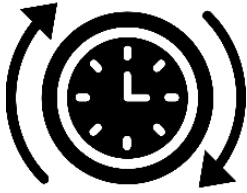
Sometimes it can be hard for someone to feel like they can say no to being in a research study. You need to pay attention to whether anyone is feeling pressured to say yes to being in a study, especially if they have a guardian or when someone has more power or control than the person.

Think about the types of people in your life who have more power than you. People who have more power than you are people who you feel like you have to listen to or who make decisions about your life. For example, if the person doing the research is their teacher or doctor, those people might have power and someone might feel like they have to participate in the research study.

Another example might be if a support person or family member really wants someone to participate in the research project or if someone is invited to be part of the research by a friend. You'll hear more from the Mental Health for All Team about how they handled these types of situations.

There are other reasons someone could have a hard time making their own choice to do research. For example, some people might feel forced to say “yes” to be in research if they are feeling rushed to make a decision.

That’s one of the reasons you should always take your time with consent and let people have the time they need to think about their decision. It can also be hard to say no to a research study if the research study offers a lot of money or other valuable compensation. That’s why you shouldn’t emphasize payments or gifts during recruitment and you should make sure they aren’t too big.



The third big idea is that consent is **ongoing**, or something that happens from beginning to end of a research study.

You should always make sure people know they can stop the study at any time even after they say yes to being in the study. You have to make sure that it is easy to stop at any time. Ongoing consent also means that people can choose to only do some of a study.



Mental Health for All Team Talks About Consent



Brendan: One of our jobs was to help figure out how to make sure that people in our study were informed. This means they understood the information about our study.

We also had to help make sure people felt comfortable saying no and could make their own choice—this is voluntary consent. We learned that making sure consent is voluntary and informed starts with recruitment.



Micah: We talked and came up with a lot of good ideas. Here are some of our tips!

Think about where you recruit people. You might want to recruit in places people know and are comfortable in. Think about the sensory environment, like lights and noise.

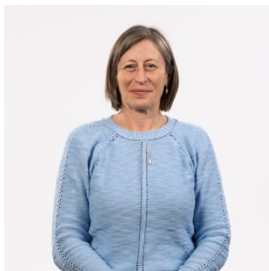
Brendan: We also talked about how to share all the information people need to know to make their decision. When we talked about the study, we made the information accessible by using pictures, easy to understand everyday words, and talking slowly. We also repeated the most important information. Remember everyone might need something different to understand.

When we did recruitment, we learned that sometimes we needed to learn a more individualized way to communicate with someone. We talked as a team and decided in these types of situations to create a list of ways to communicate and understand each other.

Micah: We talked with people and their supporters about what it looks like when they are saying yes and no. We wanted to make sure we didn't misunderstand what they were telling us.

Brendan: When we recruited people to be in our study, we gave them time to make a decision. One way to do this is by telling them all about the study and then letting them know they can decide later.

When they decide later they get more time to think and it is easier for them to say no. It might be really important to take extra time for studies that might hurt people or for studies where participants need to do a lot of things.



Katie: We practiced ways to act friendly, show we believe in people's abilities to make decisions, and help people know they can ask questions. When someone shared a worry, we gave them the information they needed to feel more comfortable.

Micah: We didn't pressure them to say yes to being in our study and we reminded them that we wouldn't be upset if they said no.



Ariel: We reminded them that even though their group home provider was excited about the study, they could still say no to being in the study and we wouldn't tell their service provider.

We knew how important it is to make it easy for people to say no, even when we were first telling them about the study. We used these communication cards so they could just point to their choice. We also included choices of telling us they needed a break or wanted to keep going.

Brendan: Ariel and Katie told us that it may be hard for people to understand that we are studying an experimental way to help them get better mental health services and that we don't know if it will work. We made sure to tell people that we didn't know if the study would help them a few times so they would understand.

Ariel and Katie also said sometimes it is hard for people to understand how the bad things that might happen can impact them. As part of the consent meeting, we helped people by making a card sort of reasons they would or would not want to be in the study. We helped them do the card sort and think about all the things that could happen in the study.

Consent information can look different for different studies. But usually consent forms have the most important information about a study, like why it is being done, what you will need to do if you are in it, the good and bad things that could happen, who is doing the research, and how the researchers will keep your information safe. Check out your workbook to see our consent form.

