VUMC Institutional Review Board
Informed Consent Document for Research

Study Title: VICCCTT2193: A Phase II Study of Itacitinib in Steroid Refractory Immune Related Adverse Events Arising from Immune Checkpoint Inhibitors
ICF Version Date: 14FEB2023 NCT05660421
PI: Douglas Johnson, MD

Name of participant: _____ Age: _____

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

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:
The purpose of this study is to find out if taking an investigational drug called itacitinib would be effective in treating patients with known or suspected problems coming from immune checkpoint inhibitors (ICI).
If you enroll in this study, you will take tablets of itacitinib orally and daily. If your condition declines after initial improvement, it's possible you would receive a second 28 day course of treatment based on physician discretion and patient agreement.
If you have improvement, steroids will be slowly reduced and complete a 28 day course of itacitinib. If there is a return of problems after stopping itacitinib, you may receive a repeat 28-day course.
If there is no response to itacitinib, you would no longer continue taking the drug.

You will have tests, exams, and procedures, including bone marrow biopsies and blood draws, that are part of your standard care. You will be asked to complete a drug diary and complete at least 3 in office visits for each round of itacitinib. Each clinic visit could last several hours.

There are risks to this study drug that are described in this document. This study will be using itacitinib SR.

This is a brief list of the most commonly seen side effects with itacitinib SR. More information regarding the potential side effects are listed in the Risk section of this consent form.

- fatigue
- anemia (low red blood cells)
- upper respiratory tract infection
- Thrombocytopenia (low platelets)

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Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

You are being asked to take part in this research study because you are known or suspected to have toxicity (side effects) arising from immune checkpoint inhibitors (ICI) and this toxicity is not responsive to steroids. The immune system has an ability to know the difference between normal and foreign cells in the body. To identify foreign cells, the immune system uses "checkpoints". Cancer cells can find ways to use these "checkpoints" to avoid being attacked by the immune system. The drugs that target these types of checkpoints are called immune checkpoint inhibitors (ICI). Sometimes ICI cause side effects by over-activating the immune system. Steroids are the usual treatment for these side effects. However, sometimes steroids do not improve or fix the side effects. The purpose of this study is to find out if taking a drug called itacitinib would be effective in treating patients with known or suspected problems coming from immune checkpoint inhibitors (ICI) that do not resolve or improve with steroids.

Investigational means the drug itacitinib is still being tested in research studies and has not yet been approved by regulatory health authorities, such as the U.S. Food and Drug Administration (FDA) for your disease. The study will provide the itacitinib.

There may or may not be a direct benefit to you as a result of your participation in this study. This research may contribute to the understanding of cancer and its treatment and may eventually lead to improvements in treatment.

This research study was developed at Vanderbilt University Medical Center (VUMC) and expects to accrue 25 total patients at VUMC. Douglas Johnson, MD at the Vanderbilt-Ingram Cancer Center (VICC) is the sponsor-investigator of this study. This study is supported by Incyte. Personal information being collected as part of this study may be shared with Incyte and Incyte could benefit financially from this research study.

Choosing to participate in this study will mean you are choosing to receive itacitinib as a means of treating problems coming from immune checkpoint inhibitors. There may be other treatment options that are available to you, including receiving only the standard therapies. You should speak to your doctor about all your treatment options prior to deciding to participate in this study.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study

at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

If you decide you would like to take part in the study and you sign this informed consent form, you will have screening tests and procedures done to make sure you are eligible to participate.

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

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, researchers don't know all the side effects that may happen. Side effects may be mild or very serious. The researchers may give you medicines to help lessen side effects. Many side effects go away soon after you stop taking the study drug(s). In some cases, side effects can be serious, long lasting, or may never go away.

Very Common (greater than or equal to 10%)

- Fatigue
- Anemia (low red blood cells)
- Pyrexia (fever)
- Upper respiratory infection
- Thrombocytopenia
- Diarrhea
- Nausea
- Constipation
- Abdominal Pain
- Dizziness
- Decreased neutrophil count (cells that help fight infection)
- Sepsis (infection that involves the bloodstream

Common (less than 10% but greater than 1%)

- Headache

You may experience side effects from some of the procedures in this study:

Blood samples: When giving blood or when having a cannula inserted in your arm, you may feel faint, or experience mild pain, bruising, irritation, or redness at the site. In rare cases, you may get an infection or damage to nerves at the site. A cannula is a small tube that stays in your arm so that you will not

need a lot of needle sticks when blood is drawn. Study staff will remove the cannula before you leave the clinic.

Colonoscopy or flexible sigmoidoscopy (either procedure ONLY in patients with enterocolitis**):**
The above procedures are examinations of the inside of the colon using a thin, flexible tube with a camera at the end and inserted into the rectum. A colonoscopy examines the entire colon, while a sigmoidoscopy covers the lower part of the colon.

Colonoscopy or flexible sigmoidoscopy risks:

- Pain and discomfort
- Heavy bleeding
- Tears in the colon
- Diverticulitis (inflammation or infection of pouches in the colon)
- Severe abdominal pain
- Problems in people with heart or blood-vessel disease

Colon biopsy:
When you have a colon biopsy, your doctor and the person performing the procedure will explain the procedure to you before it is performed. Colon biopsies typically remove a tiny sample of tissue using a needle.

Colon biopsy risks:

- Infection
- Hole in the colon
- Bleeding
- Pain
- Abdominal discomfort

Biopsy:
When you have a skin biopsy, your study doctor and the person performing the procedure will explain the procedure to you before it is performed. Skin biopsies typically remove a small piece of skin by cutting the skin.

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Biopsy risks can include:

- Pain and discomfort. The amount of pain and discomfort will vary, depending on the location of the biopsy site. These risks can be discussed with the study doctor.
- Minor bleeding at the biopsy site.
- Tenderness at the biopsy site.
- Scarring at the biopsy site.
- Rarely, an infection at the biopsy site.

You may receive an injection of lidocaine to numb the area of the biopsy site. Lidocaine, a numbing drug, may burn or cause a rash, redness, or soreness where you get the shot. There is a risk that this drug may cause problems with heart rhythm.

Risks that are not known:
Because this treatment is investigational, meaning non-FDA approved, there may be risks that we do not know about at this time.

Pregnancy or Fathering a Child
All of the risks to an unborn or a nursing child from the Study Drug are not known and may harm the unborn or nursing child.

You cannot be in this Study if you are pregnant, are trying to get pregnant, or intend to father a child during the Study and must agree to take measures to avoid it (female and male).

Female participants who can have children must agree to take appropriate actions to avoid pregnancy (with at least 99% certainty) from Screening through the Follow-Up Visits. Highly effective methods of birth control include combined (estrogen and progestogen containing) hormonal contraception associated with inhibition of ovulation (oral, intravaginal, transdermal; progestogen-only hormonal contraception associated with obstructing ovulation (oral, injectable, implantable); intrauterine device (IUD); intrauterine hormone-releasing system; bilateral tubal occlusion; vasectomized partner; or sexual abstinence. Acceptable birth control methods that result in a failure rate of more than 1% per year include: progestogen-only oral hormonal contraception, where inhibition of ovulation is not the primary mode of action; male or female condom with or without spermicide; cap, diaphragm, or sponge with spermicide; tubal ligation; and Male participants must agree to take appropriate precautions to avoid fathering a child (with at least 99% certainty) from Screening through 90 days after the last dose of Study Drug.

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You should use a condom from Screening through 90 days after the end of systemic exposure. If your partner is able to have children, the partner should also use highly effective contraception method through 90 days after the end of relevant systemic exposure as mentioned above. You should also not donate sperm from Screening through 90 days after your last dose of the Study Drug. If you have had a vasectomy clinically designated as successful, you meet the requirement for a highly effective birth control method. If you become pregnant during the Study, you must tell the Study Doctor and stop taking the Study Drug immediately. The Study Doctor will ask to medically follow the pregnancy outcome and follow up with you until the first well-baby visit to monitor your and your child's safety. The Study Doctor will report the pregnancy and outcome to the Sponsor. If you father a child during your participation in the Study, you must notify the Study Doctor immediately. If your partner becomes pregnant, your Study Doctor will ask for permission to follow the pregnancy until delivery and follow up until the first well-baby visit to monitor your partner's and your child's safety. The Study Doctor will report the pregnancy to the Sponsor and outcome to the Sponsor.

Other Risks:
One risk of giving samples for this research may be the release of your name that could link you to the stored samples and/or the results of the tests run on your samples. This may cause problems with insurance or getting a job.

To prevent this, these samples will be given a code. Only the study staff will know the code. The name that belongs to the code will be kept in a locked file or in a computer with a password, and only Douglas Johnson, MD will have access to this information.

Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. Employers with 15 or more employees may not use your genetic information that comes from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Your sample will be used to make DNA that will be kept for an unknown length of time (maybe years) for future research. The sample will be destroyed when it is no longer needed.

Privacy Risk:
One risk of giving samples for this research may be the release of PHI that could link you to the stored samples and/or the results of the tests run on your samples. This may cause problems with insurance or getting a job.

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Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. Employers with 15 or more employees may not use your genetic information that comes from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

To prevent this, these samples will be given a code. Only the study staff will know the code. The name that belongs to the code will be kept in a locked file or in a computer with a password. Only the principal investigator and their team will have access to your name.

Good effects that might result from this study:
The benefits to science and humankind that might result from this study:

- This research may contribute to a better understanding of cancer and its treatment and may eventually lead to improvements in treatment.

The benefits you might get from being in this study:

- There may or may not be a direct benefit to you as a result of your participation in this study.

Procedures to be followed:

Screening

The following must be completed ≤ 7 days prior to your first dose of study treatment:

- You will be asked questions about your past and current health including any past treatments for your condition, and any ongoing medical conditions you may have
- You will be asked about any medications you are currently taking
- You will have a physical exam and a measure of your vital signs including height and weight
- Your performance status will be assessed by questions about your ability to carry out daily activities
- If you are female with the potential of becoming pregnant, you will have a pregnancy test. This may be a blood test or a urine test
- For patients with enterocolitis (inflammation of the intestine, usually causing diarrhea), a test may be done using a camera inserted in the anus to look at the rectum and lower part of the large intestine.
- For patients with problems pertaining to the skin, a small sample of skin may be cut (biopsied) and removed for testing.
- You will be asked to describe the problems resulting from the ICI
- Blood will be drawn (about ½ tablespoon) to check the following:
  - Blood Cell Counts (numbers of each type of blood cell)
  - Coagulation (how your blood clots)

- Chemistries (proteins, elements, and minerals in your blood)
- You will be given the investigation drug
- You will be given a medication diary to track your daily dosing

Treatment

Day 8:

- You will be asked to describe the problems resulting from the ICI
- You will be given a medication diary to track your daily dosing
- You will bring the medication diary you have been completing to track your daily dosing

Day 15:

- Performance assessment (your ability to do daily activities)
- You will be asked about any medications you are currently taking
- Weight will be obtained
- You will have a measure of your vital signs
- You will be asked how you feel and about any problems you may be experiencing
- Blood will be drawn (about ½ tablespoon) to check the following:
  - Blood Cell Counts (numbers of each type of blood cell)
  - Coagulation (how your blood clots)
  - Chemistries (proteins, elements, and minerals in your blood)
- You will be asked to describe the problems resulting from the ICI
- You will bring the medication diary you have been completing to track your daily dosing

Day 22:

- You will be asked to describe the problems resulting from the ICI
- You will be given a medication diary to track your daily dosing
- You will bring the medication diary you have been completing to track your daily dosing

Day 29:

- Performance assessment (your ability to do daily activities)
- You will be asked about any medications you are currently taking
- Weight will be obtained
- You will have a measure of your vital signs
- You will be asked how you feel and about any problems you may be experiencing
- Blood will be drawn (about ½ tablespoon) to check the following:
  - Blood Cell Counts (numbers of each type of blood cell)

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- Coagulation (how your blood clots)
- Chemistries (proteins, elements, and minerals in your blood)

- For patients with enterocolitis, a test may be done using a camera inserted in the anus to look at the rectum and lower part of the large intestine.
- For patients with problems pertaining to the skin, a small sample of skin may be cut and removed for testing.
- You will be asked to describe the problems resulting from the ICI
- You will bring the medication diary you have been completing to track your daily dosing

Follow up

Day 30:

- You will be asked about any medications you are currently taking
- You will be asked to describe the problems resulting from the ICI
- For patients being followed in clinic, there is the option to have blood drawn (about ½ tablespoon) to check the following:
  - Blood Cell Counts (numbers of each type of blood cell)
  - Coagulation (how your blood clots)
  - Chemistries (proteins, elements, and minerals in your blood)

Day 60:

- You will be asked about any medications you are currently taking
- You will be asked to describe the problems resulting from the ICI
- For patients being followed in clinic, there is the option to have blood drawn (about ½ tablespoon) to check the following:
  - Blood Cell Counts (numbers of each type of blood cell)
  - Coagulation (how your blood clots)
  - Chemistries (proteins, elements, and minerals in your blood)

Optional Second Course:

Screening

The following must be completed ≤ 7 days prior to your first dose of study treatment:

- You will be asked questions about your past and current health including any past treatments for your condition, and any ongoing medical conditions you may have
- You will be asked about any medications you are currently taking
- You will have a physical exam and a measure of your vital signs including height and weight
- Your performance status will be assessed by questions about your ability to carry out daily activities

- If you are female with the potential of becoming pregnant, you will have a pregnancy test. This may be a blood test or a urine test
- For patients with enterocolitis, a test may be done using a camera inserted in the anus to look at the rectum and lower part of the large intestine (this is optional).
- For patients with problems pertaining to the skin, a small sample of skin may be cut and removed for testing (this is optional).
- You will be asked to describe the problems resulting from the ICI
- Blood will be drawn (about ½ tablespoon) to check the following:
  - Blood Cell Counts (numbers of each type of blood cell)
  - Coagulation (how your blood clots)
  - Chemistries (proteins, elements, and minerals in your blood)
- You will be given the investigation drug
- You will be given a medication diary to track your daily dosing

Treatment

Day 8:

- You will be asked to describe the problems resulting from the ICI
- You will be given a medication diary to track your daily dosing
- You will bring the medication diary you have been completing to track your daily dosing

Day 15:

- Performance assessment (your ability to do daily activities)
- You will be asked about any medications you are currently taking
- Weight will be obtained
- You will have a measure of your vital signs
- You will be asked how you feel and about any problems you may be experiencing
- Blood will be drawn (about ½ tablespoon) to check the following:
  - Blood Cell Counts (numbers of each type of blood cell)
  - Coagulation (how your blood clots)
  - Chemistries (proteins, elements, and minerals in your blood)
- You will be asked to describe the problems resulting from the ICI
- You will bring the medication diary you have been completing to track your daily dosing

Day 22:

- You will be asked to describe the problems resulting from the ICI
- You will be given a medication diary to track your daily dosing

- You will bring the medication diary you have been completing to track your daily dosing

Day 29:

- Performance assessment (your ability to do daily activities)
- You will be asked about any medications you are currently taking
- Weight will be obtained
- You will have a measure of your vital signs
- You will be asked how you feel and about any problems you may be experiencing
- Blood will be drawn (about ½ tablespoon) to check the following:
  - Blood Cell Counts (numbers of each type of blood cell)
  - Coagulation (how your blood clots)
  - Chemistries (proteins, elements, and minerals in your blood)
- For patients with enterocolitis, a test may be done using a camera inserted in the anus to look at the rectum and lower part of the large intestine.
- For patients with problems pertaining to the skin, a small sample of skin may be cut and removed for testing.
- You will be asked to describe the problems resulting from the ICI
- You will bring the medication diary you have been completing to track your daily dosing

Follow up

Day 30:

- You will be asked about any medications you are currently taking
- You will be asked to describe the problems resulting from the ICI
- For patients being followed in clinic, there is the option to have blood drawn (about ½ tablespoon) to check the following:
  - Blood Cell Counts (numbers of each type of blood cell)
  - Coagulation (how your blood clots)
  - Chemistries (proteins, elements, and minerals in your blood)

Day 60:

- You will be asked about any medications you are currently taking
- You will be asked to describe the problems resulting from the ICI
- For patients being followed in clinic, there is the option to have blood drawn (about ½ tablespoon) to check the following:
  - Blood Cell Counts (numbers of each type of blood cell)
  - Coagulation (how your blood clots)
  - Chemistries (proteins, elements, and minerals in your blood)

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Payments for your time spent taking part in this study or expenses:
You will not be paid for participating in this study.

Costs to you if you take part in this study:

If you agree to take part in this research study, you and/or your insurance will not have to pay for the tests and treatments that are being done only for research. However, you are still responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

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

Payment in case you are injured because of this research study:
If it is determined by Vanderbilt and the Investigator that an injury occurred, then you and/or your insurance may be billed for the cost of medical care provided at Vanderbilt to treat the injury. You will be responsible for any copayments or deductibles associated with the treatment of that injury.

There are no plans for Vanderbilt to pay for the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

Who to call for any questions or in case you are injured:
If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Douglas Johnson, MD [redacted]

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

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

- The study doctor feels it is not in your best interest to continue in the study,
- You fail to follow the study doctor's instructions,
- You experience an adverse reaction that requires other medical treatment,
- Required use of medication that may conflict with study treatment
- You become pregnant, or
- The sponsor or the FDA or other regulatory authority stops the study for any reason.

If you are removed from the study, the reason will be explained to you.

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

Clinical Trials Registry:
A description of this clinical trial will be available on 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 Web site at any time.

Clinical Trials Reporting Program.
Vanderbilt's NCI-Designated Cancer Center or the Sponsor registers National Cancer Institute (NCI)-supported clinical trials with NCI though their Clinical Trials Reporting Program (CTRP) to provide study related information. The data provided will include the following identifiable information that may identify you: birth month/year and five-digit zip code. NCI uses the data to manage and enhance the nation's investment in cancer research.

Confidentiality:

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

All data generated during the conduct of this clinical trial will be maintained in a confidential manner. Data will be recorded on case report forms as directed by the industry sponsor and the OnCore electronic database maintained by research study personnel. All data pertaining to this study is maintained in separate charts independent of the patient's institutional or private medical record. The Principal Investigator, research study staff, the Food and Drug Administration, the industry sponsor and

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their agents and contractors will have access to the patient's information. Research records will be kept in the Clinical Trials Shared Resources office until the study is closed. At that time, the research records will be archived and kept for an unknown period of time.

Privacy:
Any samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us, or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Study Results:
Results of your treatment will be shared with you by your study doctor. Results of this study may be presented in meetings or in publications. A summary of results will be available on www.clinicaltrials.gov, as required by U.S. Law.

Authorization to Use/Disclose Protected Health Information

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

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

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

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

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

You have the right to see and copy the PHI we gather on you for as long as the study doctor or research site holds this data. To ensure the scientific quality of the research study, you will not be able to review some of your research data until after the research study is finished.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

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

Date _____ Signature of patient/volunteer _____

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Consent obtained by:

Date

Signature

Printed Name and Title

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Consent for Genetic Research

The purpose of this study is to look at genes (DNA) and how they affect health and disease. Genes are the instruction manual for your body. The genes you get from your parents decide what you look like and how your body behaves. They can also tell us a person's risk for certain diseases and how they will respond to treatment.

Patients with similar diseases do not always obtain the same benefit from the same treatment. Therefore, a goal is to help understand why patients respond differently to treatment, and to then develop treatment that provides maximum benefit for individual patients.

As part of the study, your tumor biopsy tissue, bone marrow biopsy and aspirate, cerebrospinal fluid (CSF), blood and/or fluid samples will be collected to better understand your disease. It is possible that genetic testing may be conducted on some or all of this material. You are being asked for your permission to allow this.

It is possible that genetic testing on these samples could help to learn more about:

- The effect of treatment on your body
- Why some people respond to treatment and others do not
- Why some people have side effects
- The causes of the disease.

What we learn about you from research on your samples is unlikely to be put in your health record. No one else (like a relative, boss, or insurance company) will be given your test results.

One risk of giving samples for this research may be the release of your name that could link you to the stored samples and/or the results of the tests run on your samples. This may cause problems with insurance or getting a job. To help prevent this, these samples will be given a code. Only the study staff will know the code. The name that belongs to the code will be kept in a locked file or in a computer with a password. Dr. Johnson and his staff helping with the study will have access to your name.

Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. Employers with 15 or more employees may not use your genetic information that comes from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Your sample may be used to make DNA that will be kept for an unknown length of time (maybe years) for future research. Samples will be destroyed when no longer needed. Your samples may be used to make new products, tests or findings. These may have value and may be developed and owned by the study staff, Vanderbilt University, Vanderbilt University Medical Center, and/or others. If this happens, there are no plans to provide money to you.

Study Title: VICCCTT2193: A Phase II Study of Itacitinib in Steroid Refractory Immune Related Adverse Events Arising from Immune Checkpoint Inhibitors
ICF Version Date: 14FEB2023
PI: Douglas Johnson, MD

Your samples and information about you may be shared with others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us learn more about the causes, risks, treatments, or how to prevent this and other health problems.

At any time, you may ask to have your sample destroyed. You should contact Dr. Johnson to have your sample destroyed and no longer used for research. His mailing address is:

[redacted]

We will not be able to destroy research data that has already been gathered using your sample. Also, if your identity was removed from the samples, we will not be able to locate and destroy them. There will be no costs to you for any of the tests done on your samples. You will not be paid for the use of your samples.

Please check Yes or No to the questions below:

My blood/tissue/fluid samples may be used for current gene research in cancer:

☐ Yes

My blood/tissue/fluid samples may be stored/shared for future gene research in cancer:

☐ Yes

My blood/tissue/fluid samples may be stored/shared for future gene research for other health problems (such as arthritis, heart disease, etc):

☐ Yes

Signature: _____ Date: _____