# Informed Consent:
# What You Need to Know

## What is informed consent?

Informed consent is the process of telling interested individuals what is involved in taking part in a specific research study. Typically, this includes

- reviewing written information
- giving the potential volunteer time to review this information while considering participation (taking it home to review with friends or family, if desired)
- discussing the information verbally
- answering any questions.

Once all of the information is provided to you and your questions are answered, you will then be asked to decide whether or not to take part in the study. All decisions are voluntary, and you must provide your agreement (i.e., consent) before any study activities can begin. Usually, this involves signing a consent form. Although, for some studies, verbally agreeing to participate may be sufficient.

Once you provide consent to be in the study, you will continue to receive important information about your participation throughout the study.

## Why is informed consent important?

It's important to understand what is involved in taking part in a research study and to carefully consider what that means for you. Research can pose risks to your health, safety, and welfare, so it's important to understand exactly what those risks are. It's also important to understand that taking part in research is voluntary. You make the decision about whether or not to participate, and if you agree to take part, you can always change your mind later.

## Who can sign the form?

State law determines who can provide consent. In New York State, only individuals 18 years of age and older can provide consent. Minors, based on their age and ability, are usually asked for their agreement to participate in research, but their parent or legal guardian must also provide their permission to participate. Other special considerations are also made when a minor is a ward of the state or adults are unable to make decisions for themselves. If you have questions about who can or cannot provide consent, be sure to ask the study team.

## What do I need to know before I agree to participate?

Before you agree to be in the study, make sure you have a solid understanding of the following:

- the voluntary nature of the study
- why the study is being done
- who is doing the study
- the procedures, activities, tests, or treatments involved (including how long they will take, how often they have to be completed, and whether there are any other treatment options available rather than being in the study)
- potential risks, discomforts, or side effects
- potential benefits to participating, if any
- how your privacy will be protected
- how long your participation will last
- what will happen if you are injured while participating
- the costs to you, if any
- what to do if you change your mind about participating
- whom to contact with questions, concerns, or problems

## Points to take home

- Being in a study is voluntary—*it is your choice.*
- If you join a study, you can change your mind and *stop at any time.*
- If you have questions about anything that is not clear to you, you can ask them at any point of time before, during, or after the study.
- If you feel you need more time or information to make an informed decision about whether or not to take part in the study, do not hesitate to ask for it.

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