

<b>MEDICAL RECORD</b>	<b>CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY</b> • Adult Patient or • Parent, for Minor Patient
-----------------------	--

INSTITUTE: National Institute of Allergy and Infectious Diseases

STUDY NUMBER: 11-I-0057 PRINCIPAL INVESTIGATORS: Frank Maldarelli, M.D.

STUDY TITLE: Effect of Interferon Alpha 2b Intensification on HIV-1 Residual Viremia in Individuals Suppressed on Antiretroviral Therapy

Continuing Review Approved by the IRB on 06/15/15  
Amendment Approved by the IRB on 05/18/15 (D) Date Posted to Web: 06/24/15  
Screening

**INTRODUCTION**

We invite you to take part in a research study at the National Institutes of Health (NIH).

First, we want you to know that:

Taking part in NIH research is entirely voluntary.

You may choose not to take part, or you may withdraw from the study at any time. In either case, you will not lose any benefits to which you are otherwise entitled. However, to receive care at the NIH, you must be taking part in a study or be under evaluation for study participation.

You may receive no benefit from taking part. The research may give us knowledge that may help people in the future.

Second, some people have personal, religious, or ethical beliefs that may limit the kinds of medical or research treatments they would want to receive (such as blood transfusions). If you have such beliefs, please discuss them with your NIH doctors or research team before you agree to the study.

Now we will describe this research study. Before you decide to take part, please take as much time as you need to ask any questions and discuss this study with anyone at NIH, or with family, friends, or your personal physician or other health professional.

**Purpose of this Study**

You are invited to participate in this study because you have HIV infection and have viral loads that are suppressed below the limit of detection on antiretroviral therapy (ARVs). The therapy you are taking for HIV is effective in controlling but not curing the HIV infection. Low levels of HIV are present even when the viral load is measured below the limit of detection for virus (<50 copies RNA/mL plasma). The source of the small amount of HIV is unknown. It may come from a low-level infection, where new cells are continually infected with HIV. It is also possible that the virus is coming from cells that live for a long time after infection. We would like to learn more about the origin of residual HIV, because it will help us to understand the virus infection. We are interested in finding out whether antiviral agents other than the ARVs can affect the level of residual HIV in the blood. In this study we are investigating whether interferon alpha (Interferon, PEGINTRON, pegylated interferon alpha 2b) will affect the level of HIV viremia in individuals

<b>PATIENT IDENTIFICATION</b>	<b>CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY</b> • Adult Patient or • Parent, for Minor Patient NIH-2514-1 (07-09) P.A.: 09-25-0099 File in Section 4: Protocol Consent (2)
-------------------------------	---

STUDY NUMBER: 11-I-0057

CONTINUATION: page 2 of 6 pages

suppressed on antiretroviral therapy. Interferon is a natural substance made by the body to combat viral infections. Interferon can also be made as an injectable drug, called pegylated interferon alpha 2b (PEGINTRON®), which has been approved by the FDA for use in hepatitis C infection including in patients with HIV infection. In several earlier studies of HIV infected individuals who were not on any antiretroviral therapy, PEGINTRON® was shown to reduce the level of HIV in the blood. We are doing the present study to learn whether PEGINTRON® therapy will also reduce the residual low levels of HIV in patients who are already taking antiretroviral therapy. In this study participants will receive weekly PEGINTRON injections for 4 weeks using the standard dose of PEGINTRON that is approved by the FDA for chronic Hepatitis C. During the study we will measure the levels of HIV in the blood using sensitive tests that can detect as little as 1 copy of HIV RNA in 3 milliliters of blood (about 6/10 of a teaspoon). After the 4 weeks of PEGINTRON®, we will obtain additional blood samples for a total of 1 year. Participants will also undergo apheresis before the first dose and after the last dose of PEGINTRON; apheresis is a procedure in which we obtain white blood cells. We plan to study 10 individuals.

Enrollment in the study is a two step process. In the first step, a screening analysis is performed during which we will perform a clinical evaluation and obtain blood samples to study. Based on this analysis, which will take several weeks, we will learn whether you are eligible for the study. If you are eligible, we will proceed to the second step of enrollment, when you will actually begin treatment with interferon for 4 weeks.

**Eligibility for Study**

In order for us to determine whether it would be appropriate for you to participate in this study, we will need to perform an initial evaluation to better understand the status of your HIV. This will consist of

- A visit to our clinic
- A history and physical examination
- Routine laboratory studies; pregnancy test if you are a woman of child-bearing potential
- Blood to measure the amount of HIV virus in the blood using standard testing and ultralow viral load test
- Blood specimens for storage
- Participants considering getting a vaccine, including the seasonal influenza (flu) shot, should discuss this with the study team prior to getting vaccinated.

Women of childbearing age will have a pregnancy test within 2 weeks prior to and another one on the day of the first dose of PEGINTRON. You should not get pregnant while participating in this study and must practice 2 different methods of contraception during this time. If you are pregnant, you cannot be in the study because we do not know how the study will affect the unborn fetus. If you are not pregnant, you will be asked to use methods of birth control during the study. Women must also not be breastfeeding while taking PEGINTRON®.

This initial screening visit will take about 4 hours. The screening test results will help to determine if you're likely to be eligible to continue in the screening process. Some people may not be able to join the study because of scientific or health reasons found during the screening visit(s). The final eligibility for the study will be determined after a complete assessment by a doctor that is usually done after the screening visit, and after we have spent enough time with you discussing the protocol that you understand the risks and possible benefits. If you should not become eligible, we will inform you and explain to you why you are not eligible for this study.

If the results of your evaluation indicate that you are eligible for PEGINTRON therapy we will discuss the full protocol and provide an additional consent form for your consideration. At that time, we will describe the study procedures in detail.

STUDY NUMBER: 11-I-0057

CONTINUATION: page 3 of 6 pages

**Benefits**

There is no direct benefit to participation in the screening or in participating in the study itself. You will receive information about your health from the screening tests and physical examination. In the future, your participation may help us learn more about the causes, treatment, or prevention of HIV disease, immune dysfunction and/or related diseases. The information we obtain may help us to improve our understanding of HIV infection. We will perform the standard HIV viral load test, and also perform a sensitive research test for HIV. Although the research test can detect at low levels (1 copy/mL), this new viral load test is not approved by the FDA, and the information we obtain will not be used in making any clinical decisions regarding your care.

**Risks**

The risks from screening for this study are from the risks of blood drawing. Blood drawing is generally very well tolerated. Occasionally, pain from needle stick, bruising, or bleeding may take place; rarely fainting may occur. The amount of blood drawn will be within the limits allowed for adult subjects by the NIH Clinical Center (Medical Administrative Policy 95-9: Guidelines for Limits of Blood Drawn for Research Purposes in the Clinical Center). If you are eligible and choose to enroll in the study, there are additional risks from apheresis, from the PEGINTRON therapy, and from the combination of PEGINTRON with antiretrovirals and other therapy. We will describe those additional risks in detail if you elect to enroll. Blood samples obtained from the screening process will be stored and studied, whether you are eligible and elect to participate in the study or not. The potential risks of maintaining your specimens and of the studies we will perform with them are described below.

**REASONS FOR REMOVING YOU FROM THE STUDY WITHOUT YOUR CONSENT**

You may be removed from the study without your consent for the following reasons:

- The NIH doctor feels that staying in the study is harmful to you
- You don't keep your appointments
- The study is cancelled or stopped

**Cost**

There will be no charge to you or your health insurance company for any of the costs which are directly related to this study. However, the costs of any other medical care outside of this study during this period will be your responsibility.

**Alternatives**

This study provides no benefit and the alternative to participating is not participating

**New Findings**

The results of the screening tests will be discussed with you and you will be told of any new information learned during the screening that may influence your general care

**Remuneration**

You will be reimbursed for your time and inconvenience in participating in the screening process according to standard NIH guidelines, \$40.00 for each visit.

**Stored Samples and Future Research**

We may take extra blood and tissue samples and store them for future research. These samples will help us learn more about HIV or related conditions. In general, the research tests we perform are not like routine medical tests, and may not relate directly to your medical care, so we may not put future test results in your medical record. However, if you wish,

STUDY NUMBER: 11-I-0057

CONTINUATION: page 4 of 6 pages

someone on the study team will discuss the test results with you. We will not share these test results with your private doctor unless you ask us to do so. By agreeing to participate in this study, you do not waive any rights that you have regarding access to and disclosure of your records. For further information on those rights, please contact Dr. Maldarelli (PI) at 301-435-8019.

**Labeling of Stored Samples**

We will label your stored samples with a code that only the study team can link to you. We will keep any information that can be traced back to you private to the extent permitted by law.

**Future Studies**

Other investigators may want to study your stored samples. If so, the NIH study team may send your samples to them, (along with the coded label). The study team may also share information such as your gender, age, health history, or ethnicity. In some cases, an Institutional Review Board (IRB) will review new research proposals that would like to use your samples. The IRB is a committee that oversees medical research studies to protect volunteers' rights and welfare. Investigators will use your samples only for research. We will not sell them. Future research that uses your samples may lead to new products, but you will not receive payment for these products. Some future studies may need health information (such as smoking history or present health status) that we don't already have. If so, the NIH study team will contact you for this information.

**Risks**

The greatest risk of allowing us to store your samples will be an unplanned release of your identification from the samples due to release of this information from the stored sample database. The chances of this happening are very low.

**Benefits**

In general, future research that uses your samples will not help you, but it may help us learn what causes HIV or related immunodeficiency conditions. This research may also help us learn how to prevent or treat the condition.

**Making Your Choice**

If you agree to participate in this study, you agree to let us store your samples for future research. You also agree that we can contact you again in the future. No matter what you decide, you may still participate in other studies at NIH. However, your refusal to let us store your samples may lead to your withdrawal from this specific study. Even if you agree now to let us store your samples, you can change your mind later. If you do, please contact us and say that you do not want us to use your samples for future research.

**Genetic Testing**

Some of the blood drawn from you as part of this study will be used for genetic tests, including HLA tests, which is a genetic test of markers of the immune system. Genetic tests can help researchers study how health or illness is passed on to you by your parents or from you to your children. HLA is usually used to match bone marrow or organ transplants. For research, HLA testing might be used to try to identify factors associated with the progression of disease or related conditions. In addition, determining HLA type is necessary to be able to perform certain research studies. Some HLA types have been associated with an increased risk of certain diseases like arthritis and other rheumatologic problems. However, simply having those HLA types doesn't mean you will develop these diseases.

Some things to consider in thinking about whether or not to participate in these genetic studies include the possible effects on your emotional well being. In other words, how might you feel about yourself and your life if you learn information about risks that could affect your own health or that of your children? There may be no treatment for certain

---

**MEDICAL RECORD****CONTINUATION SHEET for either:**

NIH 2514-1, Consent to Participate in A Clinical Research Study

NIH 2514-2, Minor Patient's Assent to Participate In A Clinical Research Study

---

STUDY NUMBER: 11-I-0057

CONTINUATION: page 5 of 6 pages

conditions and this may cause some individuals to feel anxious, depressed, or stressed. Additional genetics counseling and advice is available from the National Institutes of Health to help you understand the nature and implications of findings about you and your family.

Also, relationships with other family members may be affected by finding out risks they have but did not want to know. An example would be if your children, brothers, or sisters find out they have risks for health problems because of information found out about you.

Genetic testing can also be used to determine if people are directly related. These tests can reveal that a person's biological parents are someone other than their legal parents. If these facts were not known previously they could be troubling to learn. It is our policy to not discuss such information unless it has direct medical or reproductive implications for you or your family. By agreeing to participate in this study, you do not waive any rights that you may have regarding access to and disclosure of your records. For further information on those rights, please contact Dr. Maldarelli, principal investigator.

Any genetic information collected or discovered about you or your family will be confidential. Records containing this information will be kept on password-protected computer systems and in locked and secured quarters within the Clinical Center. We will not release any information about you or your family to relatives, any insurance company, employer, or your primary care physician without your written permission. Some genetic information, such as the name of your diagnosis, will be in your medical record. An insurance company or an employer could interpret this to be a pre-existing condition to deny benefits or coverage. Although we are committed to confidentiality, a court could still subpoena your medical records. All of these issues should be carefully considered before joining the study. Genetic counselors are available to discuss these issues in greater detail to help you and your family think about the possible effects. There may be a risk that genetic information obtained as a result of participation in research could be misused for discriminatory purposes. However, state and federal laws provide some protections against genetic discrimination. Researchers who will have access to genetic information about you will take measures to maintain the confidentiality of your genetic information.

**HIV Testing**

As part of this study, we will test you for infection with the human immunodeficiency virus (HIV), the virus that causes AIDS. If you are infected with HIV you will be able to participate in this study. We will tell you what the results mean, how to find care, how to avoid infecting others, how we report newly diagnosed HIV infection, and the importance of informing your partners at possible risk because of your HIV infection.

**Conflicts of Interest**

The National Institutes of Health reviews NIH staff researchers at least yearly for conflicts of interest. The following link contains details on this process <http://ethics.od.nih.gov/forms/Protocol-Review-Guide.pdf>. You may ask your research team for additional information or a copy of the Protocol Review Guide. This protocol may have investigators who are not NIH employees. Non-NIH investigators are expected to adhere to the principles of the Protocol Review Guide but are not required to report their personal financial holdings to the NIH.

---

**PATIENT IDENTIFICATION****CONTINUATION SHEET for either:**

NIH-2514-1 (10-84)

NIH-2514-2 (10-84)

P.A.: 09-25-0099

