Consent and Authorization Document

IIT FES PET/CT for ILC

[^{18}F]Fluoroestradiol Imaging of Invasive Lobular Carcinoma Using PET/CT

Expansion Phase

Principal Investigator: **Matthew Covington, MD**

Address: **Huntsman Cancer Institute**
2000 Circle of Hope
Salt Lake City, UT 84112

Phone #: **801-585-0255**

This document may contain words and information that you do not understand. Please ask your study doctor or study staff to explain anything that is not clear to you. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends and relatives if you wish. Ask the research doctor or staff if there is anything that is not clear or if you would like more information. Take time to decide whether or not to volunteer to take part in this research study.

Once you know about the study, you will make a decision about whether to take part. If you decide to take part, you will be asked to sign this form. Your decision to take part in this study is voluntary which means you are free to decide to join this study or not to join this study.

BACKGROUND

You are being asked to participate in this research study because you have been diagnosed with Invasive Lobular Carcinoma (ILC) that has been confirmed from a biopsy. This study is being conducted by Matthew Covington, MD at the Huntsman Cancer Institute at the University of Utah.

The purpose of this consent form is to help you decide if you want to be in the research study.

You should not join this research study until all of your questions are answered.

Things to know before deciding to take part in a research study:

- The main goal of a research study is to gain new knowledge to help patients in the future.
- The main goal of regular medical care is to help each patient.
- The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.
- Parts of this study may involve standard medical care. Standard care is the treatment normally given for a certain condition or illness. Clinical (non-research related) imaging studies may be performed as part of your standard medical care and may include bone, FDG PET/CT, CT and MRI

scans. The possible bone, clinical FDG PET/CT, CT and MRI scans you receive are a part of your standard care and you would receive them whether or not you participate in this study.

- After reading the consent form and having a discussion with the research staff, you should know which parts of the study are experimental and which are standard medical care.
- Your medical records may become part of the research record. If that happens, your medical records may be looked at and/or copied by government agencies or other groups associated with the study.
- Your medical insurance may be billed for any standard medical care you receive during the research study. If your insurance company is billed then it may have access to the research records. Insurance companies may not pay for treatment that is part of a research study. Taking part in a research study could affect your current or future insurance coverage.

Purpose of the Study

In standard care for newly diagnosed breast cancer, patients with invasive lobular carcinoma (ILC) may receive contrast-enhanced computed tomography (CT) scans and bone scans or a fluorodeoxyglucose positron emission tomography (FDG-PET/CT) scan for disease assessment. These imaging exams look for the possible spread of ILC from the breast to other sites of the body (metastatic disease). Compared to other forms of breast cancer sites of ILC can be difficult to detect using these scans. This study incorporates a new type of agent to use as part of the PET/CT scan. When a radiopharmaceutical is used in combination with a CT scan, the procedure is called a PET/CT (PET = Positron Emission Tomography). The experimental PET/CT agent that will be utilized is a radioactive imaging agent called [^{18}F]Fluoroestradiol (FES). The test is called an FES-PET/CT scan.

Researchers are looking at if this method may improve detection of metastatic disease for patients with ILC. An initial phase of this study has been completed and researchers are now expanding the study to gain additional understanding of how the information from these scans may be used.

The [^{18}F]FES in this study is considered investigational and is available for experimental use at our institution by the U.S. Food and Drug Administration (FDA) under an Investigational New Drug (IND) application # 151981 (Hoffman).

This study also includes blood draws for additional research testing. On the day of the research FES-PET/CT imaging, an IV will be placed for the FES-PET/CT imaging study. Participants will have blood drawn through this IV prior to imaging for use in this research. This blood will used to look for small amounts of DNA that may be shed by your ILC into the bloodstream. An assay called Methyl Patch PCR is developed at the Huntsman Cancer Institute under the direction of K-T Varley, PhD. The goal of this additional research is to determine if the Methyl Patch PCR assay can detect this tumor DNA in blood. Results from this additional research will not be included in your medical records or returned to you or your doctor.

FUTURE USE OF SAMPLES

If there is remaining blood after performing the study assay the study team would like to store it for future research unrelated to this study. Storing samples for future research is called 'tissue banking' and is optional. You will be given the opportunity below, in the section titled 'Optional Testing', to let us know if

you would like to participate in the tissue banking. Samples will be coded so that your name is not on the sample for long term storage and will be stored in the Huntsman Cancer Institute's Biorepository and Molecular Pathology department (BMP) for future research that may include other types of analyses for tumor DNA or cancer cells. Your samples will be stored with the following information: type of specimen, diagnosis, sex, age, treatment, and treatment response. Only the study doctor and the study staff, including those who manage the tissue bank at the BMP, will have access to those identifiers. Any lab that does testing outside of HCI will not receive these identifiers. You do not have the option to have your samples de-identified. If this is not acceptable to you, you should not participate in the optional specimen banking portion of the study. All information obtained from your samples will be kept confidential as stated in the AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION section of this form.

At any time, you may ask that your samples not be used for future research and that they be destroyed by contacting the study doctor and/or study team. If you ask for this, study tests will be done, but samples will not be used for future research testing. However, any information collected from your samples before your request to destroy them will be kept by HCI.

If you decide to stop taking part in the study, but do not request that your samples be destroyed, HCI and its authorized representatives may continue to use your samples for future research and genetic testing.

Because the results from future research will not directly affect your health care, we will not share the results from future studies with you or your doctors.

Tissue samples obtained from you in this research may help in the development of a commercial product by the investigator or the benefactor or its research partners. There are no plans to provide financial compensation to you should this occur.

OPTIONAL RESEARCH

The study also has an option to have blood drawn at follow-up intervals for additional research analysis to determine if the amount of tumor DNA in your bloodstream changes during your treatment. You can let us know below, in the section titled 'Optional Testing', if you would like to participate in this additional research.

You also have the option of having another PET/CT scan using the radioactive imaging agent [^{18}F]Fluorodeoxyglucose (FDG). The FDG imaging study is approved by the FDA for patients with your type of cancer and would be performed to compare imaging results of FDG with those of FES. This FDG-PET/CT study is optional and is not required as part of your participation in this research study.
There is also an option to have an additional FES-PET/CT scan after treatment is started. The additional FES-PET/CT study performed after you start therapy would be performed to compare FES imaging results after starting therapy to FES results prior to therapy. This second FES-PET/CT scan is optional and is not required as part of your participation in this research study.

The information gathered from this study could allow future patients with invasive lobular carcinoma to have more efficient and effective tumor staging and monitoring with FES-PET/CT and Methyl Patch PCR blood assays.

STUDY PROCEDURES

Your participation in this study will consist of a screening visit, and up to three imaging sessions:

1) [^{18}F] FES-PET/CT exam,
2) Optional [^{18}F]FDG PET/CT scan and
3) Optional follow-up [^{18}F] FES-PET/CT exam.

The study includes blood draws for the Methyl Patch PCR tumor DNA assay and optional blood biobanking at the time of the first FES-PET/CT scan, and at the time of the optional second FES-PET/CT scan, if you choose to participate. If you choose to participate, optional blood draws for follow-up Methyl Patch PCR tumor DNA assessments and optional blood biobanking will occur 7 times over the 5-years of follow-up.

The study also will assess for presence of recurrent or new metastatic disease that may be identified as part of your routine clinical care and clinical imaging follow-up, and will assess survival following enrollment over a period of up to 5-years.

Screening Visit

Before the study starts, you will be asked to sign this informed consent form, and a member of the Study Staff will ask you about your general health history, treatments you have had for your breast cancer and if you have any drug allergies. The Study Staff will also record information from your medical records including previous blood test results, procedures, treatments, and plans for your breast cancer treatment.

If you agree to participate in the study and you qualify for the study, then you will be scheduled for your research PET/CT scan(s) including the tumor DNA assessment(s). The Study Staff will tell you when and where the PET/CT scan and blood draw will be performed.

Day of [^{18}F]FES-PET/CT Scan

Before the dosing of [^{18}F]FES and the PET/CT scan, a member of the Study Staff will ask you questions about any changes to your general health since your screening visit.

The following tests will be performed before dosing:

- Measurement of your height and weight
- Assessment of vital signs (blood pressure, heart rate, and temperature)
- Pregnancy test within 48 hours prior to the research PET/CT if you are not postmenopausal, or surgically sterile

The Study Staff will place an IV catheter (long, thin tube) into an accessible vein. First, the IV will be used for a blood draw for tumor DNA assessment. You will then receive the [^{18}F]FES injection through the catheter, and then will wait for approximately 60 minutes before the PET/CT scan can begin. During the scan, you will lie on your back on the scanning bed. The bed will move slowly through the PET/CT scanner. The CT portion of the scan usually takes about 1 minute, and sends X-rays through your body that are measured by the CT camera. The PET portion of the scan begins immediately after the CT scan and will last about 30-60 minutes.

It is suggested but not required that you do not eat or drink anything except plain water for at least 4 hours before the scan; you are permitted to take medications with plain water.

This entire visit should require approximately 2 to 3 hours of your time.

Immediately Following the [^{18}F]FES PET/CT Scan
Immediately following the scan, a member of the study staff will obtain your vital signs, including your blood pressure, heart rate, and temperature. A study staff member will also ask you several questions relating to any potential adverse events.

Day after the [^{18}F]FES PET/CT Scan (or up to 3 days after scan)
You will be contacted by a member of the Study Staff to discuss whether you have had any side effects within the 24 hours after you received the [^{18}F]FES.

Day of *Optional* [^{18}F] FDG PET/CT Scan
When you arrive at the molecular imaging suite, a member of the Study Staff will ask you questions about any change to your general health since your screening visit.

The following tests will be performed before dosing:

- Measurement of your height and weight
- Pregnancy test within 48 hours prior to the research PET/CT if you are not postmenopausal or surgically sterile

For the optional FDG-PET/CT scan you are required to not eat or drink anything except plain water for at least 4 hours before the scan. If needed, you may take medications with plain water.

The Study Staff will place an IV catheter (long, thin tube) into an accessible vein. You will receive the [^{18}F]FDG injection through the catheter, and then will wait for approximately 60 minutes before the PET/CT scan can begin. During the scan, you will lie on your back on the scanning bed. The bed will move slowly through the PET/CT scanner. The CT portion of the scan usually takes about 1 minute, and sends X-rays through your body that are measured by the CT camera. The PET portion of the scan begins immediately after the CT scan and will last about 30-60 minutes.

Day of Optional [^{18}F]FES-PET/CT Scan
Before the dosing of [^{18}F]FES and the PET/CT scan, a member of the Study Staff will ask you questions about any changes to your general health since your screening visit.

The following tests will be performed before dosing:

- Measurement of your height and weight
- Assessment of vital signs (blood pressure, heart rate, and temperature)
- Pregnancy test within 48 hours prior to the research PET/CT if you are not postmenopausal or surgically sterile

The Study Staff will place an IV catheter (long, thin tube) into an accessible vein. First, the IV will be used for a blood draw for tumor DNA assessment and blood biobanking. You will then receive the [^{18}F]FES injection through the catheter, and then will wait for approximately 60 minutes before the PET/CT scan can begin. During the scan, you will lie on your back on the scanning bed. The bed will move slowly through the PET/CT scanner. The CT portion of the scan usually takes about 1 minute, and sends X-rays through your body that are measured by the CT camera. The PET portion of the scan begins immediately after the CT scan and will last about 30-60 minutes.

It is suggested but not required that you do not eat or drink anything except plain water for at least 4 hours before the scan; you are permitted to take medications with plain water.

This entire visit should require approximately 2 to 3 hours of your time.

Follow-up evaluation at 6, 12, 18, 24, 36, 48 and 60 months after baseline FES-PET/CT imaging:
The University of Utah electronic medical record will be evaluated at the approximate intervals shown above to assess whether there is any evidence on clinical evaluation, clinical imaging, and/or biopsy that recurrent or new metastatic breast cancer is present. Participant survival will also be assessed at each follow-up interval.

Following assessment of the electronic medical record, the study team will call you at phone number(s) provided in the University of Utah electronic medical record to ask whether you have obtained imaging or care outside of the University of Utah/Huntsman Cancer Institute health network and, if so, these results may be requested for review.

Optional tumor DNA blood assessments and blood biobanking at 6, 12, 18, 24, 36, 48 and 60 months after baseline FES-PET/CT imaging:
If you choose to participate, you will be scheduled by the study staff to return within the approximate timeframes above to obtain a blood draw for the optional tumor DNA assessment and blood biobanking. This will require placement of an IV catheter followed by a blood draw.

What are the Uses for my Samples Collected during the Study?
Your participation in the research DNA blood assay, which is a form of genetic analysis, is a required part of this study at time of FES-PET/CT imaging, and is an optional part of this study afterwards. It will be performed in order to learn whether this blood assay may be used to predict and monitor response to therapy for individuals with invasive lobular carcinoma.

Segments of the DNA called genes are responsible for passing particular traits such as eye color from parents to children.

In the United States, the **Genetic Information Nondiscrimination Act of 2008 (GINA)** prohibits discrimination in health coverage and employment based on genetic information. GINA, together with the Health Insurance Portability and Accountability Act (HIPAA), generally prohibits health insurers or health plan administrators from requesting or requiring genetic information of an individual or the individual's family members, or using

it for decisions regarding coverage, rates, or preexisting conditions. The law also prohibits most employers from using genetic information for hiring, firing, or promotion decisions, and for any decisions regarding terms of employment. Utah State Law also offers protection against discrimination in health coverage and employment.

We may perform a whole genome or whole exome analysis on your samples. In whole genome or whole exome analysis, all or most of your genes are studied and used by researchers to find causes of diseases, such as cancer. It is also possible that this type of testing will discover a gene that you do not know about that may indicate you or a relative is at risk for a genetic disorder in the future.

You will not receive any of your genetic information that comes from the testing in this study, nor will it become a part of your medical record. The results will be kept on password-protected computers and results will be accessible only to the investigator and other authorized people.

RISKS

Your condition may or may not improve and could even get worse if you take part in this study. Your doctor will monitor you for any signs of a new or unexpected side effect.

Side effects are generally uncommon at the doses of FES used during a PET/CT study, however people have experienced discomfort at the injection site.

For tumor DNA blood assessment and blood biobanking, this study requires a blood draw with removal of no more than 40 mL of blood. For IV placement and blood draws, risks include pain, bruising, and possible infection.

Tell your doctor if you have a side effect or feel unwell. Contact your doctor immediately if you:

- Have a side effect that concerns you, or
- Are unable to perform your daily functions.

Risks related to radiation exposure from the [^{18}F]FES and [^{18}F]FDG PET/CT scan(s):

This research study involves exposure to radiation from up to two (2) FES PET/CT scans and up to one (1) FDG-PET/CT scan. These scans are being done for the research study and are not considered a part of your standard care. The risk from this radiation exposure is considered to be small and comparable to other every day risks. This amount does not include any radiation exposures that you may receive from other types of tests. A potential health problem caused by radiation exposure is a very small chance of cancer later in life. The possible radiation exposures you may receive are described below, depending on the different combination of scans that you receive.

One (1) FES-PET/CT scan and zero (0) FDG-PET/CT scans

If you are enrolled in this study, the excess radiation you will receive is about the same as a uniform whole-body dose of:	The amount of radiation that is **considered safe** for a **radiation worker** (e.g. doctor, nurse, scientist, etc.) to receive in one year:
2.2 rem* for the FES PET/CT scan	5.0 rem*

***A "*rem*" is a unit of radiation dose.**

Two (2) FES-PET/CT scans and zero (0) FDG-PET/CT scans

If you are enrolled in this study, the excess radiation you will receive is about the same as a uniform whole-body dose of:	The amount of radiation that is **considered safe** for a **radiation worker** (e.g. doctor, nurse, scientist, etc.) to receive in one year:
4.4 rem* for the 2 FES PET/CT scans	5.0 rem*

A "*rem*" is a unit of radiation dose.

One (1) FES-PET/CT scan and one (1) FDG-PET/CT

If you are enrolled in this study, the excess radiation you will receive is about the same as a uniform whole-body dose of:	The amount of radiation that is **considered safe** for a **radiation worker** (e.g. doctor, nurse, scientist, etc.) to receive in one year:
2.2 rem* for the FES PET/CT scan + 4.4 rem* for the FDG PET/CT scan	5.0 rem*
= about 6.6 total rem*	

***A "rem" is a unit of radiation dose.**

The excess cancer risk from one (1) FES-PET/CT scan and one (1) FDG-PET/CT scan is estimated to be 1 in 144. Approximately 45 people out of 100 will develop cancer sometime in their life.

Two (2) FES-PET/CT scans and one (1) FDG-PET/CT

If you are enrolled in this study, the excess radiation you will receive is about the same as a uniform whole-body dose of:	The amount of radiation that is **considered safe** for a **radiation worker** (e.g. doctor, nurse, scientist, etc.) to receive in one year:
4.4 rem* for the FES PET/CT scans + 4.4 rem* for the FDG-PET/CT scan	5.0 rem*
= about 8.8 total rem*	

***A "rem" is a unit of radiation dose.**

The excess cancer risk from two (2) FES-PET/CT scans and one (1) FDG-PET/CT scan is estimated to be 1 in 108. Approximately 45 people out of 100 will develop cancer sometime in their life.

Risks Related to Other Study Procedures

On the day of the scans you will have an intravenous catheter placed in your arm. Like blood draws, there is a risk of bruising, discomfort and pain, and in rare cases a chance of infection.

You could experience some discomfort in lying on a scan table for approximately 1.5 hours for the scanning sessions. Our study staff will assist in making sure you feel comfortable prior to beginning each scan.

Loss of Confidentiality

Although all reasonable and appropriate steps will be taken to maintain the confidentiality of your identifiable health information, there is always a possibility that your identifiable health information will be disclosed accidentally.

Another risk is that your samples and information about them may become linked to you. We will take all appropriate measures to protect study participants' privacy, and researchers will not be able to directly link your blood samples with identifiable information about you.

PREGNANCY AND BREASTFEEDING

The effects of [^{18}F]Fluoroestradiol on an unborn baby or a nursing infant are not known. Females of childbearing potential defined as an individual of childbearing age, and with a uterus and ovaries not surgically sterile, will have a pregnancy test performed within 48 hours prior to each research PET imaging to confirm a negative pregnancy result prior to participation in the research study.

It is not known whether these radiopharmaceuticals can cause fetal harm when administered to a pregnant individual or whether the radiopharmaceutical affects male fertility. You will be slightly radioactive for up to 24 hours after the injection and should avoid close contact with females who are able to have children, and with children, for 24 hours after the scan. If you are currently breastfeeding, you should not participate in this study.

UNFORESEEABLE RISKS

In addition to the risks listed above, you may experience a previously unknown risk or side effect.

BENEFITS

Taking part in this study will not directly benefit you but will hopefully help physicians to improve the care and management for patients who are diagnosed with invasive lobular carcinoma. Possible benefits for future patients include a better method to identify sites of cancer for patients with invasive lobular carcinoma.

ALTERNATIVE PROCEDURES

If you decide not to enter this study, there are other choices available. You may continue with your standard treatment and not take part in this study. If you choose not to take part in this study, your health care, and your relationship with the doctors, will not be compromised in any way.

PERSON TO CONTACT

If you have questions, complaints or concerns about this study, you can contact Dr. Covington at 801-213-8438. If you think you may have been injured from being in this study, please call Dr. Covington at 801-213-8438. The University Hospital Operator can be reached at this number: 801-581-2121 available 24-hours a day. Please ask for the hematologist/oncologist on call.

Institutional Review Board: Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by email at irb@hsc.utah.edu.

Research Participant Advocate: You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.

RESEARCH-RELATED INJURY

If you are injured from being in this study, medical care is available to you at the University of Utah as it is to all sick or injured people. The University of Utah has not set aside any money to pay the costs for such care. The University will work with you to address costs from injuries. Costs would be charged to you or your insurance company (if you have insurance), to the study sponsor or other third party (if applicable), to the extent those parties are responsible for paying for medical care you receive. Since this is a research study, some health insurance plans may not pay for the costs. By signing this consent form you are not giving up your right to pursue legal action against any parties involved with this research.

The University of Utah is a part of the government. If you are injured in this study, and want to sue the University or the doctors, nurses, students, or other people who work for the University, special laws may apply. The Governmental Immunity Act of Utah is a law that controls when a person needs to bring a claim against the government, and limits the amount of money a person may recover. See sections 63G -7-101 to -904 of the Utah Code.

VOLUNTARY PARTICIPATION

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

If you decide to withdraw from this study, please inform your Study Doctor right away.

RIGHT OF INVESTIGATOR TO WITHDRAW

Your participation in this study may be stopped at any time by the Study Doctor or the Sponsor without your consent for any reason, including:

- If it is in your best interest
- If you do not consent to continue in the study after being told of changes in the research that may affect you
- You require a medication that is not allowed while participating in the study
- You develop a condition which may negatively affect your health
- You do not follow the study instructions given by the Study Staff
- You withdraw your consent to participate
- The Sponsor decides to suspend or terminate (end) the study or the participation of this site in the study
- Other unanticipated circumstances

COSTS AND COMPENSATION TO PARTICIPANTS

Huntsman Cancer Institute will provide the [^{18}F]FES PET/CT and [^{18}F]FDG PET/CT scans free of charge.

You or your insurance company will be billed in the usual manner for procedures, tests and treatment that are considered standard of care for your disease (routine treatment you would receive even if you were not part of this study). This includes procedures such as routine medical care or need for additional imaging evaluation and possible additional biopsy procedures based on FES-PET/CT and/or FDG-PET/CT imaging results. If you have private medical insurance, you should check with the insurance provider before agreeing to take part in this study to ensure that participating in this study will not affect your medical insurance coverage.

You will be responsible for co-payments, deductibles and/or other out of pocket expenses required by your insurance carrier for medications and procedures which are considered routine care for your disease or condition.

Patients who live more than 50 miles from Huntsman Cancer Hospital may be eligible for mileage reimbursement, and those that live more than 100 miles may be eligible for hotel reimbursement up to $55 per night.

NEW INFORMATION

You will be told about any new information that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

NUMBER OF PARTICIPANTS

We expect to enroll 55 participants at the University of Utah, Huntsman Cancer Institute on the expansion phase of this study. 24 participants were enrolled in the first phase of this study.

AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION

Signing this document means you allow us, the researchers in this study, and others working with us to use some information about your health for this research study.

This is the information we will use and include in our research records:

- Demographic and identifying information like name, address telephone number, and email address
- Related medical information about you like family medical history, allergies, current and past medications or therapies, and information from physical examinations, such as blood pressure reading, heart rate, temperature, and lab results
- All tests and procedures that will be done in the study

How we will protect and share your information:

- We will do everything we can to keep your information private but we cannot guarantee this. Study information will be kept in a secured manner and electronic records will be password protected. Study information may be stored with other information in your medical record. Other doctors, nurses, and third parties (like insurance companies) may be able to see this information as part of the regular treatment, payment, and health care operations of the hospital. We may also need to disclose information if required by law.

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

- In order to conduct this study and make sure it is conducted as described in this form, the research records may be used and reviewed by others who are working with us on this research:
    - Members of the research team and the University of Utah Health Sciences Center;
    - The University of Utah Institutional Review Board (IRB), who reviews research involving people to make sure the study protects your rights;
    - Government agencies responsible to confirm research accuracy such as the United States Food and Drug Administration (FDA), and the National Cancer Institute (NCI) which is a part of the National Institute of Health (NIH),
    - Governmental agencies in other countries where the study drug may be considered for approval.

- If we share your identifying information with groups outside of the University of Utah Health Sciences Center, they may not be required to follow the same federal privacy laws that we follow. They may also share your information again with others not described in this form.
- If you do not want us to use information about your health, you should not be part of this research. If you choose not to participate, you can still receive health care services at the University of Utah Health Sciences Center.

What if I decide to Not Participate after I sign the Consent and Authorization Form?
You can tell us anytime that you do not want to be in this study and do not want us to use your health information. You can also tell us in writing. If you change your mind, we will not be able to collect new information about you, and you will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.

This authorization does not have an expiration date.

During the study, we may learn something about your health that could help you and your doctors make decisions about your healthcare. The images and results from these scans will be shared with your doctors after the imaging has been interpreted by the study team, which could take several weeks following the completion of imaging. You have a right to information used to make decisions about your health care. However, imaging results from the FES-PET/CT study will only be released to study participants upon request, and only after the imaging has been interpreted by the study team, which could take several weeks following the completion of imaging.

Optional Testing

Optional [^{18}F] FDG PET/CT Scan
If a clinical [^{18}F]Fluorodeoxyglucose (FDG) scan has not been completed as part of standard clinical care, the patient may elect to complete an optional FDG-PET/CT, the costs of which will be covered by the study. If performed, the optional FDG-PET/CT must be completed within 4 weeks (before or after) of the [^{18}F]FES-PET/CT study. If you choose not to participate in the optional [^{18}F]FDG PET/CT part of the study, your decision will not exclude you from the main study. Please **initial** the corresponding line below to let us know if you would like to participate:

[^{18}F]FDG PET/CT

initial_____ I **do** want to participate in the [^{18}F]FDG PET/CT.

initial_____ I **do not** want to participate in the [^{18}F]FDG PET/CT.

Optional [^{18}F] FES PET/CT Follow-up Scan

If you choose not to participate in the optional follow-up [^{18}F]FES PET/CT part of the study, your decision will not exclude you from the main study. Please **initial** the corresponding line below to let us know if you would like to participate:

Follow-up [^{18}F]FES PET/CT

initial_____ I **do** want to participate in the follow-up [^{18}F]FES PET/CT.

initial_____ I **do not** want to participate in the follow-up [^{18}F]FES PET/CT.

Optional blood draws for tumor DNA assessment and blood biobanking

These additional blood draws would be obtained at 7 time points over 5-years of follow-up (at approximately 6, 12, 18, 24, 36, 48 and 60 months following study enrollment). Each blood draw would remove up to 40 mL of blood for tumor DNA assessment and you have an option to allow storage of any remaining blood for future unspecified research. These de-identified blood specimens will be stored at Huntsman Cancer Institute's Biorepository.

Additional blood draws for tumor DNA assessment

If you choose not to participate in the optional tumor DNA blood assessment, your decision will not exclude you from the main study. Please **initial** the corresponding line below to let us know if you would like to participate:

initial_____ I **do** want to participate in the optional blood tumor DNA assessment.

initial_____ I **do not** want to participate in the optional blood tumor DNA assessment.

Banking for Future Use

Researchers would like to save any of your left over tissue for future unspecified cancer research as described above. If you choose not to participate in the tissue banking part of the study, your decision will not exclude you from the main study. Please **initial** the corresponding line below to let us know if you would like to participate:

initial_____ I **do** want to participate in the optional tissue banking.

initial_____ I **do not** want to participate in the optional tissue banking.

CONSENT

I confirm that I have read this consent and authorization document and have had the opportunity to ask questions. I will be given a signed copy of the consent and authorization form to keep.

I agree to take part in this research study and authorize you to use and disclose health information about me for this study, as you have explained in this document.

_____
Participant's Name

_____ _____ _____
Participant's Signature Date Time

_____
Name of Person Obtaining Authorization and Consent

_____ _____ _____
Signature of Person Obtaining Authorization and Consent Date Time

LANGUAGE INTERPRETER STATEMENT (if applicable):

I confirm that I was present as an interpreter for the duration of the consent process for this research study. I confirm that I am qualified and have the necessary skills to provide interpretation between the participant's language and English. By signing this form, I confirm that I provided a full and complete interpretation of the exchange between the researcher obtaining consent and the participant, to the best of my ability.

_____ _____ _____
Name of Interpreter Signature of Interpreter Date

Information requested for federal grant reporting purposes (optional)

Sex/Gender

❑**Male**

❑**Female**

Ethnicity
Do you consider yourself to be Hispanic or Latino? (see definition below)

Hispanic or Latino. A person of Mexican, Puerto Rican, Cuban, South or Central American, or other Spanish culture or origin, regardless of race.

Select one:

❑ **Hispanic or Latino**

❑ **Not Hispanic or Latino**

Race
What race do you consider yourself to be? SELECT ONE OR MORE OF THE FOLLOWING:

❑ **American Indian or Alaska Native.** A person having origins in any of the original peoples of North America (including, Central or South America) who maintains cultural identification through tribal affiliation or community recognition.

❑ **Asian.** A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent, including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.

❑ **Black or African American.** A person having origins in any of the black racial groups of Africa.

❑ **Native Hawaiian or other Pacific Islander.** A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.

❑ **White.** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

❑ **Unknown.**

❑ **Check here if you do not wish to provide some or all of the above information.**