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| **Official Title:** | Phase 1 Study of NT-I7 (rhIL-7-hyFc) for the Treatment of Kaposi Sarcoma in Patients With or Without Infection With HIV |
| **NCT Number**: | NCT04893018 |
| **Document Type:** | Informed Consent Form |
| **Date of the Document:** | December 23, 2022 |

# Research Study Informed Consent Document

**Study Title for Participants:** Testing an Experimental Immunotherapy Drug (NT-I7) for the Treatment of Kaposi Sarcoma in Patients with or without Infection with HIV

**Official Study Title for Internet Search on http://www.ClinicalTrials.gov:** CITN-17, Phase 1 Study of NT-I7 (rhIL-7-hyFc) for the Treatment of Kaposi Sarcoma in Patients With or Without Infection with HIV

## 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.

This study is sponsored by the Cancer Immunotherapy Trials Network (CITN). The CITN administrative coordinating center is located at the Fred Hutchinson Cancer Center and works with researchers from several cancer centers and universities across the country.

## 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:

Can we use NT-I7 to treat Kaposi Sarcoma in patients with or without infection with HIV safely and without too many side effects?

We are doing this study because we want to find out if this approach is better or worse than the usual approach for your cancer. The usual approach is defined as care most people get for Kaposi Sarcoma.

## What is the usual approach to my Kaposi Sarcoma?

The usual approach for patients who are not in a study is treatment with:

- **Antiretroviral therapy (ART)** - Recommended for all people living with HIV
- **Radiation therapy -** Occasionally used for limited disease
- **Surgery**- Occasionally used for limited disease
- **Chemotherapy** - Often used for people with systemic disease (FDA approved agents include liposomal doxorubicin and paclitaxel)
- **Biological therapy** - A type of therapy that uses substances made by the body or in a laboratory to boost, direct, or restore the body's natural defenses against cancer. Examples of biologic agents that are FDA approved to treat Kaposi sarcoma include Interferon alfa and pomalidomide
- **Topical treatment** – Aliretinoin is an example of an FDA approved topical treatment

Sometimes, combinations of these treatments are used. Your doctor can explain which treatment may be best for you. These treatments can reduce symptoms and may stop the tumor from growing for a few months or longer.

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

- You may choose to receive the standard treatment for your cancer.
- You may choose to take part in a different study, if one is available.
- You may choose not to be treated for your cancer.
- You may choose to only get comfort care to help relieve your symptoms and not get treated for your cancer.

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

If you decide to take part in this study, you will get NT-I7 every 9 weeks for up to 27 weeks (4 doses). After you finish your study treatment, your doctor will watch you for side effects. They will check you in the office or clinic 30 days after your last dose of study drug and then every 3 months until the study ends. The study will end when the last person has finished their study treatment and completed their 3-month follow-up visit.

If you stop study treatment because your cancer has returned or worsened, or because you had to start a different cancer treatment, we will ask you to come back for follow-up exams or contact you by phone every 12 weeks (3 months) to see how you are doing, until the study ends. The study will end when the last person has finished their study treatment and completed their first 3-month follow-up visit.

If your disease progresses but you do not have other concerning symptoms, your physician may discuss staying on the study drugs. Studies in patients with other types of cancer have shown a delayed response to the study medications when they are continued despite initial disease progression.

## 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 is a risk that the study drug may not be as good as the usual approach at shrinking or stabilizing your cancer.

There is also a risk that you could have side effects from the study drug. These side effects may be worse and may be different than you would get with the usual approach for your cancer.

Some of the most common side effects that the study doctors know about are:

- Skin reactions where NT-I7 is given (injection site)
- Fever
- Chills
- Tiredness
- Headache

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

Other side effects may be very serious and even result in death.

**Benefits**

There is some evidence in healthy people and people with other types of cancer that this treatment can boost the immune system in a way that may shrink or stabilize cancer, but we do not know if this will happen in people with Kaposi Sarcoma. It is unlikely that NT-I7 study treatment will help you live longer. 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. It's important that you stop safely. If you stop, you can decide if you want to keep letting the study doctor know how you are doing.

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.
- You do not follow the study rules.
- For women: You become pregnant while on the study.
- The study is stopped by the National Cancer Institute (NCI), Institutional Review Board (IRB), Food and Drug Administration (FDA), or study sponsor (CITN). 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 test the safety of a study drug called NT-I7. This study tests different doses of the drug to see which dose is safer for people. There will be about 20 people taking part in this study.

NT-I7 works by using a patient's immune system to fight cancer. It is made in a laboratory and is used to boost, direct, or restore the body's natural defenses against cancer. This type of cancer treatment is called immunotherapy. NT-17 has not been approved by the FDA for the treatment of cancer.

## What are the study groups?

Different people taking part in this study will get different doses of the study drug NT-I7. Treatment schedule: You will get NT-I7 as an injection into the muscle every 9 weeks (4 doses) for up to 27 weeks.

The first three people taking part in this study will get the lowest dose. If the drug does not cause serious side effects, the next group of people in the study will get a higher dose. The study doctor will watch each group carefully as they increase the dose. The doses will continue to increase for every new group until people have serious side effects that require the dose to be lower. Once this dose is found the study is stopped.

## 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 it is safe for you to take part in the study. If you join the study, you will have more exams, tests, and procedures to closely monitor your safety and health. Most of these are included in the usual care you would get even if you were not in a study.

Listed below are exams, tests, and procedures that need to be done as part of this study to monitor your safety and health, but may not be included in the usual care. We will use them to carefully follow the effects of the study treatment, including preventing and managing side effects.

These exams, tests, and procedures to monitor your safety and health include:

- An electrocardiogram to measure the electrical activity of your heart before you begin the study.
- A chest x-ray to look for any disease in your lungs before you begin the study. If this x-ray is abnormal, then we will continue x-rays throughout the study to see how your disease is responding to the study drugs.
- Safety blood tests at every visit to help us monitor any good or bad effects that the study drug might have on your body.

Some exams, tests, and procedures are a necessary part of the research study but would not be included in usual care. Listed below are procedures that will be done for research purposes only.

- You will need to have a biopsy for the study. This biopsy would not be used to guide your medical care; it would be done solely for research purposes. The biopsy will be collected before your first dose of the study drug, again at weeks 9 and 13. Tissue biopsy at 13 weeks is optional. If you have a previous tumor biopsy available, we may be able to use it for this study. The study biopsy takes small pieces of cancer tissue from your body. This is like the biopsy you had that helped diagnose your cancer. The biopsy will be used to see if your tumor changes over time. You will not get the results of this testing. Your study doctor will get some of the results of this testing. If you agree to take part in the study, you may need to sign a separate consent form for the study biopsy at the hospital or clinic where the biopsy is done.
- You will need to have a blood sample taken for the study. We will take a blood sample at every visit. The blood sample will be taken for research purposes to help us understand how your body, especially your immune system, is responding to the study drugs. You will not get the results of this testing. Your study doctor will get some of the results of this testing.
- You will need to have multiple injections to receive the study drug.

A patient study calendar is attached at the end of this document. It shows how often these exams, tests, and/or procedures will be done.

At the end of this document you will also be asked if any samples leftover after completion of this study may be stored for future studies. Storing samples for future studies is called “biobanking”. Biobanking your leftover samples is optional.

## 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 the study drug may not be as good as the usual approach at shrinking or stabilizing your cancer.

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.

The study drug used in this study could be very harmful to an unborn or newborn baby. There may be some risks that doctors do not yet know about. It is very important that you check with your study doctor about what types of birth control or pregnancy prevention to use during the study and for at least 3 months (90 days) after the last dose of study treatment.

**Genetic Testing Risks**

The genetic test used in this study will test your tumor for changes in gene expression and for changes in your T-cell immune response. These measures will be used to explain why certain tumor cells respond to treatment.
Since this study is only testing tumor tissue, we will not know if gene expression in your tumor is the same as in your normal tissue. If you want to find out the results of gene expression in your normal tissue, then you will need to get other tests done outside of this study.

DNA is in your cells, and it is what makes you different from everyone else.

The genetic testing is for research only. Results will not be returned to you or put in your regular medical records.

**Biopsy Risks**

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 the study biopsy that describes the risks in more detail.

**Side Effect Risks**

The drug used in this study may affect how different parts of your body work such as your liver, kidneys, heart, and blood. The study doctor will test your blood and let you know if changes occur that may affect your health.

There is also a risk that you could have other side effects from the study drug.

Here are important things to know about side effects:

1. The study doctors do not know who will or will not have side effects.
2. Some side effects may go away soon, some may last a long time, and some may never go away.
3. Some side effects may make it hard for you to have children.
4. Some side effects may be mild. Other side effects may be very serious and even result in death.

You can ask your study doctor questions about side effects at any time. Here are important ways to make side effects less of a problem:

- If you notice or feel anything different, tell your study doctor. He or she can check to see if it is a side effect.
- Your study doctor will work with you to treat your side effects.
- Your study doctor may adjust the study drugs to try to reduce side effects.

**Drug Risks**

The table below shows the most common and most serious side effects doctors know about. Keep in mind that there might be other side effects doctors do not yet know about. If important new side effects are found, the study doctor will discuss these with you.

**Possible Side Effects of NT-I7 (rhIL-7-hyFc)**

| **COMMON, SOME MAY BE SERIOUS**<br>In 100 people receiving NT-I7 (rhIL-7-hyFc), more than 20 and up to 100 may have: |
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| • Swelling and redness at the site of the medication injection<br>• Fever, chills, tiredness, headache<br>• Skin changes, itching, rash, hives, sores on the skin |

| **OCCASIONAL, SOME MAY BE SERIOUS**<br>In 100 people receiving NT-I7 (rhIL-7-hyFc), from 4 to 20 may have: |
|---|
| • Pain, including injection site, joints, chest, arms and legs, back, muscles, tumor, belly, or mouth and throat<br>• Bleeding, bruising<br>• Dry and tingly mouth, nausea or the urge to vomit<br>• Flu-like symptoms which may cause body aches<br>• Swelling of the body<br>• Loss of appetite, changes in taste, weight gain and loss, difficulty swallowing |

| **RARE, AND SERIOUS**<br>In 100 people receiving NT-I7 (rhIL-7-hyFc), 3 or fewer may have: |
|---|
| • Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, or swelling of the face or throat<br>• Damage to organs (lungs, others)<br>• Dizziness, confusion, difficulty sleeping<br>• Diarrhea, dehydration (when your body does not have as much water and fluid as it should)<br>• Kidney damage which may require dialysis<br>• Anemia which may require blood transfusions<br>• Muscle weakness<br>• Infection, especially when blood cell count is low<br>• Cough<br>• Abnormal heartbeat<br>• Swelling of lymph nodes at the injection site<br>• Redness, pain or peeling of palms and soles<br>• Blood in urine<br>• Blurred vision<br>• Fluid around the lungs which may cause shortness of breath<br>• Numbness, tingling or pain of the arms and legs<br>• Need to urinate more often than usual<br>• Increased sweating<br>• Flushing |

**Additional Drug Risks**

NT-I7 is a therapeutic protein which may activate an immune response in your body, including production of blood proteins called anti-drug antibodies (ADAs). You will have blood collected to monitor for potential formation of ADA.

NT-I7 may also lead to detection of HIV at low levels in your blood even if you are taking your HIV medications. These are sometimes called "blips", and when they have been observed in participants with HIV who have been administered similar immunotherapies, HIV usually returns to undetectable on subsequent visits as long as you continue your HIV medications.

Rarely, there are problems getting enough supplies of the study drug. If that happens, your doctor will talk with you about your options.

## 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

**For women:** Do not get pregnant or breastfeed while taking part in this study. **For men:** Do not father a baby while taking part in this study or donate sperm. **For all:** Tell your study doctor right away if you think that you or your partner have become pregnant during the study or within 3 months (90 days) after your last dose of study drug.

## What are the costs of 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 of your cancer. This includes:

- The cost of tests, exams, procedures, and drugs that you get during the study to monitor your safety, and prevent and treat side effects.
- 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.

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:

- Tumor biopsies done before your first dose of NT-I7, Week 9, and Week 13.
- Research blood tests at every visit to help us understand how your body, especially your immune system, is responding to the study drugs.

You or your insurance provider will not have to pay for NT-I7 while you take part in this study.

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 treatment options. NeoImmuneTech, Inc., will pay for the reasonable and necessary costs of treatment of the injury if you are injured as a direct result of a defect in the design or manufacture of NT-I7 that is properly administered to you. There are

no other forms of payment for treatment of medical injuries available from the study sponsors. 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 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:

- The study sponsor and any company supporting the study now or in the future. This would include any organization helping the company with the study.
- 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 FDA and the groups it works with to review research.
- The NCI and the groups it works with to review research.
- The Cancer Immunotherapy Trials Network (CITN) and other people who work at the Fred Hutchinson Cancer Center.

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 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*).

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

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

## Optional sample collections for known laboratory studies and/or storage for possible future studies

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.

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.

## Known future studies

### Optional tumor biopsy study

If you choose to take part in this optional study, researchers will collect a tumor biopsy after 1 and/or 2 cycles of NT-I7 for research on how the immune system affects tumor cells and the effect the study treatment has on the immune cells in your tumor. This will only be done if you have tumor that can be safely biopsied through the skin with a large needle.

This biopsy would **not** be used to guide your medical care; it would be done solely for research purposes.

### Optional blood draw study

If you choose to take part in this optional study, you will have additional blood collected at the same time as the rest of laboratory draws except for one visit during the fourth cycle of NT-I7 for research on how your cells are responding to treatment.

These blood draws will **not** be used to guide your medical care; and would be done solely for research purposes.

### Unknown future studies

If you choose to take part in this optional study, leftover samples (blood and tissue) will be stored. Storing samples for future studies is called "biobanking." The biobank is being run by CITN and is supported by the NCI. 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. 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 don't know what research may be done in the future using your blood and/or tissue 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.

**What is involved in this optional sample collection?**

If you agree to take part, here is what will happen next:

1. For the optional blood draw study: about 6 tablespoons of blood will be collected from a vein in your arm at each visit except for one visit during the fourth cycle of NT-I7.
   For the optional tumor biopsy study: a sample of tissue will be collected from an optional extra biopsy.
   For unknown future studies: leftover samples of blood or tissue that were collected for the study will be sent to the biobank.
2. Your samples will be stored in the biobank. There is no limit on the length of time we will keep your samples and research information. The samples will be kept until they are used for research or destroyed.
3. Researchers can only get samples from the biobank after their research has been approved by experts. Researchers will not be given your name or contact information.
4. Some of your genetic and health information may be placed in central databases for researchers to use. The databases will not include your name or contact information.

**What are the risks in this optional sample collection?**

- The most common risks related to drawing blood from your arm are brief pain and maybe a bruise.
- Generally, hospitals will keep some of your tissue. This tissue may be used to help treat your cancer in the future. There is a small risk that when this tissue sample is submitted to the biobank for this optional sample collection, your tissue could be used up.
- Your medical and genetic information is 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 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/

**How will information about me be kept private?**

Your privacy is very important to the study researchers and 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 are the benefits to taking part in this optional sample collection?**

You will not benefit from taking part.

The researchers, using the samples from you and others, might make discoveries that could help people in the future.

**Are there any costs or payments to this optional sample collection?**

There are no costs to you or your insurance. 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 if I change my mind about this optional sample collection?**

If you decide you no longer want your samples to be used, you can call the study doctor, (*insert name of study doctor*), at (*insert telephone number of study doctor *), who will let the biobank know. 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 optional sample collection?**

If you have questions about the use of your samples for research, contact the study doctor, (*insert name of study doctor *), at (*insert telephone number of study doctor*).

Please circle your answer below to show if you would or would not like to take part in each optional study:

**Samples for known future studies:**

I agree that my samples and related health information may be used for the optional tumor biopsy study described above.

YES NO

I agree that my samples and related health information may be used for the optional blood draw study described above.

YES NO

**Samples for unknown future studies:**

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

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 name** (print) | **Participant's signature** | **Date** (dd-MMM-yyyy) |
|---|---|---|

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

| **Name of study staff conducting consent discussion** (print) | **Signature** | **Date** (dd-MMM-yyyy) |
|---|---|---|

CITN-17 Study Chart

| **Procedures** | **Screening** | **Cycle 1** | | | **Cycle 2** | | **Cycle 3** | **Cycle 4** | **End of Treatment** | **30-Day Follow Up** | **Post-Treatment Follow-Up (Every 12 weeks)** |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Weeks** | | **0** | **1** | **4** | **9** | **13** | **18** | **27** | **36** | | |
| Study Drug (NT-I7) | | X | | | X | | X | X | | | |
| Informed Consent | X | | | | | | | | | | |
| Physical Exam | X | | | | X | | X | X | X | X | X |
| Electrocardiogram | X | | | | | | | | | | |
| Chest X-Ray | X | | | | | | | | | | |
| Safety Blood Tests | X | X | X | X | X | X | X | X | X | | |
| Pregnancy Test | X | X | | | X | | X | X | X | | |
| Disease Measurement | X | X | | | X | X | X | X | X | | X |
| Tumor Biopsy | | X | | | X | X *(optional)* | | | X *(only if treatment ends before Week 9)* | | |
| Research Blood Tests | | X | X | X | X | X | X | X | X | | |