**Frequently Asked Questions for Patients**

* **Should I participate in a clinical trial?**

*This is a question only you, those close to you, and your healthcare providers can answer together. Learning you have breast cancer, and deciding what to do about it, is often overwhelming. Clinical trials are the most effective way to study cancer prevention, improve breast cancer diagnosis and treatment, and address the needs of breast cancer survivors. Each trial has a specific set of criteria that determines who is eligible to participate.*

*Individuals who choose to participate in clinical research studies may do so in hopes of improving their own health or advancing scientific knowledge about the cause, treatment and prevention of disease. The health of millions has been improved because of advances in science and technology, and the willingness of thousands of individuals like you to take part in clinical research.*

* **Am I eligible for a clinical trial?**

*Your eligibility may be determined by various factors, depending on the nature of the study. If you meet the screening conditions, you will be given an “Informed Consent Form” containing a detailed written description of the project, any risks involved, and your rights as a participant.*

*If the screening process involves any type of intervention, such as obtaining a blood sample or documenting personal health information, the consent process will be conducted prior to the screening to ensure that you are informed of what will be required of you and of any potential risks to your well-being. By signing and returning the consent form you agree to participate. If you should have second thoughts about participating, or become uncomfortable during the study, you have the right to withdraw at any time without any penalty whatsoever.*

* **What are the benefits of participating in a clinical trial?**

*Participating in clinical research may have a significant impact on your life. Some people may benefit directly from participating in a study, for example, if a drug being used in the study proves to be effective. Some people may not benefit directly, but their participation may help to advance knowledge that could benefit others in the future. It is important that you are well-informed and feel confident about your decision. We encourage you to join a clinical trial to offer the chance to try new treatments and possibly benefit from them. Learning a new therapy is better than the standard treatments can open doors to other drugs and procedures that may be even more effective.*

* **Is it safe to participate in a clinical trial?**

*Clinical research studies conducted at UConn Health are approved according to federal, state and UConn Health guidelines. In fact, no study can even begin before it has been approved by the Institutional Review Board (IRB), which carefully considers the potential risks and benefits of the study before authorizing it. The safety and protection of research subjects participating in these studies are of paramount concern. If you are interested in participating in a clinical trial, you will be given an informed consent form that spells out the nature of the study and any risks that are involved and clarifies your rights as a participant. If any kind of intervention is involved in the trial, such as obtaining blood samples or documenting the participant’s health history, a careful consent process is conducted before the person actually becomes involved in the study. This ensures that the research participant knows what is expected and any potential risks. Completing and returning the consent form means the person agrees to volunteer. But if the volunteer then has second thoughts, she/he can simply withdraw from the study anytime.*

*Additionally, UConn Health has a research subject advocate (RSA), whose job is to represent the interests of the volunteers who participate in our studies. The RSA has a number of responsibilities. She/he must provide information to patients and volunteers who are participating in any clinical trial and research where there is a greater than minimal risk. Other responsibilities of the RSA include:*

* *Assisting investigators to develop data and safety monitoring plans, and helping research advisory committees review those plans;*
* *Assuring that the Health Center’s studies adhere to the IRB-approved protocol and monitoring procedures;*
* *Ensuring the reporting of any significant problems or conflicts of interest to appropriate local committees and federal agencies; and*
* *Assuring that UConn Health investigators are appropriately trained and remain current on their regulatory and patient safety responsibilities.*
* **Who conducts a clinical trial?**

*Each study conducted at UConn Health has a principal investigator (PI) who is the person in charge of the research study. The PI may be one of a number of different kinds of healthcare professionals. He or she will assemble a team of research professionals who will also be involved in managing the study. The majority of the oncology research studies are conducted through the Clinical Trials Office (CTO), by qualified and trained research professionals who help the Principal Investigators (PI) successfully conduct clinical trials at UConn Health.*

* **What are some important questions to ask about clinical trials?**

*If you are considering participating in a clinical trial, you probably have a lot of questions. Even if you are eligible to participate in a study, you should give it careful thought before deciding to become a participant. While you may benefit in a host of ways from participation, you should also be aware that participating could impact your life in many ways, as well.*

*It is important for you to make an informed decision. So, you will probably want to consult with your personal physician and members of your family before making a commitment. If you have any concerns about the project, you should also discuss them with the research team working on the research study. Here are some questions you’ll want to obtain answers to before making a decision:*

* *What is the purpose of the study?*
* *How many people will take part in the study?*
* *What kinds of tests will be required as part of the study and how often will the tests be done?*
* *Are there any risks? How likely are they to occur and what will be done to reduce the likelihood of their occurring? Am I likely to benefit directly from participating in the study?*
* *What are the study’s potential benefits to other people and to society as a whole?*
* *What potential advantages does the experimental treatment offer over the current standard of care?*
* *How long will my participation in the study be required?*
* *What discomforts, inconveniences or costs will I experience as a participant?*
* *If I choose not to take part in the study, what other options do I have at this time for treatment?*
* *Can I withdraw from the study if I experience negative side effects?*
* *Will this treatment be covered by insurance? If my insurance does not pay for the treatment, who is responsible for the costs?*
* *Will any of the treatments be free?*
* **What are your rights as a participant?**

*Signing a consent form and joining a study does not obligate you to remain in a study. In fact, you can leave at any time if you decide, for any reason, that the study is not right for you. One of your key rights is the right to informed consent. This means that you must be given all the facts about the study before you decide whether to take part.*

*All volunteers who participate in studies at UConn Health are guaranteed rights that ensure they are treated professionally and respectfully. When you take part in one of our studies you have the right to:*

* *Be treated with respect.*
* *Know the risks of participation in the study.*
* *Know what alternatives are available.*
* *Withdraw from the study without penalty. Make your decision without feeling any pressure from the research staff.*
* *Know the name, credentials and contact information of the study’s principal investigator.*
* *Know the purpose of the study.*
* *Know who will have access to your information.*
* *Know what procedures may be performed and what drugs or medicines may be used.*
* *Seek additional help or clarification during the informed consent process and at any time during the study.*
* **What are your responsibilities as a participant?**

*All volunteers who participate in studies at UConn Health are expected to comply with the specific requirements of the study. In addition, study participants are expected to adhere to a general set of requirements that apply to all participants. They include:*

* *Arriving for all scheduled appointments or calling ahead if you are unable to keep an appointment.*
* *Arranging your own transportation to and from the study site(s).*
* *Following the directions of the researchers.*
* *Making sure your contact information is up to date.*
* *Providing – to the best of your ability – accurate information about your medical history if it is relevant to the study.*
* *Seeking healthcare for any medical conditions unrelated to the study.*
* *Asking the researchers to completely answer any questions you may have at any time during the study.*
* *Informing the research staff of any negative experience you have while participating in the study.*
* *Informing the research subject advocate and, if necessary, the Institutional Review Board if you feel your rights as a study subject have been violated.*
* **What types of clinical trials are there?**

*There are four kinds of clinical trials:*

* *In treatment trials a new treatment (such as a new cancer drug or a new approach to surgery or radiation therapy) is studied.*
* *In prevention trials the study tests new approaches (such as medicines, lifestyle changes, vitamins or some other form of dietary supplements) that may lower individuals’ risk of cancer. Prevention trials may target people who have never had cancer or focus on preventing a recurrence in people who have had cancer.*
* *Screening trials focus on ways to detect cancer, especially in the early stages, when it is most treatable.*
* *And quality of life trials study how best to improve the care and comfort of cancer patients.*

*If a clinical trial is testing a new drug, it will almost certainly progress along a series of phases:*

* *In Phase I trials, researchers evaluate how new drugs should be administered, how often they should be administered, and what dosage is safe.*
* *Phase II trials extend the research conducted in Phase I and begin to study how well the new drug actually works. Usually, the focus in Phase II is on a specific type of cancer.*
* *Phase III trials test a new drug or a combination of drugs or, sometimes, a new surgical procedure by comparing those new therapies to current standards. Phase III trials almost always involve large numbers of participants and many different healthcare facilities.*
* *Phase IV trials are used to further evaluate the long-term safety and effectiveness of a treatment. These refining trials may take place after a new treatment has been approved for standard care.*
* **What do clinical trials mean for cancer patients and survivors?**

*For cancer patients, participating in a clinical trial could mean studying or comparing many different things. They can include new drugs; current drugs; new surgical methods; the use of new equipment or devices; better ways to manage side effects; support groups; complementary therapies; and innovative approaches to reducing the likelihood of contracting cancer or experiencing a recurrence.*

*Clinical trials offer breast cancer patients and survivors a number of opportunities, including:*

* *Benefiting from new treatments not yet available to patients in general,*
* *Contributing to an understanding of what works for people who have cancer and what may help others with cancer in the future, and*
* *The possibility that a treatment may help one feel better while living with cancer.*
* **Can you learn the results of a study?**

*Many study participants wish to review the results of studies in which they have participated. Once a study is complete, participants are informed of their results and given advice concerning their future medical care. You should be aware that this may not occur for some time after a study is complete, while all research data are being analyzed.*

* **Where can I find additional information on clinical trials?**

*You can find additional information by visiting the UConn Health clinical trials resource website available at* <http://www.uchc.edu/patients/clinical_trials/resources.html> and <https://clinicaltrials.gov/>