

RESEARCH PARTICIPANT INFORMATION

What is an “IRB”?

An Institutional Review Board, also called an Independent Review Board (IRB) is a group of people (or a “Board”) who review research to make sure that it will be done safely, and that protects the rights, safety, and welfare of the research participants. They also review the Informed Consent Document to make sure it provides enough information about the research in terms you can understand, so that you can decide whether or not you want to participate. If the Board feels the research is safe they will approve it. Sometimes they make changes to it so that it can be conducted more safely. About one year later they will review it again. Salus IRB has members on its Board with different backgrounds such as a lawyer, doctors, pharmacists, a psychologist, a toxicologist and additional members of the community who do not have scientific backgrounds.

IRBs follow the rules of the United States Department of Health and Human Services and the Food and Drug Administration (FDA). IRBs were originally formed to make sure that people are never involved in research studies without their knowledge or permission, and without first understanding what their participation will require, and what may happen to them in the research study. Before approving a study, the IRB considers:

- the possible risks of the study and the possible benefits of the study;
- the ways the Study Doctor will protect the privacy of participants in the study;
- the way the Study Doctor will make sure that the research participants are fully informed of their rights.

What does Salus IRB do for me?

Salus IRB is dedicated to protecting the rights and welfare of research participants. Before you agree or disagree to be in a research study, you should understand all of the potential risks and potential benefits and all of information presented in the Informed Consent Document. However, the Informed Consent Document is not meant to replace the discussion that should occur between you and the Study Doctor and/or research staff. Taking part in a study is your choice; you do not have to take part in a study. Before you make your decision, you should have all of your questions answered so that you will know the following:

- the purpose of the study and what is being tested
- the procedures to be followed, and any drug or device that will be used
- any risks or discomforts that can reasonably be expected
- any potential benefits, if any, that can reasonably be expected
- any alternative treatment options that are available, and their relative risks and benefits
- how to seek medical care if there are complications
- an explanation of anything you do not understand in terms that you do understand
- an explanation that you have the right to withdraw your consent at any time
- an explanation that the Study Doctor or study sponsor may withdraw your consent at any time
- that you will be given a copy of the signed and dated written informed consent document
- that you will be given the opportunity to decide to consent or not to consent to a research study without the intervention of anyone, without fraud, deceit, duress, coercion, or undue influence.

You are encouraged to ask as many questions as necessary before, during and after taking part in any research study. You should not agree to take part in a research study until your questions have been answered. After you have had all your questions answered, you can then decide whether or not you want to participate. You may take your time to make this decision and discuss it with a friend or your family doctor if you want to. If your family doctor is part of this research study, you may discuss your care with another doctor who is not part of this research study. You may contact Salus IRB at 855-300-0815 with any questions at any time before, during, or after your participation, with questions, comments, or concerns. Salus IRB wants to ensure that your rights, safety, and welfare are protected.