RESEARCH STUDY INFORMED CONSENT DOCUMENT

Study Title for Participants: Collect and study data from people with HIV and cancer which may help design better clinical trials and care

Official Study Title for Internet Search on http://www.ClinicalTrials.gov:
Protocol AMC-115:

Use of a Screening Tool to Describe HIV-Related Cancer Burden and Patient Characteristics in the AIDS Malignancy Consortium

Overview and Key Information

What am I being asked to do?

We are asking you to take part in this research study because you are living with both underlying HIV infection and a cancer diagnosis. We want to understand what types of cancer are treated across the AIDS Malignancy Consortium, a group of research centers the National Cancer Institute funds to help design and implement cancer prevention and treatment trials specifically for those living with HIV and cancer.

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 is 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.

Why is this study being done?

The burden and types of cancer in people with HIV (PWH) is changing as PWH are aging. Also, it is challenging to connect people with cancer (who may or may not have HIV) to clinical trials that may offer helpful treatments. The objective of this study is to collect high-quality data that will address both trends. This study is being done to answer the following questions:

How many people with HIV (PWH) present for cancer care across the AIDS Malignancy Consortium in the United States? Are there reasons that some PWH choose to participate, or not in cancer clinical trials?

What is the usual approach?

This study involves collecting information about you, your cancer diagnosis, and cancer treatment plan. Taking part in this study will not change the treatment you receive (or are receiving) for cancer or HIV.

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

- You may choose to take part in a different research study if one is available.
- You may choose to continue your HIV and cancer care without participating in any research.

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

If you decide to take part in this study, the doctor will collect basic information about you, such as your age, current HIV status and treatment, your cancer status and treatment, and your current health status at your next visit.

If further treatment for your cancer is planned, in about three months your doctor will ask for follow-up information on the status of your planned cancer treatment and your general health status again. This may happen at another in-person visit or through review of your medical records.

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

If you choose to take part in this there may be a risk to your privacy and confidentiality. The researchers will make every effort to protect your data.

Benefits

This study is not designed to change your cancer or HIV treatment plans and therefore is not designed to directly help you at this time. However, this study will help researchers learn things that may help people with HIV and cancer 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 stop, you can decide if you want to keep letting the study doctor know how you are doing.

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

Your study team will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study if they do occur.

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

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

- New information becomes available and the study is no longer in your best interest.
- You do not follow the study rules.
- The study is stopped by the Institutional Review Board (IRB), Food and Drug Administration (FDA), or sponsor (National Cancer Institute). 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 count how many people at your center have both HIV and cancer and to understand why people with HIV and cancer do, or do not, participate in clinical trials. We expect to have up to 720 people take part in this study. This will help researchers understand what new studies may be helpful for AIDS Malignancy Consortium research centers in the future.

What are the study groups?

There is only one study group in this trial. It will include everyone who agrees to participate in the trial and will be only for information collection.

The researchers will count all patients who have HIV and cancer at this site during the study, regardless of whether they agree to take part in the study. This step is for the researchers to understand how many people were asked to join the study, and why some people may not want to take part in the study.

If you agree to participate in the study, more detailed information on items such as age, cancer treatment, and general health will be collected either directly from you or from your medical record.

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

Before you begin the study, your doctor will review the results of your exams, tests, and procedures. This helps your doctor decide if you can take part in the study. Choosing to take part or not in this study will not affect the usual cancer or HIV care you will receive.

If you choose to take part in this study, a member of the research team will review your medical records to obtain information about your general health status (including HIV diagnosis, cancer diagnosis, any other medical conditions), demographic information (age, gender, race/ethnicity), and social history (smoking, alcohol/drug use). A member of the research team may ask you for some of this information in person. The research team will collect this information at the time you join the study and 12 weeks later.

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

General Risks

If you choose to take part in this study, you may have the following discomforts:

- Spend more time in the hospital or doctor's office.
- Be asked sensitive or private questions about things you may not normally discuss.

What are my responsibilities in this study?

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

- Keep your study appointments, with no more than two appointments to be planned.
- Tell your doctor about:
  - all medications and supplements you are taking
  - any side effects
  - your medical history
  - 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?

Taking part in this study may mean that you need to make one more visit to the clinic or hospital than if you were not taking part in the study. However, the study team will make every effort to try and schedule your study visits to be at the same time as your regularly scheduled cancer visits if receiving treatment.

You may:

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

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. 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.

Who will see my medical information?

Your privacy is very important to us. The study team will make every effort to protect it. However, some of your medical information may be given out if required by law. The study doctors have a privacy permit to help protect your records if there is a court case. 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 planned cancer treatment and medicines you took or underlying medical history, will be kept by the study team in a central research database. However, your name and contact information will not be put in that 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 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:

- The study sponsor, the National Cancer Institute (NCI) in the United States, and the groups it works with to review research.
- 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 AIDS Malignancy Consortium (AMC) and its representatives

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 in the future.

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 the study doctor (*insert name of study doctor[s]*) at (*insert telephone number, and email address if appropriate*).

For questions about your rights while in this study, call the (*insert name of organization or center*) Institutional Review Board at (*insert telephone number*).

How will information about me be kept private?

Your privacy is very important to the study researchers. 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 the information that is analyzed and reported. 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 other medical information.
2. Researchers who study your 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.

Optional quality of life study

If you are an English, Spanish, Italian, Chinese, Dutch, Amharic or Turkish speaker and choose to take part in this study, you will be asked to fill out 2 forms with questions about your physical and emotional wellbeing. Researchers will use this information to learn more about how HIV and cancer treatment affect people.

Since these forms are being used for research, the responses you provide will not be shared with your study doctor. If you have any serious health issues or other concerns, please talk with your doctor or nurse right away.

You will be asked to fill out these forms up to 2 times:

- At the time you agree to join the study (all participants)
- Approximately 12 weeks after you complete the first set of forms (only for participants who are currently receiving cancer treatment or who plan to begin cancer treatment)

Each form will take about 10 minutes to complete. The forms will ask about things like nausea, tiredness, and your care needs. You don't have to answer any question that makes you feel uncomfortable.

If you agree to complete the two optional quality of life surveys, you will receive $25.00 each time you complete the two requested forms. If you complete the forms at the beginning of the study and again at Week 12, you will receive a total of $50.00 for your time. If you complete the forms only at the beginning of the study, you will receive $25.00 for your time.

Please circle your answer: I choose to take part in the quality of life study and will fill out these forms:

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. I also agree to take part in any additional studies where I circled "yes".

Participant's signature: _____

Date of signature: _____

Signature of person(s) conducting the informed consent discussion:

_____

Date of signature: _____

ATTATCHMENT 1: AMC CERTIFICATE OF CONFIDENTIALITY

The NIH has given the AMC 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 in the United States. 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.