MODEL INFORMED CONSENT DOCUMENT

Protocol AMC-083: Tissue Acquisition for Analysis of Prognostic Factors, Immunology, and Genetic Progression of HIV-Associated Malignancies

Principal Investigator: _____

Research Team Contact: _____

This is a clinical trial (a type of research study). Clinical trials only include people who choose to take part. Before you decide to be a part of this research study, we will explain the risks and benefits so that you can make an informed decision. This is known as informed consent. This consent form describes the research study to help you decide if you want to take part. It tells you about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research participant. By signing this form, you are agreeing to participate in this study.

- Your decision to take part in the study is voluntary. This means that you are free to choose if you will take part in the study.
- Please take your time to ask questions and make your decision. If you have any questions, ask the research team for more information.
- You may also talk to your family or friends about taking part in this study.
- Do not sign this informed consent form unless the research team has answered your questions. You should only sign the form if you decide that you want to take part in this study.

WHAT IS THE PURPOSE OF THIS STUDY?

We are asking you to take part in this research study because you are diagnosed with human immunodeficiency virus (HIV), the virus that causes AIDS. You also have a diagnosis of a HIV-associated malignancy (cancer) or symptoms that suggest you may have a HIV-associated cancer.

The purpose of this research study is to collect tissue from people diagnosed with HIV-associated cancer. We will use these samples to look for genetic changes associated with HIV- and other virus-related cancers. We will do this by mapping out your DNA sequence and looking at DNA changes that occur in your tissue. This may lead to better ways of preventing, detecting, and treating HIV-associated cancers. It may also help us learn about other diseases.

WHAT WILL HAPPEN DURING THIS STUDY?

Body tissues are made up of cells. Cells contain DNA. DNA is unique genetic material that carries the instructions for your body's development and function. DNA can be sequenced so that your exact genetic code can be mapped out. Using this technique, we can find changes to your DNA sequence. We are looking for DNA changes that could be related to virus-associated cancer or pre-cancer conditions.

In this study, we will compare DNA from tumor tissue to DNA from normal tissue to find any differences. We will also look for relationships between the genetic information and participants' health information. The study findings may help us learn more about how to personalize treatment for virus-associated cancers or pre-cancer conditions in the future.

If you agree to take part in this study, you will give a blood sample and a tumor tissue sample. We will draw about 2 teaspoons of blood from a vein in your arm. We may ask to draw another blood sample at a later date. We will collect the sample(s) at the same time we draw blood for routine medical treatment. We will collect a small piece of your tumor tissue when we take a biopsy for your medical treatment. If there is extra tissue from an earlier biopsy that we can use for this study, we will use a small piece of that tissue. Giving tumor tissue for this research will not add to your surgery time or add any extra procedures. We will send your tissue back if your doctors need it to run more tests for your medical treatment.

We will send your samples to the laboratory. We will remove all information from your samples that could identify you and replace it with a unique patient number (UPN) and sample number. We will freeze the samples and store them for genetic sequencing (described in more detail below). To protect your privacy, all samples will only be identified by the UPN and sample number.

Collection of Health Information

In addition to the tissue and blood samples, we will also collect health information from your medical record. This will include your medical history, including your HIV diagnosis and medications, findings from recent physical exams, and laboratory test results. We will also collect information about your cancer treatments and how they are working. Only members of the study team will review your records to collect this information. We will review your records when you start the study. We will review your medical records again at 1 and 2 years after you start the study.

Storage and Release of Samples and Medical Information for Genetic Research

Your coded blood and tumor samples will be processed at the laboratory. We will send portions of your samples to different laboratories for this project.

One lab will look at your tumor tissue to confirm your cancer diagnosis. If we find that your samples do not have enough cancer cells, we will not use your samples for this study. If you give your permission, we will send your leftover study samples to the AIDS and Cancer Specimen Resource (ACSR) for future research studies (explained on page ___). We will destroy your samples if they cannot be used for this study and you do not want to donate them to the ACSR. We will not keep your health information for this research study if your samples cannot be used.

Another laboratory will sequence your DNA. This means we will map out your complete DNA sequence for this analysis. We will also compare the number and order of DNA changes in your tumor samples to normal tissue samples. This means we may map out and analyze the DNA changes related to your tumor.

We will share our findings from DNA sequencing with other researchers. These researchers may study genome sequencing, virus-associated cancer research, or other diseases. These researchers may be at the university or other centers. We may also share your data with large data repositories. A repository is a database of information for broad sharing with the research community. If we put your individual DNA sequence in one of these repositories, we will not include your name or any other information that identifies you. Only qualified researchers who get approval for using the data for other research studies may see your information.

We will not give you any results from the genetic analysis. This is because it may take several years to review the data and find which DNA changes are important for detecting, preventing, or treating cancer. We will tell you if we find that you have a communicable (transmissible) disease that we are legally required to report. However, we do not plan to run any tests for communicable diseases at this time.

HOW MANY PEOPLE WILL PARTICIPATE?

We plan to enroll up to 200 people with HIV and certain types of cancer in this study. Approximately __ people will take part in this study at _____.

HOW LONG WILL I BE IN THIS STUDY?

You will be in this study for up to two years. During these two years, we will review your office visit notes to document your health status.

We may stop your participation in the study early if the research team cannot contact you or your physician. You may also ask to stop the study early at any time (withdraw your consent). If you do withdraw your consent, we will destroy your samples and we will not collect any more of your health information. However, the research team will continue to use any data that we already collected. We cannot withdraw any data shared in online databases.

WHAT ARE THE RISKS OF THIS STUDY?

If you take part in the study, you may experience one or more of the risks described below. There may be other unknown risks or risks that we did not expect.

<u>Risks Associated with Loss of Privacy and Confidentiality</u>

Your privacy is very important to us. We will use many safety measures to protect your privacy. However, we cannot guarantee that links between you and your genetic and health information will never become known.

Although your genetic information is unique to you, you do share some genetic information with your children, parents, siblings, and other relatives. It is possible that your relatives' genetic information could be used to try to identify your sample. Similarly, it is possible that your genetic information could be used to help identify them.

The online databases for this project will NOT contain information that is usually used to identify you. However, in the future people may develop ways that would allow someone to link the genetic or medical information in these databases back to you. For example, someone could compare information in one of these databases with information from you (or a relative) in another database and be able to identify you (or your relative). It is also possible that there could be violations in the security of the computer system used to store the codes linking your genetic and medical information to you.

Some genetic variations can help to predict future health problems you and/or your relatives may have, like a genetic disease. Employers, health providers, insurance companies, and others could be interested in this information. Law enforcement agencies can use genetic information to identify a person or his/her relatives. Therefore, your genetic information potentially could be used in ways that could cause you or your family distress. We emphasize that we will do everything we can to protect your privacy.

A new federal law called the Genetic Information Nondiscrimination Act (GINA) makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This means that:

- Health insurance companies and group health plans may not request the genetic information that we get from this research.
- 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 the genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

This new federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

There may also be other privacy risks that we have not foreseen.

Risks of Blood Drawing and Tumor or Lymph Node Biopsy

- **Likely:** Discomfort, swelling, bruising, and/or bleeding at the site of the needle insertion.
- **Less likely:** Dizziness or feeling faint.
- **Rare:** Infection (symptoms may include fever, shaking, chills, fatigue, confusion, joint aches, or rapid pulse).

WHAT ARE THE BENEFITS OF THIS STUDY?

You will not get any direct benefit from being in this study. However, we hope that other people might benefit from this study in the future. The study may help research and health professionals around the world to better understand the causes of virus-associated cancers and other diseases. The study may help them find better ways to prevent, detect, treat, and cure such illnesses.

WHAT OTHER OPTIONS ARE THERE?

Before you decide to take part in this study, your doctor will discuss the other options. Because this study does not involve treatment, your only other option is not to participate.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

There are no additional costs to take part in this research study.

WILL I BE PAID FOR PARTICIPATING?

You will not be paid for taking part in this research study.

WHO IS FUNDING THIS STUDY?

The study is funded by the AIDS Malignancy Consortium (AMC). The AMC is a group of researchers who study cancer treatments for people who are HIV-positive. The AMC is sponsored by the National Institutes of Health.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

University investigators and staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact the investigator at __ and/or the Human Research Protection Office at _____.

You will get medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be billed for this treatment at the usual charge. No funds have been set aside to compensate you in the event of injury. In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

WILL YOU KEEP MY NAME ON FILE TO GIVE TO OTHERS?

We may want to call you in the future for more information or to see if you may want to take part in other studies. If you are called, you can decide if you want to be in any of the other studies and would sign another consent form to be in those studies. You are free to decide whether or not you want us to call you. Your decision about being called later for other studies will not change your being in this study. If you agree, we will keep your contact information after the study is over. A member of the research team will contact you first to ask you about taking part in other studies. We will not give your contact information to other researchers unless you are interested in taking part in another study. You may change your mind about us contacting you for other studies at any time by contacting Dr. __ at __.

I give you permission to contact me in the future about this or different research studies.

_____ Yes _____ No

Initials Initials

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

We will do our best to keep the personal information in your medical record private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, we will not use your name or any other personal information.
The following people and agencies may look at and/or copy your medical records for research, quality assurance, and data analysis.

- Government representatives, (including the Office for Human Research Protections) to complete federal or state responsibilities
- Your primary care physician if we find a medical condition that needs urgent attention
- Public health agencies to complete public health reporting requirements
- Hospital or University representatives, to complete Hospital or University responsibilities
- The [institution name] Institutional Review Board (a committee that reviews and approves research studies)

- Other researchers in other laboratories who study cancer or do other projects. These may be individual researchers at other institutions or researchers in a cooperative group.
- The NIH data repository, called the Database of Genotypes and Phenotypes (dbGaP). These are the open- and controlled-access online databases that can be found at **http://www.ncbi.nlm.nih.gov/gap**.

The Cancer Center at __ is supported by funding from the National Cancer Institute (NCI). To meet NCI requirements, we will store your all of your information in a secure database at the Cancer Center. Cancer center staff may review this database and your treatment records. All information will be secured to maintain your privacy.

We will not give identifying information such as your name, birth date, or social security number to researchers. Researchers who receive your health information or DNA sequence data will only have coded samples and data. The study team will keep the master code list that links your study records with your name and other identifying information in locked storage in a locked office (for paper copies) or on a secured network on a password-protected computer (for electronic copies). Access to either paper or electronic copies will be limited to the Principal Investigator (Dr. __), members of the study team, and members of the Tissue Bank.

This consent form and your other study records will be kept in your clinical medical record. Anyone with access to your medical record, including your health insurance company, will be able to see that you are in this research study.

Are there additional protections for my health information?

[Section may be replaced with local language or separate information sheets regarding HIPAA]

Protected Health Information (PHI) is health information that identifies you. PHI is protected by a federal law called HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study. The researchers may have to share your health information in some cases to follow state and federal laws. This includes sharing your health information with the agencies and people listed in the section titled, "How will you keep my information confidential?

Once we share your health information with someone outside of the research team, HIPAA protections may no longer apply.

The research team will only use and share your information as talked about in this form. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at __.

Although you will not be allowed to see the study information, you may contact your health care provider to ask for a copy of your health care records.

If you decide not to sign this form, it will not affect:

- Your treatment or the care from your health provider.
- Your insurance payment or enrollment in any health plans.

- Any of your regular benefits.

However, if you do not give your permission to use and share your health information, you cannot take part in the study.

If you sign this form:

- You authorize the use of your health information for this research.
- Your signature and this form will not expire as long as you wish to participate.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
    - To revoke your authorization, contact the Investigator at: [phone].
        - **If you revoke your authorization:**
            - The research team may only use and share information already collected for the study.
            - Your information may still be used and shared if necessary for safety reasons.
            - You will not be allowed to continue to participate in the study.

Certificate of Confidentiality

The NIH has given the AMC and ACSR a Certificate of Confidentiality. The Certificate does not mean that the NIH or the U.S. Government recommend that you take part in this study. This Certificate helps us keep your health information private.

Your records for this study will have information that may identify you. This Certificate lets us turn down legal demands for your study records. We can use the Certificate to turn down demands for records from a U.S. court. The Certificate can be used in any federal, state, or local legal matters. We will use the Certificate to turn down any demands for your study records. The cases where we cannot use the Certificate are explained below.

We cannot use the Certificate to turn down a demand from the U.S. Government for study records. This applies to audits or reviews of the AMC. This also applies to study records that we have to report to the FDA.

The Certificate does not stop you or your family members from sharing your health information. It does not stop you from talking about taking part in this study. You may give written permission for an insurer, employer, or other person to get copies of your study records. If you give permission, we cannot use the Certificate to say no to a request for your study records.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Tell the researchers if you are thinking about stopping or decide to stop. If you decide not to take part or leave the study early, you will not be penalized or lose any of your regular benefits.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. Please contact Dr. _____ at _____ if you have any questions about this study or if you have a research-related injury.

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office, at _____ or email _____. General information about being a research participant can be found by [insert instructions for HRPO web site]. To talk about your experience as a research subject or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

WHERE CAN I GET MORE INFORMATION?

For more information, you may call the National Cancer Institute's Cancer Information Service at:

1-800-4-CANCER (1-800-422-6237) or TTY: 1-800-332-8615.

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

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

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

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.

SIGNATURE

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to take part in this study.

I have been given a copy of all _____ [insert total of number of pages] pages of this form. I have read it or it has been read to me. The research study has been explained to me. All of my questions have been answered to my satisfaction.

Thank you for your important contribution to research studies that are trying to improve medical care.

Do not sign this form if today's date is after [insert expiration date].

_____ _____

(Participant's Signature) (Date)

_____

(Participant's name – printed)

Please mark all that apply. This section is optional.
[ ] Not Hispanic or Latino [ ] Hispanic or Latino [ ] Unknown [ ] Refused
[ ] Asian [ ] Black or African-American [ ] Caucasian [ ] Native American or Alaskan Native [ ] Native Hawaiian or Pacific Islander [ ] Other [ ] Unknown [ ] Refused
The Office of Management and Budget has declared that Hispanic/Latino is an ethnicity. National Institutes of Health, in an effort to ensure diversity in research, requests that you report your ethnicity. (http://grants.nih.gov/grants/funding/women_min/women_min.htm)

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that he or she understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____

(Signature of Person who Obtained Consent) (Date)

_____

(Name of Person who Obtained Consent - printed)

Investigator Acknowledgement:

I acknowledge and approve of the completion of the informed consent process for this participant.

_____ _____

(Signature) (Title)

_____ _____

(Printed name) (Date of signature*)

* Please note: the date of Investigator signature may be different from the other signature dates as this serves only as acknowledgement of the consent.

OPTIONAL AIDS AND CANCER SPECIMEN RESOURCE (ACSR) DONATION OF LEFTOVER TISSUE SAMPLES

After all of the tests for this study are finished, there may be unused blood and biopsy tissue left over. We would like your consent to donate your leftover samples to the AIDS and Cancer Specimen Resource (ACSR).

The ACSR is funded by the National Cancer Institute to collect, store, and distribute tissues and biological fluids from HIV-positive and HIV-negative people to qualified scientists. The ACSR makes these samples available for scientists to do other research studies. This research may be about cancers and pre-cancers associated with HIV disease. This research may also involve analyzing your genes or looking for genetic factors. The ACSR screens all research plans to be sure that the samples are used to advance scientific research.

Donating your leftover samples to the ACSR will not require any extra tests or procedures. You are free to choose if you want to donate your leftover samples to the ACSR. You do not have to donate your leftover samples to take part in this study. If you do not give your consent, we will destroy your leftover samples at the end of the study.

If you agree to donate leftover samples, we will send them to the ACSR for future use. The ACSR may ask for some medical information from your study records. This information may be useful to researchers who perform studies using your samples. The AMC will not give the ACSR your name or any information that could personally identify you.

We will make every effort to protect your privacy. We will not keep information that links you to your samples after the study is over. You may withdraw your consent to donate your leftover samples at any time during the study. After the study is over, the AMC and the ACSR will not be able to identify your specific samples. We will not be able to link the results of studies on your samples back to you. We cannot give you or your doctors the results of any tests for this reason.

You may not have any direct benefit from donating your leftover samples to the ACSR. However, research done using your samples may help other people in the future. These studies may help us learn more about how to prevent and treat HIV-associated cancers. You will not be paid for donating your leftover samples to the ACSR.

You may contact the research team if you have any questions about donating your leftover samples.

Please circle your answer to show whether or not you would like to take part in each option:

1. **I agree to donate my leftover samples to the ACSR for future research that may be used to learn about, prevent, diagnose, or treat HIV-related diseases and cancer.**

   YES NO

2. **I agree to donate my leftover samples to the ACSR for future research that may include genetic testing to learn about, prevent, diagnose, or treat HIV-related diseases and cancer.**

   YES NO