

## Topic 2.2 Unit: Rules for scientific research with people

Let's talk 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, and



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 three big ideas are called the Belmont principles.

The three big ideas in the **Belmont principles** are:

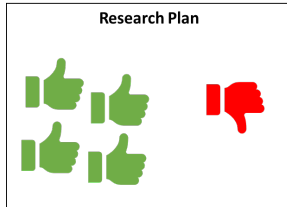
- respect for persons
- beneficence
- justice



**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.

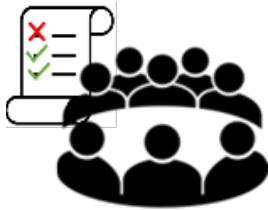
Respect for Persons is related to disability rights and self-determination, because people are in charge of their research decisions. You should make sure people always get the support they need to be in charge of their decisions.



**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.



There are also 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 has to 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.