Study Title for Participants: Collection of research data and samples from patients who experience immunotherapy side effects

Official Study Title for Internet Search on http://www.ClinicalTrials.gov: Alliance A151804 Establishment of a national biorepository to advance studies of immune-related adverse events **(NCT #04242095)**

Overview and Key Information

What am I being asked to do?

We are asking you to take part in a research study. This study has public funding from the National Cancer Institute (NCI), part of the National Institutes of Health (NIH) in the United States Department of Health and Human Services. We do research studies to try to answer questions about how to prevent, diagnose, and treat diseases like cancer.

We are asking you to take part in this research study because you are receiving a type of cancer treatment called immunotherapy and you have experienced an immunotherapy-related side effect.

Most patients tolerate immunotherapy well. However, patients sometimes experience uncommon but serious side effects due to these treatments. Researchers would like to understand better how to predict, prevent, and treat these side effects. We are collecting clinical data and samples from patients who receive immunotherapy and experience one or more serious side effects. We would like permission to collect your data and samples and store them for use in future research studies. This is called "biobanking."

Taking part in this study is your choice.

You can choose to take part or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

This document has important information to help you make your choice. Take time to read it. Talk to your doctor, family, or friends about the risks and benefits of taking part in the study. It's important that you have as much information as you need and that all your questions are answered. See the "Where can I get more information?" section for resources for more clinical trials and general cancer information.

This study is conducted by the Alliance for Clinical Trials in Oncology, a national clinical research group supported by the National Cancer Institute. The Alliance is made up of cancer doctors, health professionals, and laboratory researchers, whose goal is to develop better treatments for cancer, to prevent cancer, to reduce side effects from cancer, and to improve the quality of life of cancer patients.

Why is this study being done?

This study is being done to answer the following questions:

Why do some patients experience serious side effects from immunotherapies, and why do other patients not experience these side effects? How can we identify these patients and prevent, reduce and treat these side effects more effectively?

To answer these questions, it is helpful to have clinical data and samples collected from patients who have experienced these side effects from immunotherapy. For example, by studying blood samples collected after side effects occur, researchers can look for markers that may predict whether a patient is more likely than usual to experience these side effects.

What is the usual approach to follow-up of immunotherapy side effects?

Clinical data and samples are collected for research studies or sometimes as part of usual cancer treatment. However, the data and samples from patients who are receiving immunotherapy and experience related side effects are not usually collected together in a standardized way for research purposes to study these side effects.

What are my choices if I decide not to take part in this study?

- You may choose to have the usual approach described above.
- You may choose to take part in a different research study, if one is available.

What will happen if I decide to take part in this study?

If you decide to take part in this study, you will be giving permission for researchers to collect samples and data within 7 days after you experience an immunotherapy-related side effect and again one month after the side effect occurred. We will collect images of any pathology slides made to diagnose the side effect. If you experience a side effect called hyperprogression or one called pneumonitis, your scans will also be sent to a central image library for review. If you experience a side effect called dermatitis, photos of your skin (not including your face) will be sent in with your clinical data for review. You will be followed for one year after the time that the side effect took place.

What are the risks and benefits of taking part in this study?

There are both risks and benefits to taking part in this study. It is important for you to think carefully about these as you make your decision.

Risks

We want to make sure you know about a few key risks right now. We give you more information in the “What risks can I expect from taking part in this study?” section.

If you choose to take part in this study, there are the standard risks associated with obtaining blood samples, such as pain and bruising.

There may be some risks that the study doctors do not yet know about.

Benefits

This study is not likely to help you. However, it may help the study doctors understand how immunotherapy drugs cause side effects and how to diagnose and treat them. This study may help the study doctors learn things that may help other people in the future.

If I decide to take part in this study, can I stop later?

Yes, you can decide to stop taking part in the study at any time.

If you decide to stop, let your study doctor know as soon as possible.

Your 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.

Are there other reasons why I might stop being in the study?

Yes. The study doctor may take you off the study if:

- Your health changes and the study is no longer in your best interest.
- New information becomes available and the study is no longer in your best interest.
- The study is stopped by the National Cancer Institute (NCI), Institutional Review Board (IRB), Food and Drug Administration (FDA), or study sponsor (Alliance). The study sponsor is the organization who oversees the study.

It is important that you understand the information in the informed consent before making your decision. Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask your study doctor or nurse.

What is the purpose of this study?

The purpose of this study is to develop a national biobank of samples and data about patients who experience side effects when they take immunotherapy drugs for their cancer. We want to find out why some people experience side effects and why others do not. We also want to learn more about how to diagnose and treat these side effects more effectively. There will be about 240 people taking part in this study.

More information about biobanking is included in the "Biobanking" section below.

What are the study groups?

All patients participating in this study are receiving immunotherapy for their cancer. Patients may be enrolled to this study after experiencing one or more side effects.

You will be registered to this study and then asked to provide the following samples within 7 days, and then again after 1 month:

- A small amount of tissue that might have been or may be collected from biopsies that are done for the purpose of your other study treatment or to diagnose the side effect, and/or slides or images made from this tissue for diagnostic purposes,
- A blood sample (about 5 ½ tablespoons each time), and
- An optional stool sample, if you experience a side effect affecting your bowels. You will be asked whether you agree to provide stool samples in a separate question later.

If you experience a side effect called hyperprogression or one called pneumonitis, your scans will also be sent to a central image library. This will include scans taken prior to enrolling in this study, at the time that you enroll to this study, and one month after enrollment.

If you experience a side effect called dermatitis, photos of your skin will be sent in with your clinical data. This will include photos taken at the time that you enroll to this study, and one month after enrollment. A member of your care team or designated medical photographer will take the photos. Your face will not be captured on these photographs. These photographs will not include your name or other personal information and will be saved in the Alliance database.

In addition, the study doctors will collect information about your health and your treatment for one year after you enroll on the study.

Your study doctor will also send the researchers some of the tissue left over from your biopsy that would have already been performed to diagnose your cancer.

Another way to find out what will happen to you during this study is to read the chart below. Start reading at the left side and read across to the right, following the lines and arrows.

		Within 1 to 7 days after registration	Within 4 weeks after registration
You experience certain immunotherapy drug-related side effects →	**You agree to take part in this biobanking study: Registration** →	Collection of samples and data	Collection of samples and data

What exams, tests, and procedures are involved in this study?

Other than providing samples and data for the biobank as described above, you will have no other tests or procedures for this study. A description of what is involved with biobanking is included here.

Biobanking

Researchers are trying to learn more about cancer and other health problems using blood and tissue samples from people who take part in clinical trials. By studying these samples, researchers hope to find new ways to prevent, detect, treat, or cure diseases.

Also, any health-related information, such as your response to cancer treatment, results of study tests, and medicines you took, will be stored for future use.

Some of these studies may be about how genes affect health and disease. Other studies may look at how genes affect a person's response to treatment. Genes carry information about traits that are found in you and your family. Examples of traits are the color of your eyes, having curly or straight hair, and certain health conditions that are passed down in families. Some of the studies may lead to new products, such as drugs or tests for diseases.

Storing samples for future studies is called "biobanking." The biobank is being run by Alliance for Clinical Trials in Oncology and is supported by the NCI. This is a publicly funded study. Samples from publicly funded studies are required to be shared as broadly as possible. However, we will protect your privacy. The goal of this is to make more research possible that may improve people's health.

The biobank is a public research resource. It has controlled access. This means that researchers who want to get samples and data from it must submit a specific research request. The request identifies who they are and what their planned research project is. Before getting the samples and data, the researchers must agree to keep the data private, only use it for their planned research project, and never use it to try to identify you.

Right now, we do not know what research may be done in the future using your samples. This means that:

- You will not be asked if you agree to take part in the future research studies.
- You and your study doctor will not be told when or what type of research will be done.
- You will not get reports or other information about any research that is done using your samples.

Unknown future research studies may include sequencing of all or part of your DNA. This is called genomic sequencing. Sequencing allows researchers to identify your genetic code. Changes in your genetic code may just be in your tumor tissue. These are called somatic changes. Changes may also be in your normal tissue and passed down through your family.

For example, these genetic changes may be passed down to your children in the same way that eye and hair color are passed down. These are called germline changes.

If only tumor tissue is sequenced, we will not know if a genetic change in your tumor is also in your normal tissue. This is why sometimes both normal tissue and tumor tissue are sequenced. This helps researchers understand if a genetic change happened only in your cancer tissue, or in your normal tissue as well.

Finding these changes would not affect your treatment. However, they could affect your health in other ways. Results will not be routinely returned to you, however if changes are found that could cause health problems, then your study doctor may discuss the results and your options with you, such as additional confirmatory testing or genetic counseling, unless you choose not to receive this information at the time your study doctor notifies you of the results.

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

General Risks

If you choose to take part in this study, there is a risk that there may be pain, discomfort or bruising in the part of the body from where the blood is collected.

- The most common risks related to drawing blood from your arm are brief pain and maybe a bruise.
- Your medical and genetic information are unique to you. There is a risk that someone outside of the research study could get access to your study records or trace information in a database back to you. They could use that information in a way that could harm you. Researchers believe the chance that someone could access and misuse your information is very small. However, the risk may increase in the future as people find 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 and get or keep health or life insurance. There are laws against the misuse of genetic information, but they may not give full protection. For more information about the laws that protect you, ask your study doctor or visit: https://www.genome.gov/10002328/

This study may also use samples of your biopsied tissues. Generally, your hospital will keep some of your tissues. These tissues may be used to help treat your cancer in the future. Because this study will need to use some of this tissue, there is a small risk that it could be used up.

You also may have the following discomforts:

- Spend more time in the hospital or doctor's office.
- Be asked sensitive or private questions about things you normally do not discuss.
- May not be able to take part in future studies.

Genetic Testing Risks

Researchers may test your tumor and/or normal tissue for one or more genetic changes. If genetic changes are found in the tumor, tests may be needed to determine whether they are also present in your normal tissue. Changes found in your normal tissue may be passed down in families. For example, these genetic changes may be passed down to your children in the same way that eye and hair color are passed down.

Genetic tests of normal tissue including blood can reveal information about you and also about your relatives. Your study doctor will talk with you about what testing your normal tissue may mean for you and your family. He or she also may suggest that you talk with a genetics counselor to learn more. You or your insurance plan would have to pay for any genetic tests and visits to a genetic counselor done outside of this study.

Biopsy Risks

The study will collect samples of tissues from biopsies obtained as part of other studies you are on or as part of your usual care. Common side effects of a biopsy are a small amount of bleeding at the time of the procedure, bruising, and pain at the biopsy site. Pain can be treated with regular pain medications. Rarely, an infection can occur. You may sign a separate consent form for a biopsy that describes the risks in more detail.

Stool Collection Risks

If you agree to provide a stool sample, this may be a burden to you, but there are no additional risks associated with collecting the sample.

What are my responsibilities in this study?

If you choose to take part in this study you will need to:

- Keep your study appointments.
- Tell your doctor about:
    - all medications and supplements you are taking
    - any side effects
    - any doctors' visits or hospital stays outside of this study
    - if you have been or are currently in another research study.

What are the costs of taking part in this study?

You and/or your insurance provider will not have to pay for exams, tests, and procedures done for research purposes only or that are covered by the study. These include:

- Blood draws
- Tissue Samples
- Stool collection (if you agree)

Taking part in this study may mean that you need to make more visits to the clinic or hospital than if you were getting the usual approach to treat your cancer. You may:

- Have more travel costs.
- Need to take more time off work.
- Have other additional personal costs.

You will not be paid for taking part in this study. The research may lead to new tests, drugs, or other products for sale. If it does, you will not get any payment.

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

If you are injured as a result of taking part in this study and need medical treatment, please talk with your study doctor right away about your treatment options. Contact information for your study doctor is listed on the consent cover page. The study sponsors will not pay for medical treatment for injury. Your insurance company may not be willing to pay for a study-related injury. Ask them if they will pay. If you do not have insurance, then you would need to pay for these medical costs.

If you feel this injury was caused by medical error on the part of the study doctors or others involved in the study, you have the legal right to seek payment, even though you are in a study. Agreeing to take part in this study does not mean you give up these rights.

No funds have been set aside to compensate you in the event of injury.

Who will see my medical information?

Your privacy is very important to us. The study doctors will make every effort to protect it. The study doctors have a privacy permit to help protect your records if there is a court case. However, some of your medical information may be given out if required by law. If this should happen, the study doctors will do their best to make sure that any information that goes out to others will not identify who you are.

Some of your health information, such as your response to cancer treatment, results of study tests, and medicines you took, will be kept by the study sponsor in a central research database. However, your name and contact information will not be put in the database. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

There are organizations that may look at or receive copies of some of the information in your study records. Your health information in the research database also may be shared with these organizations. They must keep your information private, unless required by law to give it to another group.

Some of these organizations are:

- Montana Cancer Consortium
- The study sponsor, the Alliance for Clinical Trials in Oncology.

- The NCI Central IRB, which is a group of people who review the research with the goal of protecting the people who take part in the study.
- The NCI and the groups it works with to review research.
- The NCI's National Clinical Trials Network and the groups it works with to conduct research, including the Imaging and Radiation Oncology Core (IROC).

In addition to storing data in the study database, data from studies that are publicly funded may also be shared broadly for future research with protections for your privacy. The goal of this data sharing is to make more research possible that may improve people's health. Your study records may be stored and shared for future use in public databases. However, your name and other personal information will not be used.

Some types of future research may include looking at your information and information from other patients to see who had side effects across many studies or comparing new study data with older study data. However, right now we don't know what research may be done in the future using your information. This means that:

- You will not be asked if you agree to take part in the specific future research studies using your health information.
- You and your study doctor will not be told when or what type of research will be done.
- You will not get reports or other information about any research that is done using your information.

There are laws that protect your genetic information. However, there is a risk that someone could get access to your genetic information and identify you by name. In some cases, employers could use your genetic information to decide whether to hire or fire you. The study doctors believe the risk of this happening is very small. However, the risk may increase in the future as people find new ways of tracing information. For more information about the laws that protect you, ask your study doctor.

Where can I get more information?

You may visit the NCI web site at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

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.

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact information for your study doctor is listed on the consent cover page.

For questions about your rights while in this study, call the Operations Office of the National Cancer Institute (NCI) Central Institutional Review Board (CIRB) at 888-657-3711.

How will information about me be kept private?

Your privacy is very important to the study researchers and the Biobank. They will make every effort to protect it. Here are just a few of the steps they will take:

1. They will remove identifiers, such as your initials, from your sample and information. They will replace them with a code number. There will be a master list linking the code numbers to names, but they will keep it separate from the samples and information.
2. Researchers who study your sample and information will not know who you are. They also must agree that they will not try to find out who you are.
3. Your personal information will not be given to anyone unless it is required by law.
4. If research results are published, your name and other personal information will not be used.

What if I change my mind about this sample collection?

If you decide you no longer want your samples to be used, you can call the study doctor, who will let the biobank know. Contact information for your study doctor is listed on the consent cover page. Then, any sample that remains in the Biobank will be destroyed or returned to your study doctor. This will not apply to any samples or related health information that have already been given to or used by researchers.

What if I have questions about this sample collection?

If you have questions about the use of your samples for research, contact the study doctor. Contact information for your study doctor is listed on the consent cover page.

Optional studies that you can choose to take part in

This part of the consent form is about optional studies that you can choose to take part in. They are separate from the main study described above. These optional studies will not benefit your health. The researchers leading this study hope the results will help other people with cancer in the future. The results will not be added to your medical records and you or your study doctor will not know the results.

Taking part in this optional study is your choice. You can still take part in the main study even if you say "no" to this study. There is no penalty for saying "no." You and your insurance company will not be billed for this optional study. If you sign up for, but cannot complete this study for any reason, you can still take part in the main study.

Circle your choice of "yes" or "no" for the following study.

Optional stool collection

If you experience a specific side effect affecting your bowels and if you agree below, you will be asked to provide stool samples. You will be given a kit for collecting these samples. This may be a burden to you, but there are no additional risks associated with collecting the sample.

You and/or your insurance provider will not have to pay for the stool collection kit.

Please circle your answer below to show if you would or would not like to take part in this part of the study:

I agree that my stool samples and related health information may be kept in a biobank for use in future health research.

YES NO

Contact for Future Research

I agree that my study doctor, or someone on the study team, may contact me or my doctor to see if I wish to participate in other research in the future.

YES NO

This is the end of the section about optional studies.

My signature agreeing to take part in the study

I have read this consent form or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed and dated copy of this form. I agree to take part in the main study.

Participant Signature: _____

Date: _____

Signature of Person Obtaining Consent: _____

Date: _____

Time of consent: _____ (AM) (PM)
(Required for initial consent only)