Consent and Authorization Document

HCI IIT FLIGHT

A Phase II Study of Itacitinib (INCB039110) and Extracorporeal Photopheresis (ECP) for First-Line Treatment in Chronic Graft Versus Host Disease

Principal Investigator: **Catherine Lee, MD**

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

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

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

Summary
You are being asked to participate in this research study because you have been diagnosed with chronic Graft versus Host Disease (GVHD). Typically, chronic GVHD is treated with high doses of corticosteroids, such as prednisone. Corticosteroids are anti-inflammatory drugs typically used to lessen swelling, redness, itching, and allergic reactions. While corticosteroids can treat chronic GHVD up to 50% of the time, the treatment is often associated with unwanted long-term side effects.

In this study, researchers will look at the use of oral itacitinib with extracorporeal photopheresis (ECP) as a treatment for chronic GVHD. ECP is a photo-immune therapy in which your blood is removed with a machine and the white blood cells are separated from the whole blood by apheresis. The white blood cells are combined with a photoactive drug and then activated with ultraviolet A (UVA) light. The machine then returns the blood to your system. The ECP-treated blood helps to control chronic GVHD. ECP will be given on this study as standard of care treatment per local institutional guidelines.

This study has two parts. Part 1 will determine what dose of itacitinib to use in combination with ECP. Part 2 will look at how effective the combination is in treating moderate to severe chronic GVHD. The study will also look at the safety of the combination and how effective it is long term.

Itacitinib has not been approved by U.S. Food and Drug Administration (FDA) for the treatment of chronic GVHD and is considered investigational in this study. An investigational drug is a drug that is being tested and is not approved for sale in the United States by the FDA.

The purpose of this consent form is to help you decide if you want to be in this research study. You should not join this research study until all of your questions are answered. Once you know about the study, you will decide about whether to take part. If you decide to take part, you will be asked to sign this form. Your decision to take part in this study is voluntary which means you are free to decide to join this study or not to join this study.

Key Information for You to Consider
• **Voluntary Consent**. You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate or discontinue your participation. • **Purpose**. This study has 2 parts. Part 1 will determine how much itacitinib to use in combination with extracorporeal photopheresis (ECP). Part 2 will use the dose of itacitinib determined in Part 1 to expand the study to more patients to look more at how safe the combination is and how well it is working. • **Duration.** You may receive treatment for up to 12 cycles. Each cycle is 28 days. • **Procedures and Activities.** You will be asked to undergo a number of tests (Screening) to be certain that you are able to participate. If you qualify, then you will receive study treatment and also undergo additional testing to evaluate your disease, the treatment, and any side effects (Treatment Period). Details of the procedures to be completed during the study are listed below. • **Risks.** Some of the more common foreseeable risks or discomforts of your participation include: anemia, headaches, and fever. More detailed information can be found in the RISKS section found below. • **Benefits**. We do not know if you will benefit from taking part in this study, although the knowledge gained from this study may help others in the future who have chronic GVHD. • **Alternatives.** As an alternative to participation, you could receive standard of care treatment, take part in another study, or receive comfort care.

The study is being conducted by Dr. Catherine Lee at Huntsman Cancer Institute of the University of Utah.

What is expected from you?

If you participate in this study you will be expected to:

- Attend all your appointments and follow all instructions given to you by the study doctor and/or study staff.

Tell the study doctor or study staff:

- How you feel and about possible side effects that you are experiencing.
- About any changes in your health.
- About any medication that you take while you are in this study, including any new prescription, over the counter medications, or herbal supplements, even if they are prescribed by another doctor. You may not be able to take certain medications while you are participating in this trial. Your study doctor will inform you what these are.
- If you change your address, telephone number, or other contact information.
- If you plan to receive any medical treatments during the study (such as elective surgery or radiation).

You should:

- **Not** eat anything containing pomegranates, pomegranate juice, grapefruits, grapefruit juice, or Seville oranges as these may interfere with the study drug.
- **Avoid** direct and indirect sunlight and wear dark glasses, hats, and sunscreen of at least 15 SPF for 24 hours after each treatment, as your eyes and skin will be temporarily more sensitive to sunlight.
- **Limit** the amount of fatty foods, such as fried foods, fatty meats and food high in saturated fat, 1 day prior to ECP treatment.

STUDY PROCEDURES

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

Screening Period

During the screening period you will have the following procedures:

- The study team will collect your demographic information including change in residence, annual income, insurance type, and employment status.
- Medical history will be collected as well as details about what medications and vitamins you are currently taking
- A physical exam and a measure of your vital signs, height, and weight.
- Blood drawn for standard lab testing to ensure you are healthy enough to take part in this study.
    - This will include cholesterol and coagulation (how fast your blood clots) tests.
- Blood drawn to evaluate your disease.
- If you are a female, with the potential of becoming pregnant, you will have a pregnancy test.
- HIV and hepatitis testing. The physician and/or a certified HIV counselor will explain HIV testing to you before testing, and you will have an opportunity to ask questions. The physician will explain the test results to you in a confidential manner. You will be provided with appropriate counseling by the physician and/or a certified HIV counselor if the result of the test is positive. If you do not want to be tested, you may choose not to participate in this research study.
- An evaluation of your ability to perform everyday activities (performance status).
- An ECG (Electrocardiogram) to check your heart function.
- A Pulmonary Function Test with spirometry to evaluate your lungs.

- A 2-minute walk test. During the test your distance traveled, while walking for 2 minutes without assistance, will be recorded.
- Monitoring for infection.
- An assessment of your chronic GVHD and your symptoms.
- Monitoring for evidence of disease relapse or recurrence.
- You will be asked to complete study questionnaires asking about your symptoms, mobility, your health and how you feel.
  In part 2 of the study, blood will be drawn for additional research related to this study.

Treatment Period

Once you are approved to join this study, you will begin study treatment with one week of itacitinib only. Once the first week of itacitinib treatment is complete you will start ECP treatment as well. These combination treatments will be given to you in "cycles." Each cycle is 28 days.

You will receive ECP treatment, as standard of care, twice weekly on consecutive days for 8 weeks. At the end of 8 weeks, you will start a standard gradual reduction (taper) of your ECP schedule as determined by your doctor.

You will take your prescribed dose of itacitinib every morning at home for up to 6 cycles. If you have a favorable response to itacitinib after 6 cycles of treatment, you may continue to receive itacitinib for up to one year. After one year, your itacitinib dose may be gradually reduced (tapered) per your doctor's discretion. Once your dose reduction is complete, you will then return for follow-up visits.

For the duration of treatment and during the ECP and itacitinib tapers, immune suppression used for GVHD prophylaxis will be continued at the dose determined by your study doctor.

You will come to the clinic on the first day of each cycle. During the first cycle, you will have an additional visit on day 15. At each of these visits, you will have various procedures completed. Some of the procedures will be done as part of your standard care. Some will be done because you are participating in this study.

If you experience any changes in your body or develop any new or worsening side effects during or after the study treatments, you should inform your study doctor or study staff immediately.

Your study doctor will give you more information about your treatment plan.

Procedures during the Treatment Period:

While receiving treatment, you will have the following procedures performed at each of your clinic visits:

- Your study team will ask about any changes in medications that you are taking and changes in how you are feeling to check for potential side effects.
- A physical exam and a measure of your vital signs and weight.
- Blood drawn for standard lab testing to check your health
- An evaluation of your ability to perform everyday activities (performance status).

- An assessment of your chronic GVHD and your symptoms.
- Infection monitoring
- Monitoring for evidence of disease relapse or recurrence
- You will be asked to complete the study questionnaires asking about your symptoms, mobility, your health and how you feel.
- The 2-minute walk test.

In addition, you will have the below procedures performed on Day 1 of cycle 4, cycle 7 and cycle 10:

- Spirometry testing to evaluate your lungs.
- Blood drawn for cholesterol testing and immune status

In part 2 of the study you may also have additional blood drawn for research testing, including genetic testing, on the below procedures performed on Day 1 of cycle 1, at the time of response, and at cycle 7 or at progression of disease.

You will continue on the study treatment as described above unless your disease gets worse, you have intolerable side effects, you decide to stop, your doctor decides it would be in your best interest to stop, or the study ends.

Progressive Disease Visit

At any time, including in follow-up, if you are found to have progression of your disease, the following procedures will be performed:

- Your study team will ask about any changes in medications that you are taking and changes in how you are feeling to check for potential side effects.
- A physical exam and a measure of your vital signs and weight.
- Blood drawn for standard lab testing to check your health. These tests include testing for cholesterol level and immune status.
- Blood drawn to evaluate your disease.
- An evaluation of your ability to perform everyday activities (performance status).
- Spirometry test to evaluate your lungs.
- The 2-minute walk test.
- Monitoring for infection.
- An assessment of your chronic GVHD and your symptoms.
- Monitoring for evidence of disease relapse or recurrence.
- You will be asked to complete the study questionnaires asking about your symptoms, mobility, your health, and how you feel.
- Blood drawn for additional testing, including genetic testing, related to this study.

End of Treatment (EOT)

About 30 days after you stop taking itacitinib you will return to clinic for an end of treatment visit.

During this visit, the below procedures will be performed:

- The study team will collect your demographic information including change in residence, annual income, insurance type, and employment status.
- Your study team will ask about any changes in medications that you are taking and changes in how you are feeling to check for potential side effects.
- A physical exam and a measure of your vital signs and weight.
- Blood drawn for standard lab testing to check your health. These tests include testing for cholesterol and immune status.
- Blood drawn to evaluate your disease.
- An evaluation of your ability to perform everyday activities (performance status).
- An ECG (Electrocardiogram) to check your heart function.
- Spirometry testing to evaluate your lungs.
- The 2-minute walk test.
- Monitoring for infection.
- An assessment of your chronic GVHD and your symptoms.
- Monitoring for evidence of disease relapse or recurrence.
- You will be asked to complete the study questionnaires asking about your symptoms, mobility, your health, and how you feel.
- Blood drawn for additional testing, including genetic testing, related to this study.

Follow-up

You will return to clinic for follow-up visits every 12 weeks after your removal from study treatment for up to 12 months.

At these visits the following procedures will be performed:

- A physical exam and a measure of your vital signs and weight.
- Blood drawn for standard lab testing to check your health.
- An assessment of your chronic GVHD and your symptoms.
- The 2-minute walk test.

RISKS

You may have side effects from the drugs or procedures used in this study. Side effects can vary from mild to very serious and may vary from person to person. Everyone taking part in the study will be watched carefully for any side effects. However, the study doctor and other doctors do not know all of the side effects that could occur. Your study doctors may give you medications to help lessen side effects, and you may need to temporarily or permanently stop treatment. Many side effects go away soon after you stop what is causing them. In some cases, side effects can be serious and may be long lasting problems or may never go away. There also is a rare risk of death. You should talk to your study doctor about any side effects you have while taking part in the study.

Risks Related to itacitinib

Itacitinib may cause one or more of the side effects listed below. These effects were found in other studies that used itacitinib. Some of these effects were found when itacitinib was used in combination with other drugs and may not be exactly the same when itacitinib is used alone. These risks have been separated out below.

Risks found in a study where itacitinib was used alone:

Very Common (1 or more in 10 people may experience this side effect):

- Anemia
- Fever

Common (1 or more in 100 people may experience one or more of these side effects):

- Headache

Risks found in studies where itacitinib was used in combination with other treatments:

Very Common (1 or more in 10 people may experience this side effect):

- Anemia
- Neutropenia (low levels of infection fighting cells)
- Pneumonia
- Fever
- Thrombocytopenia/platelet count decreased (low levels of platelets, the blood clotting cells)
- ALT increased (liver test abnormality)
- AST increased (liver test abnormality)
- Fatigue
- Nausea
- Vomiting
- Cough
- Diarrhea

Common (1 or more in 100 people may experience one or more of these side effects):

- Sepsis (when a body has a systemic response to an infection)
- Rash
- Rash, maculo-papular type (type of rash typically defined by a flat, red area covered in small bumps)
- Colitis (inflammation of the colon that may lead to stomach pain, cramping, and diarrhea)

Risks of ECP

Risks of ECP include those from the use of IV or catheter use. You may have pain, bruising, bleeding or infection at the insertion site.

As part of the ECP treatment you may possibly experience:

- Decreased red blood cell count
- Decreased platelet count
- Loss of taste
- Low blood pressure
- Weakness or lack of energy or strength
- Fatigue
- Fever
- Vomiting

Reports of rare side effects include:

- Rash
- Allergic reaction
- Nausea

ECP treatments may increase your risk for thromboembolic events (blood clots). Symptoms of blood clots may include:

- Shortness of breath
- Cough
- Chest pain
- Fever
- Cyanosis (blue discoloration of the skin)
- Leg pain (with or without swelling)
- Dizziness
- Irregular heartbeat.

If you develop any of these symptoms immediately seek urgent medical attention at the nearest emergency room.

Your eyes and skin may also be more sensitive to sunlight for the 24 hours after your treatment. After treatment follow the directions regarding sun protection as listed earlier in this consent.

Risks of blood draws or IV

Risks associated with a blood draw or IV include pain, bruising, bleeding, infection, or fainting. Every effort will be made to prevent these.

Risks of HIV Testing

A positive HIV test result may cause you significant anxiety. A positive test may result in un-insurability for life, health, or disability insurance policies for which you may apply in the future. Although prohibited by law, discrimination in housing, employment, or public accommodations may result from

disclosure of a positive test result. The HIV test and the test results are confidential, except where you have authorized disclosure or where the disclosure is otherwise required or permitted by law.

Genetic Risks and Loss of Confidentiality

Although all reasonable and appropriate steps will be taken to maintain the confidentiality of your identifiable health information, there is always a possibility that your identifiable health information will be disclosed accidentally. Personal, private information about you will be protected against disclosure to other family members, but you should be aware that accidental disclosure of genetic information can have implications for a relative. Results could affect relationships with family, friends, or acquaintances and also may affect employment and/or insurance.

Other Risks

There are also non-physical risks associated with taking part in this study, such as the risks associated with a breach of privacy or confidentiality. The risks of such improper disclosure are very small because Huntsman Cancer Institute has adopted strict privacy and confidentiality procedures for this research.

REPRODUCTIVE RISKS

You should not become pregnant while you are in this study because the drugs in this study may affect an unborn baby. You also may not breastfeed while on this study.

If you are a female who can become pregnant, you will have a pregnancy test done prior to starting on study treatment. You must also agree to use highly effective birth control while participating in this study and for 30 days after the last dose of itacitinib. Examples of medically acceptable birth control include hormonal contraceptives (oral pills or implants), medically prescribed IUDs, and double barrier methods, e.g., condom with spermicide. Check with your study doctor about what kind of birth control methods to use. Some methods may not be approved for use in this study.

If you are a male who is sexually active, you must agree to use highly effective birth control while taking study treatment and for 30 days after the last dose of itacitinib.

If you think that you or your partner may be pregnant, at any time while on this study, inform your study doctor immediately.

UNFORESEEABLE RISKS

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

BENEFITS

It is hoped that the patients in this trial will benefit from this treatment, however we cannot guarantee or promise that you will receive any benefits from this research. The study drug may or may not help treat your chronic GVHD. It is possible that you will receive no direct health benefit from being in this study.

It is hoped that the information learned from this study may help future patients with chronic GVHD. This research may give rise to new or improved drug treatments.

ALTERNATIVE PROCEDURES

You do not have to be in this study to get help for your chronic GVHD. You may choose not to take part in this study and discuss other treatment options, and their related benefits and risks, with your study doctor.

Some other things you might do are:

- Use Standard of Care treatment only.
- Use other investigational treatments.
- Get supportive care.
- Choose to have no further treatment.

PERSON TO CONTACT

If you have questions, complaints, or concerns about this study, you can contact Dr. Lee at 801-585-0255. If you think you may have been injured from being in this study, please call Dr. Lee at 801-585-0255. Dr. Lee is available Monday-Friday from 8:00am-5:00pm. The University Hospital Operator can be reached at this number: 801-581-2121 available 24-hours a day. Please ask for the hematologist/oncologist on call.

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

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

RESEARCH-RELATED INJURY

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

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

VOLUNTARY PARTICIPATION

Taking part in this research study is voluntary. You may decide not to take part or you may leave the study at any time. Refusal to take part or the decision to withdraw from this study will involve no penalty or loss of benefits to which you are otherwise entitled.

Tell the study doctor if you are thinking about stopping or decide to stop, as it may be necessary to do certain tests in order to ensure your safety. If you choose not to return for an assessment, we may ask for medical records from your current general practitioner in order to continue to monitor your health.

If you decide not to continue in the study at any time, your study doctor will arrange for you to receive alternative treatment and any necessary assessments or procedures according to standard of care.

RIGHT OF INVESTIGATOR TO WITHDRAW

Your study doctor may decide to take you off this study at any time without your consent for any of the following reasons:

- if your disease becomes worse,
- if he or she believes it is in your best interest,
- if you do not follow the study rules,
- if you miss study visits and/or procedures,
- or if you have serious side effects

There is also the possibility that the investigator may close the study before your participation is complete and without prior warning. If any of these events were to happen, your study doctor would assist with arrangements for your continued care as appropriate.

COSTS AND COMPENSATION TO PARTICIPANTS

Some of the procedures and treatments you'll have while you are on the study are considered "standard of care" for your type of illness. Even though you will be a part of the study, these types of procedures and treatments will be billed to you and/or your insurance company just like regular medical care. Some procedures you'll have while you are on the study are considered "study related" and are not billed to you and your insurance company. You should ask your study coordinator and treating physician for details about the specific procedures for which you or your insurance company will be financially responsible.
You may be eligible for assistance with costs associated with travel for purposes of research participation. Please speak with your study coordinator or physician for details. If eligible, you may be asked to provide receipts in order to receive reimbursement. It will be necessary for us to collect your Social Security Number for your reimbursement. You will need to provide this information on a Federal W-9 Form that is filed with our accounts payable department. No other information (e.g., the name of this study) will be provided to that office. This amount will not be reported to the Internal Revenue Service (IRS).

The study drug, itacitinib, will be provided to you free of charge in this study.

NEW INFORMATION

You will be given any new information about the study treatments that may affect your willingness to start or continue in the study as it becomes available.

During the study, we may learn something about your health that could help you and your doctors make decisions about your healthcare. If this happens, we will tell you about these results. We will contact you and make arrangements to discuss this with you.

NUMBER OF PARTICIPANTS

We expect to enroll up to 9-18 participants in Part 1 of this study and an additional 40 participants in Part 2.

AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION

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

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

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

How we will protect and share your information:

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

- A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This 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.

- In order to conduct this study and make sure it is conducted as described in this form, the research records may be used and reviewed by others who are working with us on this research:
  - Members of the research team and the University of Utah Health Sciences Center;
  - The University of Utah Institutional Review Board (IRB), who reviews research involving people to make sure the study protects your rights;
  - Incyte Corporation and their affiliates

- Government agencies responsible to confirm research accuracy, such as the United States Food and Drug Administration (FDA).
- Governmental agencies in other countries where the study drug may be considered for approval.

- If we share your identifying information with groups outside of the University of Utah Health Sciences Center, they may not be required to follow the same federal privacy laws that we follow. They may also share your information again with others not described in this form.

- In the United States, the Genetic Information Nondiscrimination Act of 2008 (GINA) prohibits discrimination in health coverage and employment based on genetic information. GINA, together with the Health Insurance Portability and Accountability Act (HIPAA), generally prohibits health insurers or health plan administrators from requesting or requiring genetic information of an individual or the individual's family members, or using it for decisions regarding coverage, rates, or preexisting conditions. The law also prohibits most employers from using genetic information for hiring, firing, or promotion decisions, and for any decisions regarding terms of employment. Utah State Law also offers protection against discrimination in health coverage and employment. The Affordable Care Act (ACA) prohibits discrimination in health insurance based on pre-existing conditions. This law provides substantial protection for individuals with genetic conditions or who are at risk of future health conditions based on genetic test results.

- All positive contagious diseases, such as HIV, hepatitis B, and hepatitis C tests must be reported to the Utah State Health Department. The State and Local Health Departments have established procedures for contacting individuals who have had contact with persons testing positive for communicable diseases. Your partner(s) will be notified. If your test is positive, you will not be eligible for this study. The follow-up to a positive test will be done according to standard procedures. The results will be securely stored in a locked filed cabinet, accessible only to the investigator and other authorized people.

- If you do not want us to use information about your health, you should not be part of this research. If you choose not to participate, you can still receive health care services at the University of Utah Health Sciences Center.

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

This authorization does not have an expiration date.

You have a right to information used to make decisions about your health care. However, your information from this study will not be available during the study; it will be available after the study is finished.

CONSENT

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

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

_____
Participant's Name

_____ _____ _____
Participant's Signature Date Time

_____
Name of Person Obtaining Authorization and Consent

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

LANGUAGE INTERPRETER STATEMENT (if applicable):

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

_____ _____ _____
Name of Interpreter Signature of Interpreter Date

Information requested for federal grant reporting purposes *(optional)*

Sex/Gender

- ❑ **Male**
- ❑ **Female**

Ethnicity

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

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

Select one:

- ❑ **Hispanic or Latino**
- ❑ **Not Hispanic or Latino**

Race

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

- ❑ **American Indian or Alaska Native.** A person having origins in any of the original peoples of North America (including Central or South America) who maintains cultural identification through tribal affiliation or community recognition.
- ❑ **Asian.** A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent, including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.
- ❑ **Black or African American.** A person having origins in any of the black racial groups of Africa.
- ❑ **Native Hawaiian or other Pacific Islander.** A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.
- ❑ **White.** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.
- ❑ **Unknown.**

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

Initial and Date