Why participate in a clinical research study?

Your role in research is valued and protected.
Not only do the same ethical and legal requirements that regulate the practice of medicine apply to clinical studies, there are additional protections in place. Investigators are required by laws and regulations to follow very specific procedures. If you participate in a research study, you will be monitored frequently to check your health and progress. In addition, you have the right to leave the research study at any time.

All clinical studies have to be pre-approved by an Institutional Review Board (IRB) before participants can be enrolled. The IRB is an independent group made up of medical experts, non-scientists, and community members. It is the IRB’s job to make sure the study is as safe as possible and that there are benefits to doing the research. If you would like more information about your rights as a research subject, please contact the Office of Research Compliance:

**CONTACT US**

**MaineHealth Office of Research Compliance**

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Portions of this text was used from the National Institutes of Health’s Clinical Center website on Participating in Clinical Studies, and the US Department of Veterans Affairs Research & Development.
What is a clinical research study?
Clinical trials or studies are research studies in which real people participate as volunteers. The goal of clinical research studies is to help doctors find ways to treat disease. Before the general public can use drugs and devices, they have to be tested in smaller groups of people to make sure they are both safe and effective. Patients at MaineHealth hospitals and health facilities may be invited to take part in a clinical research study. This brochure will help you decide if being in a clinical research study is right for you or your family member.

Why participate?
- You have a chance to play an active part in your own healthcare and help others, too.
- It might help you directly by giving you access to an investigational drug or procedure you would not otherwise be able to receive at that time.
- Or, you may agree to participate so you can contribute to medical research and help find safer or better treatments for others, even though you may not receive any direct benefit from the research.

Who can participate?
Before you can take part in a clinical research study, you must first be “screened” to be sure you are right for the study and that the study is right for you. All studies will follow established guidelines describing who should be included in or excluded from the study. Sometimes a study will be looking for people with a particular medical condition, and sometimes a study will want healthy volunteers. It is entirely up to you whether you participate in a clinical research study. It is voluntary. If you decide not to participate you are not required to do or sign anything. Then you simply receive the treatment that you would otherwise normally receive.

Questions
If you are asked to be in a study you will be given a consent form with information about the study and a chance to discuss the study with a researcher. Take time to think about your choice and seek out a trusted advisor (relative, friend, nurse, etc.). You can bring someone with you to talk with the researcher and consider the following questions:

- What is the study about and who will be in it?
- Who is doing the study?
- What tests and procedures are involved?
- Why do the investigators think the drug or procedure being tested may be effective?
- Am I willing to be assigned (randomized) to either study group? Will I be satisfied with this decision while I am participating in this study?
- Do I have a strong preference to be assigned to one study group over another? If you do, a randomized study may not be a good fit.
- What are the possible negative things (risks) that could happen to me in the study?
- What are the possible positive things (benefits) to me in the study?
- How do the possible risks and benefits compare with the treatment I am getting now?
- How might this study affect my daily life?
- How long will the study last?
- How will my privacy be protected?
- Who will pay for the study drug and procedures?
- What type of long-term care will I receive?
- How will I know if the study drug or procedure is working? Will the results of the study be provided to me?
- Who will be in charge of my care during the study?