SUMMARY OF CHANGES

Prospective Observational Study of the Frequency of Site-Specific New and Existing Cases of Cancer in People Living with HIV/AIDS- in Latin America

Version 3.0

NCI Protocol #: AMC-S008
Local Protocol #: AMC-S008

NCI Version Date: 22JAN2021
Protocol Date: 22JAN2021

I. Scientific and Substantive Changes:

#	Section	Comments
1.	What is the purpose?	The number of participants that will take part in this study has been revised from 200 to 400 for consistency with the protocol.

II. Administrative and Editorial Changes:

#	Section	Description of Changes
1.	Global	The version number and date were updated from version 2 dated 02OCT2019 to version 3 dated 22JAN2021.
	What will happen if I decide to partake in this study?	Follow up period was extended and may be completed 1-3 months after enrollment, for consistency with the protocol.

^Notes for Local Investigators:

- The goal of the informed consent process is to provide potential study participants with clear, accurate, unbiased, and sufficient information so that they can make informed choices about participating in research. The ICD is one part of the consent process. It provides a summary of the study, describes foreseeable risks, discusses the individual's rights as a study participant, and documents their willingness to participate. The ICD, however, is only one piece of an ongoing exchange of information between the investigator and study participant.

- Sections that will require edits from local site investigators are highlighted in yellow. These instructions and formatting should remain in the consent form for the local sites. Local sites should remove them from the consent form for patients.

RESEARCH STUDY INFORMED CONSENT DOCUMENT

Study Title for Participants: Counting the number of people living with HIV/AIDS and with new and existing cancers at 4 clinics in Latin America

Official Study Title for Internet Search on http://www.ClinicalTrials.gov: AMC-S008: Prospective Observational Study of the Frequency of Site-Specific New and Existing Cases of Cancer in People Living with HIV/AIDS- in Latin America

OVERVIEW AND KEY INFORMATION

What am I being asked to do?

We are asking you to take part in a research study. 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 have HIV/AIDS and cancer. We want to understand what types of cancer are treated at this center, and how your cancer has been or will be treated.

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.

Why is this study being done?

This study is being done to answer the following question:

How many people have HIV/AIDS and cancer at four centers in Latin American and what has their care and treatment been?

We are doing this study because we want to find out what the approach for your cancer and to plan future research studies for cancers in people living with HIV/AIDS at these centers in Latin America.

WHAT IS THE USUAL APPROACH?

This study only involves collecting information about you and your cancer treatment. Taking part in this study will not change the way you are given care or treatment for your HIV/AIDS or your cancer.

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 care without 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 information about your 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 one to three (1-3) month(s) your doctor will follow-up and collect the same information again. This may happen at another visit, over the phone, or through 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

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 there may be a risk to your privacy. The researchers will make every effort to protect it and your data will be secured.

Benefits

This study will not help you. This study will help the study doctors learn things that will help 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:

- 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).

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 cancer center have HIV/AIDS and cancer and to understand how people are being treated and cared for. We expect to have up to 400 people take part in the trial. This will help researchers understand what new studies may be helpful for your area in the future.

WHAT ARE THE STUDY GROUPS?

There is only one study group in this trial. It will have all people who sign up to the trial in it and will only be 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. The researchers will count patients in a way that cannot be linked to your identity.

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. If you join the study, you will have more questions about your cancer care. Choosing to take part or not in this study will not affect the usual care you will receive.

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 normally do not 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.
- Tell your doctor about:
    - all medications and supplements you are taking
    - if you have been or are currently in another research study.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

You will not be charged for taking part in this study.

You and/or your insurance plan will need to pay for the costs of medical care you get as part of the study, just as you would if you were getting the usual care for your cancer. This includes:

- your insurance co-pays and deductibles.

Talk to your insurance provider and make sure that you understand what your insurance pays for and what it doesn’t pay for if you take part in this clinical trial. Also, find out if you need approval from your plan before you can take part in the study. Ask your doctor or nurse for help finding the right person to talk to if you are unsure which costs will be billed to you or your insurance provider.

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.

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.

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 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 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
- Any local regulatory authorities who may have access to the data

Your study records also will be stored for future use. However, your name and other personal information will not be used. Some types of future research may include looking at your records and those of other patients to see who had side effects across many studies or comparing new study data with older study data. However, 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 necessarily 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.

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*).

^Note to Local Investigator: Contact information for patient representatives or other individuals at a local institution who are not on the IRB or research team but take calls regarding clinical trial questions can also be listed here. ^

Unknown future studies

If you choose to take part in this study 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.

We don’t know what research may be done in the future using your health information 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 information

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 your 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 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.

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

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'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.