Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Dr. A. Bapsi Chakravarthy, MD **Revision Date: 5/26/2020**
BREp 1898Study Title: Concurrent Capecitabine and Radiotherapy in the Adjuvant Treatment of Resistant Breast Cancer: A Prospective Feasibility Trial
Institution/Hospital: Vanderbilt-Ingram Cancer Center **NCT03958721**

This informed consent applies to adult patients with breast cancer undergoing or planning for active treatment.

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

What is the purpose of this study?

You are being asked to take part in this research study because you have breast cancer that has previously been treated with chemotherapy and surgery. Your physicians are now recommending a chemotherapy called capecitabine, also called Xeloda, and radiation therapy, in order to treat any remaining cancer. At Vanderbilt, this medicine and radiation are often given together, in order to decrease total treatment time and because giving both the medicine and radiation together may be more effective. Giving this medicine and radiation separately is listed in the current guidelines for breast cancer therapy, but giving this medicine and radiation together is not.

There are risks to this study. These may include increased skin rash at the site of radiation. Taking the chemotherapy pill and radiation together may be more effective at treating your cancer. Taking the chemotherapy pill and radiation together also decreases your total treatment by 2 months. If you do not wish to participate in this study, you may receive the chemothe rapy and radiation separately, or an alternative chemotherapy as discussed by your doctor.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information. If you participate in this study, you will receive radiation and the chemotherapy pill together.
About 20 people will take participation in this study.

What will happen and how long will you be in the study?

If you enroll in this study, details about your treatment course will be collected from the medical record and used for research purposes. You will receive surveys by email or by telephone before, during, and after your treatment asking you for your opinions on the treatment. There are no additional tests, clinic visits, or treatments associated with this study. All care you would receive during this study would be provided to you as a part of routine medical care regardless of your participation in this study and billed to insurance as usual.

Costs to you if you take part in this study:

If you agree to take part in this research study, you and/or your insurance will not have to pay for the tests and treatments that are being done only for research. However, you are still responsible for paying for the usual

care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

Side effects and risks that you can expect if you take part in this study:

The chemotherapy used in this study may affect how different parts of your body work such as your liver, kidney, heart, and blood. Your physician will be monitoring your health and let you know if changes occur that may affect whether you stay on this course of treatment.

The tables below show the most common and most serious side effects that researchers know about. There might be other side effects that researchers do not yet know about. If important new side effects are found, your physician will discuss these with you.

Possible Side Effects of Capecitabine:

COMMON, SOME MAY BE SERIOUS In 100 people receiving Capecitabine, more than 20 and up to 100 may have:
• Swelling of the body • Blisters on the skin • Redness, pain or peeling of palms and soles • Pain • Diarrhea, loss of appetite, nausea, vomiting • Sores in mouth which may cause difficulty swallowing • Anemia which may require blood transfusions • Infection, especially when white blood cell count is low • Bruising, bleeding • Feeling of "pins and needles" in arms and legs • Tiredness • Fevers

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Capecitabine, from 4 to 20 may have:
• Blurred vision, dry or itchy eyes

- Muscle spasms, body aches
- Abnormal heartbeat
- Restlessness, irritability
- Swelling of face fingers and lower legs
- Constipation
- Difficulty with balancing

RARE, AND SERIOUS

In 100 people receiving Capecitabine, 3 or fewer may have:

- Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face and throat
- Difficulty speaking, walking or seeing
- Internal bleeding which may cause blood in vomit or black tarry stools
- Damage to the heart

Side Effects of Breast Radiation Therapy:

- **Short-term:**
  - Skin reactions, including redness, skin peeling, loss of hair, & swelling
  - Tiredness
- **Long-term**
  - Changes in breast appearance
  - Chronic pain
  - Hardening of the treated area
  - Lymphedema, or swelling of the arm
  - Difficulty moving or rotating shoulder
  - Damage to the heart
  - Damage to the lungs
  - A new cancer caused by radiation

Giving capecitabine and radiation together is very common for the treatment of other types of cancer. There may be an increased risk of skin irritation or skin pain.

This treatment may hurt an unborn child. If you take part in this study, you and any person you have sex with must use approved birth control such as birth control pills, birth control shots, IUD, diaphragm, or condoms while you are in this study. If you become pregnant or father a child while you are in this study, you must tell your doctor at once. Also, women must not breast feed while in this study. If you are a woman and are able to become pregnant, you will have a (insert the appropriate measurement: blood or urine) test to make sure that you are not pregnant before you receive treatment in this study.

As this study involves the use of your identifiable, personal information, there is a chance that a loss of confidentiality will occur. We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Risks that are not known:

Because receiving capecitabine and radiation is not common in breast cancer, there may be risks that we do not know about at this time.

Payment in case you are injured because of this research study:

There are no plans for Vanderbilt to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

Good effects that might result from this study:

a) The benefits to science and humankind that might result from this study: decreased treatment times for patients with breast cancer, development of a more effective treatment for breast cancer

b) The benefits you might get from being in this study: shorter treatment time of 18 weeks instead of 26 weeks, possibly more effective treatment.

Other treatments you could get if you decide not to be in this study:

-Capecitabine followed by radiation therapy
-Radiation therapy only
-Capecitabine only
-Other chemotherapies as discussed with your physician
-Hormone treatment only
-Other treatments as discussed with your physician
-Other clinical trials
-No treatment

Payments for your time spent taking part in this study or expenses:

No payments are associated with taking part in this study. Enrolling in this study allows us to gather and report scientific knowledge on the medical care that has already been recommended for you by your physicians.

Reasons why the study doctor may take you out of this study:

- You decide to withdraw from the study or from treatment.
- If in the judgment of the study doctor, further treatment would not be in your best interest
- Substantial non-compliance with the requirements of the study
- Any adverse event which, in the Investigator's opinion, [illegible]

- Disease progression
- If you or a legal surrogate request to stop the treatment.
- If you are or become pregnant during the course of the study.
- Use of illicit drugs or other substances that may, in the opinion of the Investigator, have a reasonable chance of contributing to toxicity or otherwise interfering with results.
- Interruption in the chemotherapy administration for greater than 14 days
- Development of an illness or situation which would, in the judgement of the investigator, affect assessments of clinical status and study endpoints to a significant degree

What will happen if you decide to stop being in this study?

If you decide to stop being part of the study, you should tell your study doctor. Deciding to not be part of the study will not change your regular medical care in any way.

Who to call for any questions or in case you are injured:

If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact the principal investigator Dr. Bapsi Chakravarthy at (615) 322-2555.

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Clinical Trials Registry:

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Confidentiality:

Your privacy is very important to us and the researchers will make every effort to protect it. Your information may be given out if required by law. For example, certain states require doctors to report to health boards if they find a disease like tuberculosis. However, the researchers will do their best to make sure that any information that is released will not identify you. Some of your health information, and/or information about your specimen, from this study will be kept in a central database for research. Your name or contact information will not be put in the database.

Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr. Chakravarthy and her staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

Privacy:

Any samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any financial benefit from any of your samples.

These tests may help us or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Authorization to Use/Disclose Protected Health Information:

To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?

The people who may request, receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?

You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?

Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?

You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. Chakravarthy in writing and let her know that you withdraw your consent. Her mailing address is:
Radiation Oncology, Vanderbilt University Medical Center
Preston Research Building, Rm B-1003, 2220 Pierce Ave, Nashville, TN 37232-5671

At that time, we will stop getting any more data about you. But, the health data we stored before you withdrew your consent may still be used for reporting and research quality.
If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

Date	Signature of patient/volunteer

Consent obtained by:

Date	Signature
	Printed Name and Title

Time