The decision as to whether to participate in a clinical trial is an important one. You do not have to participate in any research offered to you. Your participation in research is voluntary. Therefore, take your time making this decision. You should seek the advice of trusted family members, friends or healthcare professionals before and during the research.

To help you make an informed decision, you have the right to receive information about the study. This information should always be given to you in writing (e.g., in a written "informed consent form" or "research information sheet") as well as orally.

The information must be presented to you in a language that you can understand. The person who presents this information to you should explain in detail what the study is trying to find out, what will happen to you (e.g., what treatments will be given to you), and what you will need to do. In addition, you should be told how much time you will need to be involved in the study (e.g., how many visits and the duration of those visits), what risks or discomforts you may experience during your participation, and what benefits, if any, that the study may offer you.

After the most important information of the study has been presented to you, you have the right to:

- Be given adequate time to decide whether to be in the research study and to make that decision without any pressure from the people who are conducting the research.
- Refuse to be in the study. Refusal to participate will not have any adverse effect on the care you receive.
Your Rights as a Research Participant, continuation...

- If you opted to start participating in a study, you can stop participating at any time after you begin the study without penalty.
- Ask any questions about the research study or other procedures involved.
- Be informed whether there are any costs associated with being in the study and whether you will be compensated for participating in the study.
- Be informed of who will have access to information collected about you, and how your confidentiality will be protected.
- Receive the names of the person/offices to contact with questions about the research, about research-related injury, and about your rights as a research subject.
- Be informed about other non-research treatment choices you have if the study involves treatment or therapy.
- Receive a signed and dated copy of the consent form, when one is required for research.
- Receive a Research Participant feedback form, so that you can provide your opinion about your experience as a research participant.

The most important thing a research participant should do is take an active role and communicate with the study team before, during and after the research. You should always ask questions if you are not clear about something, if you are curious about something, or if it seems like the research plan is different from what you understood.

If you feel uncomfortable with what you are doing, or if you think you might be experiencing issues with your health, let the study team know so that they can help you.

Educational Resources for Research Participants
U.S. Federal and Drug Administration (FDA)

The FDA has posted the following information to help potential research participants learn more about clinical trials. Click on the hyperlinks to access the information.

Clinical Research Versus Medical Treatment
Understand the differences between clinical research and medical treatment. Find answers to your questions about clinical trials, such as why they are done, who should consider participating, and issues to consider before joining a trial.
What are the Different Types of Clinical Research
Understand the different types of research and the four clinical trial phases, such as their purpose and how many people participate in each of the phases.

Informed Consent for Clinical Trials
Understand what informed consent is and the questions you need to know before signing informed consent.

To access the above information in Spanish click [here](#).

The Office of Human Research Protection (OHRP) has posted the following educational resources so that you can learn about the regulations that protect research volunteers, why these regulations are in place, and who enforces them.

Why are there regulations to protect research participants? The regulations we have today to protect research participants came about after a series of events in the twentieth century in which doctors and scientists abused the trust that society placed in them. To learn the history of these regulations, click [here](#).

What regulations protect research participants? To learn about the federal rule titled “Common Rule” and the additional protections for research participants click [here](#).

Who oversees the regulations protecting research participants? The Office for Human Research Protections (OHRP) is part of the U.S. Department of Health and Human Services (HHS). To learn about OHRP and what this office does click [here](#).

Is all human subjects research regulated? Many research studies do not come under the Common Rule. However, there may be other regulations that provides protections. To learn more about this click [here](#).

Who is responsible for protecting human subjects in research? To learn the regulations, institutions, and individuals who protect research participants click [here](#).

To access the above information in Spanish click [here](#).