

Rights and Responsibilities of a Research Study Participant

As a participant in a research study, you will have responsibilities. You will be expected to arrive for all scheduled appointments, call the research facility if you have a reaction to a study drug or device, and to follow the study related instructions that are given to you. Certain studies require more visits than regular medical care. You may also be asked to make phone calls pertaining to the study protocol. Therefore, this may mean more out-of-pocket expenses, such as parking, babysitting or missed work time.

As a research participant, you have several rights:

- ❖ You have the right to decide if you do not wish to participate or if you wish to quit the research study with no penalty or loss of benefits at any time.
- ❖ You have the right to ask any and all questions that may occur before, during or after about the research study.
- ❖ You do not waive any legal rights by joining a research study or by signing a consent form.
- ❖ You have the right to receive a copy of the consent form.
- ❖ You have the right to be informed about the research study. The main source of information is the consent form. However, you are encouraged to ask the Principal Investigator questions in order to make an informed choice regarding your participation.
- ❖ You have the right to be made aware that the ethical and legal codes that govern medical practice also apply to clinical trials.

Being in a research study is an important decision. **If you do not understand some and/or all of the information being presented to you about the research being conducted, you should contact the study staff.** It is important to discuss your expectations before you agree to be in a research study.

Risks and Benefits of Participation

Joining a research study involves risk. These risks can vary from study to study. For each study, the risks involved should be clearly explained in the consent form. You, as the study participant, should understand what risks are anticipated in any research study that you are considering. With any study, there can be unanticipated risks. There may be unpleasant, serious or even life-threatening side effects to some of the procedures.

Receiving benefits will vary from study to study. Just as the risks are different, so are the benefits. However, there are some research studies where a study participant may benefit directly and his/her disease or condition will be positively impacted. The main goal of a research study is to be able to collect information that can be used to better understand and/or help others in the future.