About Research Studies

What if I change my mind?

You may change your mind at any time and drop out of a study. It will have no effect on the cost of care or the kind of care you receive. However, you may be asked to return for additional tests for safety reasons on certain studies. Please ask for more details.

Who conducts these research studies?

Almost all professional health care providers including doctors, nurses, therapists, dieticians and social workers, conduct research. The study physician, or principal investigator, has overall responsibility for the study. Other people, co-investigators, may share some of the work that needs to take place for a successful study. The study coordinator is the person who makes appointments and collects information during the study. Together, the study physician and study coordinator identify possible participants for the study and obtain their consent. The study staff closely follows each person enrolled in the study during the time the study is ongoing.

If you would like more information or if you have questions about your rights as a research subject, please call the Lifespan subject advocate at 401-444-5843.

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Lifespan

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Research and Human Subject Protections at Lifespan

Lifespan

Consent Is the First Step

Medical care has improved in the last 40 years. New medical treatments have been developed, in large part, through research conducted in laboratories, clinics and hospitals. Clinical research, research conducted with people, is vital to developing new medications and treatments.

At Lifespan hospitals and our associated clinics, our staff participates in clinical research. This allows us to offer our patients the most current care available.

While you receive care at a Lifespan hospital or clinic, you may be asked to take part in a research study, or you may be asked to give permission for a family member who is not able to make the decision for himself or herself. We understand that our invitation to be a part of a research study may come at a time of emotional stress, but we will explain the study, answer your questions and allow you time to make your decision.

You (or your representative) must give permission for you to participate in a research study. You may not be in a study without your knowledge and consent. A consent form may appear complex because it is important that you have all the information needed to make a decision. A consent form must contain the following:

- an invitation to be a part of the research project
- an explanation of why the study is being done
- a statement about the company or agency that is funding the study, if there is one
- detailed information about any risks of the treatment as well as any benefits of participating in the study
- information about other treatments that might be available if you choose not to be a part of the study
- identify who will have access to your personal health information and who will be able to use the information obtained by the study
- identify whom you may ask for more information about the study or about your rights as a participant in the study

What Is the IRB?

Before any study is started, the people involved must develop a plan for the research. The plan and a consent form are reviewed by the Institutional Review Board (IRB). All studies conducted at Lifespan are reviewed and approved by the IRB. This board is made up of doctors, nurses, pharmacists and community members. The IRB is responsible for ensuring the safety of people enrolled in research studies. This board reviews the study and decides if the study is being carried out in the best way to lessen risks and benefit patients. If the IRB does not approve the study, it cannot start. The study physician, or principal investigator, must come back to the IRB any time there is a change in the study and to report the progress of the study at least once per year.

The consent form is reviewed to make sure it contains complete information and to ensure that the forms are written so that they may be understood by people unfamiliar with medical terminology. You will receive a copy of the consent form after you have signed it so you may refer back to it as the study progresses.

You are under no obligation to participate in any research study. Your decision will not affect the care you receive at Lifespan hospitals or clinics.

To Answer Your Questions

Most people have questions when they are invited to take part in a research study. Commonly asked questions are:

Will I receive payment for volunteering?

Research study costs are sometimes paid for by companies or grants that reimburse volunteers for their time. Not all studies pay for participation; however, you may receive testing and medications free of charge.

Will I personally benefit if I volunteer?

Research is usually conducted to answer a question or to determine if one treatment is better than another. You may not directly benefit from the study while you are participating.

Does my doctor need to know about the study? Do I need his or her approval?

At your request, your doctor will be made aware of the study. You should feel free to discuss the study with family and friends.

What if I don't want to be a part of a study?

After receiving an invitation to join and listening to all the information about the study, you decide whether or not you wish to participate. You are under no obligation to participate in any study.