

Research Brochure for Patients

What is a Clinical Research Study?

A clinical research study is sometimes called a clinical trial. Clinical trials show if a medication or a medical device works and if it is safe. In order for a medication or medical device to be approved by the Food and Drug Administration (FDA), it must be tested in clinical trials.

The same ethical and legal requirements that govern the practice of medicine apply to clinical studies. Clinical research studies are very closely controlled and have built-in safeguards. Investigators are required by law to follow very specific procedures. Patients are monitored frequently to check their health progress.

Clinic Research studies at SLICA

St Luke's Idaho Cardiology Associates, (SLICA) is the largest cardiology practice group in the state of Idaho. For nearly a decade, the Clinical Research Department of SLICA has participated in national and international clinical trials specific to the treatment of heart disease.

Our goal at SLICA is to provide our patients and community with superior research services that are consistently ethical, caring and honest in the pursuit of the advancing healthcare and improving lives.

What are the benefits and risks of joining a clinical trial?

Benefits:

- Gain access to new research treatments before they are widely available
- Obtain increased medical care at leading health care facilities during the trial
- Help others by contributing to the development of a new medication or device

Risks:

The risks involved in taking part in a clinical trial are that the study drug might not work or may cause side effects. Side effects are problems that may be associated with the study drug or procedure. These effects can range from unpleasant symptoms to life-threatening reactions. You will be told if there are any known side effects before you agree to take part

What are your rights as a participant in a research study?

Self Determination - participation in a clinical trial is completely voluntary and you have the right to decide if you will participate or not.

Privacy - you have the right to decide when and how much of your private information will be shared or withheld from others. This includes information about your beliefs, behaviors, and opinions.

Anonymity and Confidentiality - based on the right to privacy, you have the right to assume that data collected will not be shared with others not involved with the study in which you have agreed to participate.

Fair Treatment - you are entitled to know the benefits and risks of a study and have your role specifically explained to you.

Protection from Discomfort and Harm - you can expect that every effort will be made to prevent discomfort and harm to you as a result of your participation in a study.

What is an Informed Consent Document?

If you are interested in joining a research trial, you will be presented with a document called an Informed Consent. This document will have complete information about the trial, written in easy to understand language.

The study staff (Clinical Research Coordinator) or the study physician (Principal Investigator) will go over the Informed Consent with you. They will make sure that you understand everything about the trial, including any possible risks and the possible benefits. If you are still interested in participating in the trial, you will be asked to sign the Informed Consent form.

Please keep in mind:

- Research trials are completely voluntary, and it is ok not to participate.
- Take all the time you need to make your decision, discuss the trial with family, friends, and your physician.
- Signing the consent form means you understand what is involved.
- By signing the consent form, you are not giving up any of your rights as a research participant.
- Even after signing the consent form, you may withdraw from the study at any point.

Please contact our Research Department for further information:

@idahocardiology.com or (208) 322-1680.