Cancer research studies are coordinated by physicians and scientists from Cleveland Clinic, University Hospitals and Case Western Reserve University (CWRU) through the NIH National Cancer Institute (NCI) designated Case Comprehensive Cancer Center (Case CCC). The goal of this collaboration is to enhance cancer treatment and research in Northeast Ohio. This study is being offered at *(insert institution(s))*Cleveland Clinic (CC) and/or University Hospitals (UH).

#### Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

**Why am I being invited to take part in a research study?**

We invite you to take part in a research study because \_\_\_\_\_\_\_\_\_\_\_\_\_. *(Fill in the circumstance or condition that makes subjects eligible for the research.)*

**What should I know about a research study?**

• Someone will explain this research study to you.

• Whether or not you take part is up to you.

• You can choose not to take part.

• You can agree to take part and later change your mind.

• Your decision will not be held against you.

• You can ask all the questions you want before you decide.

**Why is this research being done?**

The purpose of this study is to *(insert purpose)*.

*(Insert name of research drug)* is an investigational (experimental) drug that works by *(give background on drug’s actions)*. *(Insert name of research drug)* is experimental because it is not approved by the Food and Drug Administration (FDA).

*When conflict of interest management is required in the consent document, a variation the following language can be inserted:*

*One or more of the Investigators conducting this study serve as consultants for the company that makes products used in this study.  These financial interests are within permissible limits established by the local institutional Conflict of Interest Policy.  If you have any questions regarding conflicts of interest, please ask you study doctor or call the Cleveland Clinic Institutional Review Board at (216) 444-2924 or University Hospitals Institutional Review Board at (216) 844-1529. [Select appropriate IRB(s)]*

**How long will the research last and what will I need to do?**

You will receive the *(insert description of intervention, e.g., study drugs)* for *(insert intervention length). After you finish (insert description of intervention),* your doctor will continue to watch you for side effects and follow your condition for *(insert study follow-up length).*

You will be asked to \_\_\_\_\_\_\_\_\_ (*include a high level summary of the procedures that will be done. For example: You will be given an investigational drug and asked to be asked to come for 3 study visits. You will give a total of 3 blood samples and fill out questionnaires asking about how you feel.)*

More detailed information about the study procedures can be found under “What extra tests and procedures will I have if I take part in this study?”

**Is there any way being in this study could be bad for me?**

*(This beginning section of the consent form should identify the most important risks, e.g., emotional distress resulting from a series of questions in a social-behavioral research project or similar to the information that a physician might deliver in the clinical context in telling a patient how sick, e.g., the chemotherapy drugs will make them, but with a particular emphasis on how those risks are changed by participating in the study)*

More detailed information about the risks of this study can be found under “What possible risks can I expect from taking part in this study?”

#### What possible benefits can I expect from taking part in this study?

###### (Text Example: Phase 1 Studies)

 You will receive medical care during the study. You may not receive direct benefit from being in this study. However, taking part may help patients with [insert type of disease] better care in the future.

###### (Text Example: Phase 2 Non-randomized Studies)

 We cannot know if you will have any benefit as a result of your participation in the study; it is possible the study treatment may improve your cancer, which may give you relief from some symptoms, improve your quality of life or prolong your survival. However, it is possible that your condition could worsen. Your participation in this study will help to obtain information about treating subjects with *(insert disease type*).

###### (Text Example: Phase 2 and 3 Randomized Studies

We cannot know if you will have any benefit as a result of your participation in the study; it is possible the study treatment may improve your cancer, which may give you relief from some symptoms, improve your quality of life or prolong your survival. However, it is possible that your condition could worsen. Your participation in this study will help to obtain information about treating subjects with *(insert disease type).*

**What is the usual approach to my** (insert type of disease)?

*(Insert standard of care treatment options for disease.)*

#### What are my other choices if I do not take part in this study?

If you decide not to take part in this study, you have other choices. For example:

* you may choose to have the usual approach described above
* you may choose to take part in a different study, if one is available
* or you may choose not to be treated for cancer. For example: comfort/palliative care

## Detailed Information: The following is more detailed information about this study in addition to the information listed above.

#### What are the study groups?

#### *NOTE: Please remember to select the study group appropriate for the research being conducted. DO NOT copy and paste directly from template as some examples may include radiation therapy and chemotherapy*

###### (Text Example: Phase 1 Dose Escalation Studies)

Different doses of the study drug (insert name of research drug) will be given to several study participants. The first several study participants will receive the lowest dose. If the drug does not cause serious side effects, it will be given to other study participants at a higher dose. The doses will continue to increase for every group of study participants until side effects occur that require the dose to be lowered. Then the study is stopped. You (insert appropriate information, e.g., will/will not) be able to receive additional doses of the drug.

###### (Text Example: Phase 2 Non-randomized Studies)

All study participants will get the same study intervention. It will include the usual radiation therapy and chemotherapy (insert usual chemotherapeutic). All study participants will also get the study drug (insert name of research drug).

###### (Text Example: Randomized Phase 2 Treatment Studies and Chemoprevention Studies)

This study has two study groups. Group 1 will receive the study drug (insert name of research drug) and Group 2 will receive a placebo, a (insert appropriate description for the placebo, e.g., pill/liquid) that looks like the study drug but contains no medication.

A process will be used to assign you, by chance, to one of the study groups. Neither you nor your doctor can choose which group you are in. This is done by chance because no one knows if one study group is better or worse than the other.

***NOTE for randomized studies that are also blinded:*** *in the event of a medical emergency, the study doctor may or may not be able to find out drug/drugs participant is being given.*

###### (Text Example: Phase 3 Randomized Studies)

This study has two study groups.

* Group 1 will get the usual (insert description of intervention, e.g., hormone or chemotherapy) drug used for this type of cancer (insert name of drug[s]).
* Group 2 will get the usual (insert description of intervention, e.g., hormone or chemotherapy) drug used for this type of cancer (insert name of drug[s]) plus a study drug called (insert name of research drug).

A process will be used to assign you, by chance, to one of the study groups. Neither you nor your doctor can choose which group you are in. This is done by chance because no one knows if one study group is better or worse than the other.

***NOTE for randomized studies that are also blinded:*** *in the event of a medical emergency, the study doctor may or may not be able to find out drug/drugs participant is being given.*

(Study calendar should be added to the last page of the consent document for participant reference.)

**Example:** To find out what will happen to you during this study read the chart below. Start reading at the left side and read across to the right, following the lines and arrows.

Randomize

(A process will randomly put you in a study group)

Group 2

(Study group)

You agree to take part in the study

Group 1

 (Usual approach group)

###### (Text Example: Phase 3 Randomized Studies with Multiple Randomizations)

All participants in this study will be given chemotherapy and radiation therapy.

* Group 1 will get the usual chemotherapy (insert names of drugs, e.g., carboplatin and docetaxel) and the usual radiation dose (insert dose, e.g., 60 Gray).
* Group 2 will get the usual chemotherapy (insert names of drugs, e.g., carboplatin and docetaxel) with a higher radiation dose than usual (insert research dose, e.g., 74 Gray).
* Group 3 will get the usual chemotherapy (insert names of drugs, e.g., carboplatin and docetaxel) and the usual radiation dose (insert dose, e.g., 60Gray) and a study drug called (insert name of research drug, e.g., cetuximab).
* Group 4 will get the usual chemotherapy plus the higher radiation dose plus the study drug called (insert name of research drug, e.g., cetuximab).

A process will be used to assign you, by chance, to one of the study groups. Neither you nor your doctor can choose which group you are in. This is done by chance because no one knows if one study group is better or worse than the other.

***NOTE for randomized studies that are also blinded:*** *in the event of a medical emergency, the study doctor may or may not be able to find out drug/drugs participant is being given.*

#### What extra tests and procedures will I have if I take part in this study?

###### (Use the following text for all studies requiring extra exams, tests, and/or procedures. Remove any procedures that are not performed:)

Most of the exams, tests, and procedures you will have are part of the usual approach for your cancer. However, there may be some extra (insert appropriate word, e.g., exams, tests, and/or procedures) that you will need to have if you take part in this study.

*(Below are examples and definitions of additional samples that are often collected.)*

***Pharmacokinetic (PK) studies*** *measure the amount of the study drug you have in your blood at various times after you begin the study drug / the start of its infusion. These PK tests will study how your body processes the drugs. At each time point, about insert amount of blood will be drawn for research purposes.*

***Pharmacodynamic (PD) studies*** *look at how the study drug affects your body. At each time point, about (insert amount) of blood will be drawn for research purposes.*

***Pharmacogenetic studies***

*“Pharmacogenetic” research looks at how differences in people’s genetic makeup (DNA/RNA) may cause them to react to or handle drugs differently. At each time point (see study calendar), about (insert amount) of blood will be drawn for research purposes. Your DNA sample will only be used for the specific purpose described in this consent form. When the study is complete, your sample will be destroyed (or all identifiers connecting your identity to the samples will be destroyed).*

***Biomarkers:*** *At specified time points, blood and hair samples will be collected to see whether the study drug is producing changes to the genes and proteins related to your cancer.*

***Immunogenicity (IG) tests*** *determine if your body’s immune system is mounting a response to the study drug. At each time point, about (insert amount) of blood will be drawn for research purposes.*

***Florescence activated cell sorting (FACS)*** *also called flow cytometric analysis, is done to see how the study drug effects your immune system. At each time point, about (insert amount) of blood will be drawn for research purposes.*

***Research biopsies***

*Tumor and/or skin biopsies will be done to check the characteristics of your tumor. Both your tumor and your skin have cells that could be affected by the study drug, even if you do not have a skin cancer. If your tumor is accessible, a tumor biopsy will be done. If it is not accessible, a skin biopsy will be done. If your tumor is accessible, but you would also like to provide a skin biopsy, both will be done.*

*A skin biopsy is the removal of a small (pencil eraser-sized) circle of skin using a cookie cutter-like instrument. This procedure involves numbing the designated area of skin with lidocaine (similar to what dentists use) and removing a circle or “plug” of skin. Although the lidocaine can tingle or hurt briefly during the numbing process, you should not feel any pain while the punch biopsy is being obtained. The circle is then closed using one to two fine stitches per site, which prevents bleeding, speeds healing, and improves the appearance. The stitches are removed 7-14 days later. This procedure takes ½ to 1 hour depending on the number of biopsies taken.*

*A tumor biopsy is the removal of a small (pencil eraser-sized) circle of tumor using a cookie cutter-like instrument. The duration of the biopsy procedure is approximately 30 minutes. The biopsy instrument may be placed into the tumor by your physician either in the office or in radiology. The procedure will be done using local anesthesia to minimize discomfort from the biopsy. During a biopsy of the abdomen (for example, biopsy of the liver or lymph nodes in the belly), you will be asked to lie flat and a doctor will clean the area on your belly. The doctor will then numb the area with a local anesthetic so that you do not feel the biopsy. The doctor will ask you to hold your breath and not move while he or she places the needle into your tumor and withdraws a small core of tissue which remains trapped inside the needle. It is very important that you not move or breathe during the biopsy.*

***For Genetic Studies***

*Describe whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen*

**Before you begin the study:**

You will need to have the following extra (insert appropriate word, e.g., exams, tests, and/or procedures) to find out if you can be in the study:

(List exams, tests, and procedures that either would not be done for the usual approach or are performed more frequently than usual. Use bulleted format. Examples of extra exams, tests and procedures (spell out all acronyms the first time they are used:)

* MUGA (Multi Gated Acquisition) scan
* Blood tests for studies of drug levels
* CT (Computed tomography) scan of abdomen
* Bone scan

###### (The following text example is provided for studies which include **mandatory** specimen collection:)

(Insert specimen type: Small pieces of cancer tissue removed by surgery, biopsies; A blood sample; A urine sample*)* will be taken for the study (state when the sample will be taken, for example, before you begin study drug; after the third dose; etc.) This sample is required in order for you to take part in this study because the research on the sample is an important part of the study. (Include brief description of how the specimen will be collected, e.g., “The research biopsy is done in a similar way to biopsies done for diagnosis.” Include a brief description of how the specimen will be used.)

(If applicable, include whether any of the specimen left over will be stored for biobanking. If so, indicate that this will be discussed in the section on optional studies.)

(If applicable, describe how the test results will be stored to protect privacy, e.g., “Your privacy is very important and the researchers will make every effort to protect it. Your test results will be identified by a unique code and the list that links the code to your name will be kept separate from your sample and health information.” Also include whether or not the results will be available to the study participant or study doctor.)

Neither you nor your health care plan/insurance carrier will be billed for the collection of the (insert sample type) that will be used for this study.

###### (Use the following text for all studies requiring extra exams, tests, and/or procedures:)

If the exams, tests, and procedures show that you can take part in the study, and you choose to take part, then you will need the following extra (insert appropriate words, e.g., exams, tests, and/or procedures). They are not part of the usual approach for your type of cancer.

**During the study the following will be additional research procedures:**

(Examples of exams, tests, and procedures; *enter frequency of non-standard of care*

*procedures and/or test)*

* Blood tests
* CT scans
* Bone scans
* Bone marrow biopsies
* Echocardiogram or MUGA scans

#### What possible risks can I expect from taking part in this study?

If you choose to take part in this study, there is a risk that:

**NOTE to consent form authors:** (Select reasonably foreseeable risks and discomforts that are not physical side effects from the bullets below and/or include others, as relevant. Keep bulleted lists to no more than four items, if possible.)

* You may lose time at work or home and spend more time in the hospital or doctor’s office than usual
* You may be asked sensitive or private questions which you normally do not discuss
* (For randomized studies only) The study drug(s)/study approach may not be better, and could possibly be worse, than the usual approach for your cancer.)
* (For studies requiring genetic testing) There is a risk someone could get access to the personal information in your medical records or other information researchers have kept about you. Someone might be able to trace this information back to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with new ways of tracing information. In some cases, this information could be used to make it harder for you to get or keep a job. There are laws against misuse of genetic information, but they may not give full protection. The researchers believe the chance these things will happen is very small, but cannot promise that they will not occur.)
* (There can also be a risk in finding out new genetic information about you. New health information about inherited traits that might affect you or your blood relatives could be found during a study.)

The (specify type of study intervention, such as surgery, radiation therapy, drugs, etc.) used in this study may affect how different parts of your body work such as your liver, kidneys, heart, and blood. The study doctor will be testing your blood and will let you know if changes occur that may affect your health.

There is also a risk that you could have side effects from the study drug(s)/study approach.

Here are important points about side effects:

* The study doctors do not know who will or will not have side effects.
* Some side effects may go away soon, some may last a long time, or some may never go away.
* Some side effects may interfere with your ability to have children.
* Some side effects may be serious and may even result in death.

Here are important points about how you and the study doctor can make side effects less of a problem:

* Tell the study doctor if you notice or feel anything different so they can see if you are having a side effect.
* The study doctor may be able to treat some side effects.
* The study doctor may adjust the study drugs to try to reduce side effects.

The tables below show the most common and the 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, the study doctor will discuss these with you.

|  |
| --- |
| **NOTES to consent form authors on how to present possible side effects:**  |
| 1. Side effects of study group(s):
	* + 1. For single-arm studies, list all possible side effects of the study drugs according to the recommendations given in 2-6 below.
			2. For multiple-arm studies with a control, the Table(s) of Possible Side Effects for the control arm should appear first and be followed by the Tables of Possible Side Effects for the drugs/agents used in the experimental arm(s).
			3. If the experimental arm consists of the usual treatment drugs/regimens (the control arm) plus experimental agent(s)/drug(s), the Table of Possible Side Effects for the usual treatment should not be repeated. The following statement should appear before the Table of Possible Side Effects for the investigational drugs/agents: “In addition to side effects outlined above for Group 1 and Group 2, people in this study who are in Group 2 may also experience the possible side effects of (insert name of research drug) listed below.”
2. **Side effects of procedures:**
	* + 1. **When describing risks for procedures, describe risks only for procedures that are beyond what would be considered as occurring during the usual treatment approach. The determination of deeming a procedure as part or not part of the usual treatment approach is left to the discretion of the investigator.**
			2. **Examples of procedures that are not part of the usual treatment approach could include an unusually large amount of blood to be drawn for PK, central line placement to administer the investigational agent, research biopsy, etc.**
3. Side effects of supportive drugs named in the consent form:
	* + - 1. Non-experimental supportive drugs need not have their side effects listed unless the treatment they support is the research question tested in the study. For example, side effects of Bactrim need not be listed when transplant is part of a study unless transplant is the actual study question in the trial.
4. Side effects of classes of medications:
	* + - 1. If general classes of approved medications, such as a hormonal therapy or anti-emetics – where no specific drug is named – are required by the protocol, these do not need to be listed, nor their possible side effects included, in the consent form.
5. Extremely specific possible side effects which are not perceived by the study participant, such as minor changes in lab values, should not be included in the consent form. Lab value changes that could be perceived by the study participant, or could be indicative of harm, should be listed, for example, the phrase “you could have liver damage,” would be much more understandable to the study participant than “you could have elevated liver enzymes” or “you could have an elevation in (such-and-such lab value).”
6. Definitions of frequency categories:
	* + - 1. “Common, some may be serious” - There is no standard definition of the frequency of risks included in this category however, as a guideline, “Common, some may be serious” can be viewed as occurring in greater than 20% and up to 100% of patients receiving the drug/agent.
				2. “Occasional, some may be serious”- There is no standard definition of the frequency of risks included in this category however, as a guideline, “Occasional, some may be serious” can be viewed as occurring between 4 and 20% of patients.
				3. “Rare, and serious” - Side effects that occur in less than 3% of patients do not have to be listed unless they are serious, in which case they should appear in the “Rare, and serious” category. This categorization will need to be modified for prevention studies.
				4. “Serious” is defined as side effects that may require hospitalization or may be irreversible, long-term, or life-threatening.
				5. “Possible, some may be serious” – This is a unique frequency category and may be used, when appropriate, for informing study participants of possible side effects related to IND agents for which the frequency of individual side effects has not yet been determined.
 |

|  |
| --- |
| 1. **NOTE on stating possible side effects for imaging agents**: Certain FDA regulations will need to be considered when imaging agents are used depending on the imaging agent (IND vs. commercial) and the protocol. As examples of such guidances, please refer to: FDA’s draft guidance for industry standards for clinical trial imaging endpoints, found at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM268555.pdf, and FDA’s final guidance: “Developing Medical Imaging Drug and Biological Products” found at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm092895.htm. Radiation Safety Committees may also require the mention of certain radiation-related information in the informed consent form.
 |

| The following bullets are required for NCI’s Cancer Therapy Evaluation Program (CTEP)-sponsored studies. Consent form authors for studies from other sponsors have the option of using them: |
| --- |
| * + - 1. CTEP is in the process of developing tables of possible side effects for its IND agents as well as for many other drugs commonly used in cancer treatment trials. These Tables should be inserted as illustrated below for the agents/drugs used in the cancer treatment trial. A list of agents/drugs for which tables of possible side effects have been developed, as well as the tables themselves, are available on CTEP’s website at the following URL: http://ctep.cancer.gov/protocolDevelopment/#informed\_consent
1. If a study uses a drug for which CTEP has not built a table of possible side effects, the same URL can be accessed for the tools and instructions to custom-build a table.
2. For custom-built tables of possible side effects, the same format and frequency categories should be used.
 |

Possible side effects of *(insert name of standard of care drug)*, which is the usual approach for this type of cancer:

| COMMON, SOME MAY BE SERIOUSIn 100 people receiving *(insert name of SOC drug)*, more than 20 and up to 100 may have: |
| --- |
| * *List risks in bullet points*
 |

| OCCASIONAL, SOME MAY BE SERIOUSIn 100 people receiving *(insert name of SOC drug)*, from 4 to 20 may have: |
| --- |
| * *List risks in bullet points*
 |

| RARE, AND SERIOUSIn 100 people receiving *(insert name of SOC drug)*, 3 or fewer may have: |
| --- |
| * *List risks in bullet points*
 |

In addition to side effects outlined above, you may also experience the possible side effects of *(insert name of investigational drug)* listed below.

| COMMON, SOME MAY BE SERIOUSIn 100 people receiving *(insert name of investigational drug)*, more than 20 and up to 100 may have: |
| --- |
| * *List risks in bullet points*
 |

| OCCASIONAL, SOME MAY BE SERIOUSIn 100 people receiving *(insert name of investigational drug)*, from 4 to 20 may have: |
| --- |
| * *List risks in bullet points*
 |

| RARE, AND SERIOUSIn 100 people receiving *(insert name of investigational drug)*, 3 or fewer may have: |
| --- |
| * *List risks in bullet points*
 |

###### (Table example of risk presentation for Radiation Therapy Studies. *Examples should be modified to add possible side effects related to treatment location.)*

*(Possible Side Effects of Research Radiation Therapy)*

| COMMON, SOME MAY BE SERIOUSIn 100 people receiving radiation therapy, more than 20 and up to 100 may have: |
| --- |
| * *Reddening, tanning, or peeling of the skin*
* *Mild pain*
* *Hair loss*
* *Tiredness*
* *Diarrhea, nausea*
* *Anemia, which may require transfusion*
* *Infection, especially when white blood cell count is low*
 |

| OCCASIONAL, SOME MAY BE SERIOUSIn 100 people receiving radiation therapy, from 4 to 20 may have: |
| --- |
| * *Thickening and numbness of the skin*
* *Sores or ulcers on the skin or near the cancer location*
* *Permanent hair loss*
* *Bleeding from the skin*
* *Sores in mouth which may cause difficulty swallowing*
 |

| RARE, AND SERIOUSIn 100 people receiving radiation therapy, 3 or fewer may have: |
| --- |
| * *Damage to internal organs*
* *Abnormal opening in internal organs which may cause pain and bleeding*
 |

## Potential Risk or Discomfort from Research Procedures *(only list research-related*

## *procedures)*

Blood Draws

The insertion of the needle to draw blood is painful; however, the discomfort is usually brief. For most people, needle punctures to get blood samples do not cause any serious problems; however, they may cause bleeding, bruising, discomfort, infections, dizziness, or fainting.

Bone Marrow Biopsy

There are also risks associated with taking samples of your bone marrow. Your study doctor will insert a needle into your hip or breast bone to withdraw a sample of fluid containing bone marrow cells. The risks of bone marrow sampling commonly include discomfort, pain, redness, swelling, and/or bruising where the sample is taken from your hip or chest. Sometimes bleeding can occur at the place where the sample is drawn. Fainting and infection can happen, but rarely. Many patients also experience soreness or stiffness in the hips for several days after the procedure.

CT Scans

If you take part in this research, you will have one or more medical imaging studies which use radiation. The radiation dose we have discussed is what you will receive from this study only, and does not include any exposure you may not have received or will receive from other tests. The CT scan that you will receive in this study will expose you to low amounts of radiation. Every day, people are naturally exposed to low levels of radiation that come from the sun and the environment. This type of radiation is called “background radiation.” No one knows for sure whether exposure to low amounts of radiation is harmful for your body. However, scientists believe that being exposed to too much radiation can cause harmful side effects, including causing a new cancer.   The amount of radiation that scientists think can cause harmful side effects equals more than 15 times the amount of extra radiation you would receive from being in this study. Also, scientists believe the number of people who would be at risk for developing a second cancer from being exposed to large amounts of radiation to be about 1 out of every 1,000.

MUGA scan

During a MUGA scan, a small amount of a radioactive substance called a radionuclide (or radioactive tracer) is injected into your bloodstream. The injection of the radionuclide may cause some slight discomfort. Allergic reactions to the radionuclide are rare.

Echocardiogram

Uses sound waves to evaluate your heart. These high-frequency sound waves have not been shown to have any harmful effects

Electrocardiogram (ECG)

Some people's skin reacts to the sticky patches that attach the electrodes to the chest for the ECG. This skin irritation usually disappears when the patches are removed. Some men may have some chest hair shaved.

Magnetic Resonance Imaging (MRI)

If you take part in this research, you will have an MRI (magnetic resonance imaging and/or magnetic resonance spectroscopy). MRI uses a magnet and radio waves to make images (pictures) of the inside of the head and/or body. There have been no ill effects reported from exposure to the magnetism or radio waves used for these studies; however, it is possible that harmful effects could be recognized in the future. A known risk is that the magnet could attract certain kinds of metal that may cause injury to you. We will ask you about metal within your body (this includes certain dyes used in tattoos and body piercings). If there is any question about potentially hazardous metal within your body, you will not be able to participate in this research study. We will also keep the MRI room locked so that no one carrying metal objects enters the room while you are having this scan performed. In addition, the MRI scanner makes a loud buzzing noise that could affect hearing ability. You will be provided with earplugs and assistance in their use in order to protect your hearing. You will be able to communicate with the scanner technologist using an intercom and/or signaling device. The technologist will try to help you feel as comfortable as possible in the scanner. You can ask to stop the scan and be removed from the scanner at any time by using the intercom or signaling device.

*(Include the following statement when contrast dye is used with MRI:)*

There is a very slight risk of an allergic reaction if contrast material is injected. Such reactions usually are mild and easily controlled by medication. If you experience allergic symptoms, a radiologist or other physician will be available for immediate assistance.

**Gadolinium-based** contrast agents (dyes) may increase the risk of a rare but serious disease called nephrogenic systemic fibrosis in people with poor kidney function. Nephrogenic systemic fibrosis triggers thickening of the skin, organs and other tissues. There is no effective treatment for this debilitating disease.

Bone Scan

A bone scan is a test that helps diagnose and track bone disease. A bone scan will be done when you first start the study. For a bone scan, you will receive an injection of a tracer into a vein in your arm. You will need to lie still on a table while a machine with an arm-like device supporting the camera passes over your body to record the pattern of the tracer being absorbed by your bones. This is painless. A scan of your entire skeleton will take up to 60 minutes. You may find the injection and the need to lie still during the scanning procedure mildly uncomfortable. The risk of an allergic reaction to the tracer is extremely rare.

X-ray

We are all exposed to radiation on a daily basis both from natural (sun and earth) and man-made sources that we call background radiation. The amount of radiation from a x-ray is lower than what you are exposed to through natural sources of radiation in the environment.

The x-ray technologists and radiologists use the smallest possible dose of radiation and provide a protective lead apron when multiple x-rays are necessary.

DEXA scan

The amount of radiation from a DEXA scan is lower than what you are exposed to through x-rays.

Biopsies

Risks associated with biopsies include pain, redness, swelling, low blood pressure, excessive bleeding, bruising, or draining at the needle site, abnormal wound healing, fever, infection, and allergic reaction to the medication used to numb the skin over the biopsy site. Two to 3% of patients require hospitalization after a tumor biopsy. Rarely, an infection can occur.

(If applicable, include, “You will sign a separate consent form before the biopsy is taken. This will be a standard surgical consent form from the institution where the biopsy procedure takes place.”)

Risks specifically associated with lung biopsy are pneumothorax (collapse of lung), air embolus (air in a blood vessel), hemopericardium (blood around the heart), and lung torsion (twisting that interrupts the blood supply to the lung).

HIV testing

As part of this protocol, you will be tested for HIV (human immunodeficiency virus, which is the virus that causes the acquired immunodeficiency syndrome (AIDS). You will be notified of the results of the testing, and counseled as to the meaning of the results, whether they are positive or negative. If the test indicates that you are infected with HIV, you will receive additional counseling about the significance for your medical care and possible risks to other people. We are required to report all positive results to the Ohio State Board of Health. The test results will be kept confidential to the extent permissible under the law. If you do not want to be tested for HIV, then you should not agree to participate in this study.

Hepatitis testing

The state of Ohio and applicable regulations require laboratories to report new cases of Hepatitis B, and Hepatitis C infection to governmental agencies. The reports may include the patient’s name, social security number, and other identifying information. Information about these new infections is used to track these diseases statewide and nationwide. Other than this required reporting, your results will be treated confidentially by the research study staff.

##### (Use the following text for all studies:)

Let your study doctor know of any questions you have about possible side effects. You can ask the study doctor questions about side effects at any time.

Reproductive risks: You should not get pregnant, breastfeed, or father a baby while in this study. The (specify intervention) used in this study could be very damaging to an unborn baby. Check with the study doctor about what types of birth control, or pregnancy prevention, to use while in this study.

***(Risks from Pharmacogenetic Testing)***

Risks of being in genetic testing include the misuse of personal, genetic information. All personnel who will have access to genetic information about you are ethically and legally obligated to maintain the confidence of that information. However, there can be no absolute guarantees. Although rare, misuse of such information has caused problems for persons related to their employment and/or their life and/or health insurance and other benefits or entitlements.

## What happens to the information collected for the research?

*If identifiable private information or identifiable specimens will be collected during the research, add one of the following statements:*

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

OR

Your information or samples that are collected as part of this research will not be used or distributed for future research studies, even if all of your identifiers are removed.

#### Can I stop taking part in this study?

Yes. You can decide to stop at any time. If you decide to stop for any reason, it is important to let the study doctor know as soon as possible so you can stop safely. If you stop, you can decide whether or not to let the study doctor continue to provide your medical information to the organization running the study.

The study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

The study doctor may take you out of the study:

* If your health changes and the study is no longer in your best interest
* If new information becomes available
* If you do not follow the study requirements
* If the study is stopped by the sponsor, Institutional Review Board (IRB) or FDA.

#### What are my rights in this study?

Taking part in this study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

#### What are the costs of taking part in this study?

Your involvement in this research study is voluntary and you will not be paid for your participation.

The study agent, *(insert name of research drug)*, will be provided free of charge by *(insert Sponsor)*, while you are participating in this study. Neither you nor your insurance provider will be responsible for the costs of any research-only tests or procedures. The blood work for research purposes will not be charged to you. It will be paid for by the research study.

You and/or your health plan/insurance company will need to pay for some or all of the costs of treating your cancer in this study (i.e., medical history, review of medications, physical exams, performance status, routine blood tests, pregnancy test, x-rays and/or scans for tumor measurement). Some health plans will not pay these costs for people taking part in studies. Check with your health plan or insurance company to find out what they will pay for. Taking part in this study may or may not cost your insurance company more than the cost of getting regular cancer treatment.

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute’s Web site at http://www.cancer.gov/clinicaltrials/learningabout.

#### What happens if I am injured or hurt because I took part in this study?

If you believe that you are injured as a result of the research procedures being performed, please immediately contact the study doctor.

*(If a Sponsor is providing reimbursement for research-related injury treatment:)*

In the event you suffer a research related injury as a result of being in this study, Cleveland Clinic and/or University Hospitals will provide appropriate medical treatment for such injury in a timely manner. Provision of such medical treatment does not imply any negligence or other wrongdoing on the part of Cleveland Clinic and/or University Hospitals or any of the physicians or other personnel involved in the study. If you believe that you have been injured as a result of participating in the study, please immediately contact your Cleveland Clinic and/or University Hospitals study doctor even if you may have already been seen or treated by another doctor. If you are seen or treated by a doctor other than the study doctor, you should inform such doctor that you are in this study and, if possible, take this document with you as it may help such doctor treat you.

If you have a private medical insurance plan, your plan may be billed for the costs of treatment as appropriate. If there are any costs that are not paid by your medical insurance plan, the Sponsor has agreed to pay research related injury treatment costs, provided certain coverage eligibility criteria are met. You will still be responsible for any co-payments, co-insurance or deductibles required by your medial insurance plan.

If you are covered by Medicare, Medicaid HMO plans or any other governmental healthcare insurance or if you are not covered by a health insurance plan, the Sponsor has agreed to pay the costs of treatment of a research related injury, provided certain criteria are met. If you have Medicare or another governmental insurance plan, the Sponsor may request your Social Security number, as the Sponsor may have mandatory reporting requirements under the Medicare Mandatory Reporting provisions.

The specifics of Sponsor coverage criteria for this study can be provided upon request by contacting your study doctor.

Cleveland Clinic and/or University Hospitals has not set aside any money to pay you or to pay for your treatment if you suffer a research related injury as a result of being in the study. There are no plans for Cleveland Clinic and/or University Hospitals to provide other forms of compensation (such as lost wages, pain and suffering, or other direct or indirect losses) to you for research related injuries. You are not waiving any legal rights by signing this form, including the right to seek compensation for an injury. Further information about research-related injuries is available by contacting the (choose as applicable) Cleveland Clinic Institutional Review Board at (216) 444-2924 or University Hospitals Cleveland Medical Center’s Research Subject Rights phone line at (216) 983-4979.

*(If no one is providing reimbursement for research-related injury treatment:)*

If injury occurs as a result of your involvement in this research, medical treatment is available from University Hospitals, Cleveland Clinic or another medical facility but you/your medical insurance will be responsible for the cost of this treatment.  A research injury is an injury that happens as a result of taking part in this research study.  If you are injured by a medical treatment or procedure that you would have received even if you weren’t in the study, that is not considered a “research injury”. There are no plans for payment of medical expenses or other payments, including lost wages, for any research related injury.  To help avoid injury, it is very important to follow all study directions.

Further information about research-related injuries is available by contacting the (*choose as applicable)* Cleveland Clinic Institutional Review Board at (216) 444-2924 or University Hospitals Cleveland Medical Center’s Research Subject Rights phone line at (216) 983-4979.

## What else do I need to know?

*(Include if commercial potential exists from the use of data, tissues, blood, or DNA*.)

Your information and samples *(both identifiable and de-identified)* may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans *(or replace with plans when using identifiable information/samples)* to tell you, or to pay you, or to give any compensation to you or your family.

*(When applicable, include whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and for research involving biospecimens.)*

Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the researchers will/will not contact you to let you know what they have found. If the researchers return genetic test results to you, it may be because they think you could have a health risk and want to recommend that the test should be re-done by a certified clinical laboratory to check the results. If this happens, then you may want to get a second test from a certified clinical laboratory, consult your own doctor, or get professional genetic counseling. You may have to pay for those additional services yourself.

#### ADDITIONAL STUDIES SECTION: *(Indicate clearly to participants that this is a separate section)*

#### This section is about optional studies you can choose to take part in

##### *(Use the following text if optional studies are included:)*

This part of the consent form is about optional studies that you can choose to take part in. You will not get health benefits from any of these studies. The researchers leading this optional study hope the results will help other people with cancer in the future.

The results (specify: will/ will not) be added to your medical records and you or your study doctor (specify: will/will not) know the results.

You will not be billed for these optional studies. You can still take part in the main study even if you say “no” to any or all of these studies. If you sign up for but cannot complete any of the studies for any reason, you can still take part in the main study.

Circle your choice of “yes” or “no” for each of the following studies.

##### **1. Optional imaging study – extra scan**

If you choose to take part in this study, you will have an extra (insert name of standard clinical imaging procedure, e.g., PET scan). This scan is already used in medical care but it would be taken at a time point in your treatment that is not usual. Researchers would use this scan to (briefly describe purpose, e.g., try to learn more about how treatment works on cancer).

If you agree to have this extra scan, it would involve (briefly describe procedures, e.g., blood draw, contrast agent, time). The risks would be (briefly describe, focusing on risks of extra scan, e.g., additional radiation risk, risk of contrast). (As applicable, insert: The scan [may or would] be used to guide your medical care. or The scan would only be used for research and not to guide your medical care.) (If applicable, include the following statement:) There are educational materials available about this type of scan. Ask your study doctor about them, if you would like more information.)

I agree to allow *(restate optional procedure:)*.

Yes No Initials

##### **2. Optional imaging study – research scan or procedure**

If you choose to take part in this study, you will have an experimental (insert descriptor - scan or procedure) called (insert name of investigational imaging scan/procedure). Researchers hope this kind of (insert descriptor - scan or procedure) might one day be used to (briefly describe purpose, e.g., learn more about cancer and how treatment works on cancer). This (insert descriptor - scan or procedure) is still being tested and researchers do not know how accurate or useful it is.

If you agree to have this (insert descriptor - scan or procedure), it would involve (briefly describe procedures). The risks would be (briefly describe, e.g., risks of investigational contrast agent). The (insert descriptor - scan or procedure) would only be used for research and not to guide your medical care.

I agree to allow *(restate optional procedure:)*.

Yes No Initials

##### **3.** **Optional Quality of Life Study**

If you choose to take part in this study, you will be asked to fill out a form with questions about (briefly state topic, e.g., your physical and emotional well-being). Researchers will use this information to (briefly describe purpose, e.g., learn more about how cancer and cancer treatment affects people).

You will be asked to fill out this form at (insert number) times: (insert bulleted list of time indicators, e.g., before surgery, after surgery before chemotherapy, and mode, e.g., inpatient, mail, or phone). Each form will take about (insert number) minutes to complete. The forms will ask about things like (briefly describe, e.g., fatigue, diarrhea). You may feel uncomfortable answering some of the questions, and you can skip any you do not want to answer.

I agree to allow *(restate optional procedure:)*.

Yes No Initials

**HIPAA AUTHORIZATION**

**Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study**

If you volunteer to participate in this research, your protected health information (PHI) that identifies you will be used or disclosed to *(name of* *Principal Investigator(s))*, MD, and the research study staff at Cleveland Clinic and/or University Hospitals for the purposes of this research and to Case Western Reserve University for administration.

The PHI that we may use or disclose (release) for this research may include your name, address, phone number, date of birth, Social Security number, information from your medical record, lab tests, or certain information relating to your health or condition..

Some of the tests and procedures done solely for this research study may also be placed in your medical record so other doctors know you are in this study. Upon completion of the study, you may have access to the research information that is contained in your medical record.

In addition to the investigators and research staff listed above, your PHI may be looked at by other groups involved with the study such as the Cleveland Clinic Institutional Review Board, University Hospitals Institutional Review Board *(select only applicable Institutional Review Board)* and the Case Comprehensive Cancer Center Protocol Review and Monitoring Committee. Your PHI may also be used by and/or disclosed (released) to:

* *(Sponsor of study)*, its study monitors and representatives
* *(Sponsor’s* collaborators and licensees *(people and companies who partner with Sponsor)*
* Case Comprehensive Cancer Center members and collaborators
* The Food and Drug Administration;
* The Department of Health and Human Services;
* The National Cancer Institute (NCI);
* Other Institutional Review Boards;
* Data Safety and Monitoring Boards;
* (Insert other parties as appropriate)

Once your personal health information is released it may be re-disclosed and no longer protected by privacy laws.

Your research information may be used and disclosed indefinitely, but you may stop these uses and disclosures at any time by writing to:

*(UH Principal Investigator)*, MD or *(CC Principal Investigator)*, MD

Case Comprehensive Cancer Center Case Comprehensive Cancer Center

University Hospitals Cleveland Medical Center Cleveland Clinic

11100 Euclid Ave. 9500 Euclid Ave.

Cleveland, OH 44106 Cleveland, OH 44195

Your participation in the research will stop, but any information previously recorded about you cannot be removed from the records and will continue to be used as part of this research. Also, information already disclosed outside the Cleveland Clinic and/or University Hospitals cannot be retrieved. This will not affect your rights to treatment or benefits outside the research study.

The Cleveland Clinic and/or University Hospitals will not use your information collected in this study for another research purpose without your written permission; unless the Cleveland Clinic Institutional Review Board (IRB) and/or University Hospitals Institutional Review Board assures your privacy and confidentiality is protected. The IRB is a committee whose job it is to protect the safety and welfare of research subjects.

By signing this informed consent form, you are authorizing such access to your research and medical record information. If you choose not to sign this consent form, you will not be able to participate in this research study. This Authorization does not have an expiration date.

**Voluntary Participation**

Your participation in this research study is voluntary. Choosing not to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. If information generated from this study is published or presented, your identity will not be revealed.

In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating.

**Questions about the Research**

If you have any questions, you can ask the Principal Investigator and/or research staff at *(insert the telephone numner,(216) xxx-xxxx).*

Emergency or after-hours contact information

If you are a University Hospitals patient, and you need to contact study staff outside normal business hours, you may contact 216-844-3951 and you will be transferred to the answering service, which can put you in contact with *(insert the name of the UH PI)* or the oncologist (cancer doctor) on call.

If you are a Cleveland Clinic patient, you should contact the page operator at (216) 444-2200 or toll free at (800) 223-2273, and ask for the oncologist (cancer doctor) that is on call.

**Where Can I Get More Information?**

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about: concerns regarding the study, research participant’s rights; research-related injury; or other human subjects issues, you may contact the Institutional Review Board (IRB) at (*choose as applicable)* Cleveland Clinic IRB 216-444-2924 or the University Hospitals Cleveland Medical Center’s Research Subjects Rights Phone line at 216-983-4979.

You may call the National Cancer Institute's Cancer Information Service at:

1-800-4-CANCER (1-800-422-6237)

You may also visit the NCI Web site at http://cancer.gov/

* For NCI’s clinical trials information, go to: http://cancer.gov/clinicaltrials/
* For NCI’s general information about cancer, go to http://cancer.gov/cancerinfo/

You will get a copy of this form. If you want more information about this study, ask your study doctor.

**US National Institutes of Health (NIH) Clinical Trial Database:**

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, if applicable, 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.

**Signature**

Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

*[Signature format for studies enrolling only adults]*

Signature of Participant Date Printed Name of Participant

 *[USE THIS WHEN A WITNESS IS USED IN THE CONSENTING PROCESS (Common examples include: Inclusion of illiterate individuals, blind individuals or individuals who cannot physically sign but are able to provide informed consent.)]*

Signature of Witness Date Printed Name of Witness

I have discussed the information contained in this document with the participant and it is my opinion that the participant understands the risks, benefits, alternatives and procedures involved with this research study.

Signature of Person Obtaining Consent Date

Printed Name of Person Obtaining Consent

*[Signature format for studies enrolling children]*

Printed Name of Participant Date

Signature of Participant or Child’s Signature if this form is used to obtain assent

(for minors ages ≥14 years of age)

*[If Participant is a minor]*

Printed Name of Parent or Legal Guardian Date

Signature of Parent or Legal Guardian Relationship to Participant Date

­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Second Signature of Parent or Legal Guardian Relationship to Participant Date

I have discussed the information contained in this document with the participant and it is my opinion that the participant understands the risks, benefits, alternatives and procedures involved with this research study.

Signature of Person Obtaining Consent Date

Printed Name of Person Obtaining Consent

*[Signature format for studies of children, classified as 45 CFR 46.406 requiring both parent’s signatures(remove for non pediatric population studies)]*

Printed Name of Participant Date

Child’s Signature if this form is used to obtain assent (for minors ages ≥14 years of age)

Printed Name of Parent or Legal Guardian Date

Signature of Parent or Legal Guardian Relationship to Child Date

I have discussed the information contained in this document with the participant and it is my opinion that the participant understands the risks, benefits, alternatives and procedures involved with this research study.

Signature of Person Obtaining Consent Date

Printed Name of Person Obtaining Consent

Second Parent Signature Relationship to Child Date

If only one parent can sign this consent, indicate the reason that applies to the other parent. (Acceptable reasons for this category must not be based on convenience):

 □ Deceased

□ Unknown

 □ Legally incompetent

□ No legal responsibility for the care and custody of the child

 □ Not reasonably available - indicate why: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*[If Participant is a Legally Incompetent Adult]*

Printed Name of Legally Authorized Representative [LAR] Date

Signature of Legally Authorized Representative [LAR] Date

I have discussed the information contained in this document with the LAR and it is my opinion that the LAR understands the risks, benefits, alternatives and procedures involved with this research study.

Signature of Person Obtaining Consent Date

Printed Name of Person Obtaining Consent