



About Clinical Trials

The ultimate goal of research at The Christ Hospital is to improve health care. Many of the men and women who provide medical care at The Christ Hospital are conducting clinical trials to try to improve the quality of that care. Clinical trials are research studies that involve patient volunteers to help find better ways to prevent, diagnose and treat diseases. To study possible improvements, our researchers need to compare different treatments, drugs, or procedures to see how they work. Today's research will guide the improvements for tomorrow's cancer care. As a patient at The Christ Hospital, you may be asked to participate in such a research study.

For more information about rights of research participants, please contact the IRB Office at 513-585-2742. You can also learn more about research with humans at any of these Web sites:

- Office for Human Research Protections
<http://www.hhs.gov/ohrp>
- National Center for Bioethics
<http://www.tuskegee.edu/bioethics>
- NIH Bioethics Resources on the Web
<http://www.nih.gov/sigs/bioethics>

Would you like more information about clinical trials?

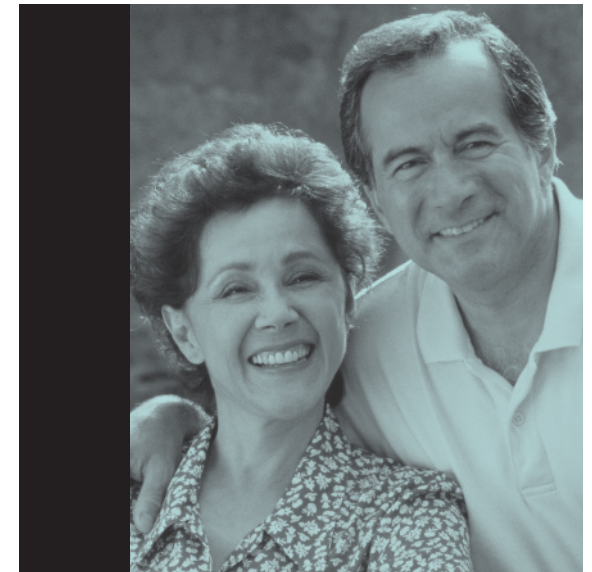
If you think you might be interested in taking part in a clinical trial and would like to speak to someone for more information, please contact our research coordinator at:

The Christ Hospital Research Department
2139 Auburn Avenue
Cincinnati, OH 45219
513-585-0844

www.TheChristHospital.com

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Are you interested in taking part in a clinical trial?

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What happens during a clinical trial?

When patients choose to take part in a clinical trial, the care they are given is much like the care they would otherwise receive. However, there is often additional monitoring for the purpose of learning about potential side effects and benefits of the clinical trial. Some trials simply test a study regimen and all participants receive this same regimen. Other trials may compare a study regimen to the standard treatment. In this type of study, participants are randomly assigned to receive one or the other. Neither the participant nor their doctor can choose which one they will receive for important scientific reasons. Some people worry that they will not know which drug they are receiving or that they will receive a placebo, sometimes called a “sugar pill.” Placebos are never used in place of a treatment that is known to work. Participants will always be told before agreeing to take part if a placebo is going to be considered.

Should I participate in a clinical trial?

The decision to take part in a clinical trial is a personal one. You may wish to talk to your family and loved ones, as well as members of your health care team, before deciding. As with all current standard treatments, there can be possible risks as well as benefits from taking part in clinical trials. Study drugs may be found to be more or less effective than current standard treatments and have side effects not yet known. You will be informed of these risks as much as possible. Your health care team will give you the information you need to make the decision that is right for you.

What is “informed consent?”

Informed consent means that patients must be told the key facts about a clinical trial before deciding whether to take part. If the patient agrees to take part, the informed consent process involves signing a form that details the entire clinical trial, possible side effects, and potential risks and benefits. Participants may withdraw their decision to participate at any time for any reason.

Is it safe?

Of utmost importance is the assurance that your rights as a research participant are protected, regardless of the nature of the study or the participant group in which you may be placed. The Christ Hospital Institutional Review Board (IRB) is the body which oversees the research being performed at The Christ Hospital. The IRB is charged with assuring research is conducted within established regulations and conform to the policies and procedures of the Hospital developed to protect the rights and safety of human research subjects.

Research Participant’s Bill of Rights:

If you are asked to participate in a research study, you have the right to:

- Be told what kind of study it is and why it is being done.
- Be given an explanation of the procedures to be used, as well as a description of any drug or device to be used.
- Be given a description of any discomforts and risks to be expected, as well as whether there will be any financial costs to you or your insurance company.
- Be given an explanation of benefits to be expected, if any.
- Be told of procedures, drugs, or devices that might help you if you do *not* participate in the study, as well as how the risks and benefits of such options compare with those of participating.
- Be told of any treatment or alternative treatment, if any, available to you during and after the study.
- Be given an opportunity to ask any questions about the study or the procedures involved.
- Be told of new findings that could change your willingness to consent and be informed that you may withdraw your consent to participate at any time, without penalty to you.
- Be given a copy of any consent form used in relation to the study.
- Be given the time and opportunity to decide freely whether to consent or not consent to participate in the study.

