Official title: A phase 2, open label study of the safety, antiretroviral activity and pharmacokinetics of 3BNC117 during a short analytical treatment interruption in HIV-infected subjects

NCT number: NCT02446847

Document date: 09/21/2015

Clinical Investigation Consent Form

IRB Rev 2014

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You are being asked to join a research study, which will take place at The Rockefeller University Hospital. This form tells about the research. You should ask questions of the person who is explaining this form to you. After you feel that you understand the research, if you want to be part of the study, you will be asked to sign the form. You can always ask more questions and can later change your mind about staying in the study.

If you join the research study, you will take part for a total of 38 weeks. The research study as a whole will last about 3 years.

About 15 people will take part in the research study.

Title of the research study:

A phase 2, open label study of the safety, antiretroviral activity and pharmacokinetics of 3BNC117 during a short analytical treatment interruption in HIV-infected subjects

I. What this research study is about, and the reason for doing this research.

The research will test a drug called 3BNC117, which is a monoclonal antibody to HIV, the virus that causes AIDS (acquired immune deficiency syndrome). A monoclonal antibody is an artificial substance made in the laboratory. An antibody is a substance that the body makes in response to an infection. The monoclonal antibody we are testing attaches to HIV, and can block HIV from attacking cells in your body and from spreading to other parts of the body. 3BNC117 is being developed to treat and potentially prevent HIV infection. In this study we will test this monoclonal antibody in HIV-positive people with well-controlled HIV infection, and who are on combination antiretroviral therapy (HIV medications). The monoclonal antibody, 3BNC117, being tested was designed by scientists at The Rockefeller University and was manufactured at Celldex Therapeutics Inc.

One of the reasons to do this study is to find out if it is safe to give this antibody. Another reason is to determine how this antibody might affect HIV levels in HIV-infected individuals during a brief pause of their HIV medications.

You are being asked to participate in this research because you are HIV-infected and are on combination antiretroviral therapy.

The antibody will be given directly into your blood stream. This means that the medicine is given into a vein or intravenously. How this will be done is explained in Section II, What is going to happen in this research study?

Requirements to join this research:

- Age from 18 to 65 years old;
- HIV-1 infection confirmed by laboratory tests;
- Undetectable HIV viral loads for at least 12 months while on a combination of HIV medications;
- Current CD4 cell count > 500 cells/µl and no prior CD4 cell count < 200 cells/µl;
- HIV that is sensitive to 3BNC117. We will know if the HIV in your body is sensitive to 3BNC117 by testing blood you have already donated for another study (MCA-823).
- You agree to pause your HIV medication (ART) for 12 weeks after you receive the antibody, and agree to return to the clinic every week for follow-up visits.
- If you are a sexually active male or female, participating in sexual activity that could lead to pregnancy you must agree to use an effective method of contraception throughout the study period. You must also agree to use male or female condoms during the time of pausing your HIV medication. If you are female, you will have pregnancy tests at most study visits.
- If your ART includes a Non-Nucleoside Reverse Transcriptase Inhibitor [NNRTI], i.e. Atripla Complera, Itelence, or Sustiva you must be willing to a switch for 4 weeks to dolutegravir, which we can provide to you during this time.

You cannot join this research if you have:

- History of AIDS-defining illness within 1 year prior to enrollment;
- Used systemic corticosteroids, immunosuppressive anticancer, or other medications considered significant by the trial physician within the last 6 months;
- Any clinically significant acute or chronic medical condition, other than HIV infection, or significant laboratory abnormality, that in the opinion of the investigator would preclude participation;
- Any history of significant cardiovascular disease such as coronary artery disease, myocardial infarction, percutaneous coronary intervention with placement of cardiac stents;
- Uncontrolled hypertension, as defined by a systolic blood pressure > 180 and/or diastolic blood pressure > 120, whether or not you are taking anti-hypertensive medications;
- Current cigarette use in excess of 1 pack per day;
- History of Diabetes type 1 or 2 and/or currently use insulin or oral hypoglycemic medications;
- Chronic Hepatitis B or Hepatitis C infection;
- Current ART regimen includes either Selzentry (maraviroc) or Fuzeon (enfuvirtide);

- History of resistance to two or more antiretroviral drug classes;
- Received any vaccination within 14 days prior to receiving the monoclonal antibody;
- Received monoclonal antibody therapy of any kind in the past;
- Participated in another clinical study of an investigational product currently or within past 12 weeks, or expect to participate during this study;
- History of severe reaction to a vaccine or drug infusion or history of severe allergic reactions.
- If you are pregnant or breastfeeding.

II. What is going to happen in this research study?

Consent Process: Informed consent is a process to help you understand the purpose of the research study, what will happen in the study, possible risks and benefits, and your right to withdraw from the study at any time. All of this information will be explained to you in detail. You should ask any questions you have until you feel that you understand what is asked of you to participate. You may then want to enroll, or you may decide not to join the study. The decision to participate is entirely up to you. Even after the study has started, you may at any time ask more questions, and decide to withdraw from the study.

Study Procedures:

Experimental Drug Infusion

In this study you will receive an experimental drug called 3BNC117. The United States Food and Drug Administration (FDA) has not approved this experimental drug for general use by the public. However, we have told the FDA about this study and they have given us permission to conduct this study. This study will evaluate how your blood cells respond to 3BNC117.

The antibody, 3BNC117, will be given directly into your blood stream. This means that the medicine is given into a vein or intravenously. This means a small plastic tube will be placed into a vein in your arm. Then the medicine will be given through the plastic tube.

You will receive two infusions of 3BNC117 at a dose of 30mg/kg. The amount of 3BCN117 that you will receive will be calculated based on your body weight. For example, if you weigh 70 kg (or 154 lbs), you will receive 2100 mg of 3BNC117 (30 mg of 3BNC117 for each kg of body weight).

After administration of 3BNC117, blood will be taken to measure 3BNC117 levels in your blood and the effect of 3BNC117 on blood cells and on the amount of HIV virus in your blood (HIV viral load). You will also be asked questions to determine if you are having any side effects. Details of the study procedures are found below.

You will be followed for 36 weeks after your first of two 3BNC117 infusions.

ART Discontinuation

You will take your HIV meds once more on the day after the first 3BNC117 infusion. Your HIV meds will then be discontinued.

If your ART includes a Non-Nucleoside Reverse Transcriptase Inhibitor [NNRTI], i.e. Atripla Complera, Itelence, or Sustiva, the NNRTI will be switched to a medication called Dolutegravir (Tivicay), 4 weeks prior to pausing all HIV meds. You will restart taking HIV meds at week 12.

During the 12 weeks you will be off HIV meds, your HIV viral loads will be monitored weekly and you will be asked to restart taking your HIV meds if:

- Your HIV viral load is ≥ 200 copies/ml, and confirmed by a repeat test;
- Your HIV viral load measurement is ≥ 10,000 copies/ml at any time;
- You become pregnant;
- Your CD4+ count drops ≤ 350 cells/µl, and confirmed by a repeat test;
- If you develop symptoms of fever, rash, swollen glands, headache, sore throat, nausea or vomiting, you will be asked to come in for an unscheduled visit. ART will be resumed if the study team determines that you are experiencing these symptoms due to increased HIV levels.

If your meds were not restarted within three weeks after you stopped taking them, you will receive a second infusion of 3BNC117 on day 21.

If your viral load remains suppressed by week 12, you will be asked by the study doctor if you would like to stay off your HIV medications while in the study, with continued close follow up.

If you continue off your HIV meds beyond week 12, your HIV viral load will be monitored every week. Your CD4+ counts will be monitored every 2 weeks. You will be asked to restart taking your HIV meds for any of the 5 reasons listed above.

Any change in your HIV medication regimen will be done in collaboration with your HIV primary care physician.

Pre-Screening

Before screening, you will have had the opportunity to review information about the details of the study. You will have the opportunity to talk to the study investigators and ask them questions.

Screening Visit

- Screening will determine whether or not you are eligible for the study.
- If you agree to be screened, you will sign a copy of the Informed Consent Form confirming that you have been informed about the study and voluntarily agree to take part. You will be given a signed copy of this consent form and the original consent form will be kept in your medical record.
- You will be asked questions about your general health.
- If prior results are not available, an HIV test will be performed to confirm HIV-1 infection. Before having the HIV test, you will be asked to sign a separate informed consent form.
- Up to 30 ml (2 tablespoons) of blood will be drawn to test for Hepatitis B/C, syphilis, to evaluate liver and kidney functions, for complete blood count, to see if your blood is able to clot (PT/PTT), for a pregnancy test, and to evaluate other health conditions.
- A urine specimen will be collected to check that your kidneys function normally.
- All sexually active study volunteers will be asked to use a reliable form of contraception from 10 days prior to receiving 3BNC117 and for the duration of the study, and to use female or male condoms while not taking their HIV medications.
- Medical history will be obtained and a physical exam will be performed which includes measuring your blood pressure, heart rate, respiration, weight, height (at screening only) and temperature.
- You may not be allowed to participate in this study if the tests indicate you have an acute or chronic infection, other than HIV, or if you are pregnant or breastfeeding.

If you are a female who can have a baby, a pregnancy test will be required at most study visits.

Blood will also be taken to measure the HIV viral load. We will also measure the CD4 and CD8 cell counts. CD4 cells (also called helper T cells) work for the immune system by helping other cells in the body fight infections. CD4 cell counts drop during HIV infection. Up to 15 ml (1 tablespoon) of blood will be taken for these tests.

Your study doctor will review the results of these tests, your medical history and your examination. If your screening test results, medical history and examination are acceptable you may participate in the research.

Study Participation

If you want to participate in the research and the research doctor agrees, you will return to the clinic for the day 0 visit (visit at which you will receive the study drug).

Some parts of this study are experimental. Here, the word "experimental" means that the test or the investigational agent given is "not part of the usual routine care of patients". Research blood tests will evaluate the amount of HIV in your body after you receive the study drug and the function of your blood cells that protect you from infection before and after receiving 3BNC117. These tests are experimental.

You will receive two intravenous (IV) doses of 3BNC117 into a vein in your arm. You will be followed for a total of 36 weeks after the first 3BNC117 infusion.

Details of the study procedures are found below.

Infusion Visit:

- On day 0 and day 21 you will receive the study drug and you will be monitored for 4 hours after the study drug is given.
- In addition you will have the following procedures prior to drug infusion:
    - You will have the opportunity to speak with members of the study team and ask any questions;
    - A physical examination will be performed, including your vital signs;
    - You will be asked questions about your health and medications;
    - Up to 10 ml (2 teaspoons) of blood will be drawn to evaluate liver and kidney functions, for complete blood count, and for a pregnancy test;
    - Additional blood samples will be collected for research purposes (up to 90 ml or 6 tablespoons of blood).
    - A urine sample will be collected;

- The study drug will be given directly into your blood stream through a vein in your arm. This is called an infusion. The infusion takes approximately 60 minutes. You will be closely observed during and for 4 hours after drug infusion.

- On the day following each drug infusion (days 1 and 22) your vital signs will be taken, you will receive a repeat physical examination and will be asked about any new complaints. On day 1 you will also receive your HIV medication. This will be the last time you will take your medication for the next 12 weeks.

Follow-up visits:

You will be asked to return to the outpatient clinic for a total of 15 visits on weeks 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 14, 24, and 36.

If your HIV viral load remains suppressed by week 12 and you choose to remain off your HIV medications, you will return to the clinic every week for follow up after week 12. During these visits, vital signs will be taken, you will be asked about any changes in your medical condition and any new or discontinued medications. Depending on the specific

study visit, approximately 3-8 tablespoons of blood will be drawn to study any effect of 3BNC117 on your blood cells, a limited physical examination may be performed, as well as a urine pregnancy test.

Blood will also be taken to measure the amount of HIV in your blood at all study visits except for Day 1 after receiving the study drug. We will also measure the CD4 and CD8 cell counts at Weeks 2, 4, 6, 8, 10, 12, 14, and the final study visit. Up to 15 ml (1 tablespoon) of blood will be taken for these tests at these visits.

Given the close monitoring of safety and extensive research blood draws that will be performed over the course of the study, a total blood volume of 550 ml (approximately 34 tablespoons or 1 pint of blood), but not more than that, will be collected within any 8-week period.

Laboratory testing conducted on your blood or tissues during the research study will fall into two general categories, 1) New York State-approved tests, and 2) experimental tests that have not been certified by New York State.

We will tell you or your doctor about any tests related to the research protocol that are performed by a New York State-approved laboratory, if the results may affect your health or safety.

In this study, you will not receive routine care for any medical conditions related to this protocol or any other medical conditions that you might have.

Your medical information and test results will be written in your Hospital chart. The researchers of the study may also keep separate records with information about you and your study tests.

Dr. Caskey and her research team will also keep separate records with information about you, including research results. Your name will not appear in these research records.

If we need to get medical information from other doctors or other health care providers who have seen you, we will ask you to sign a consent form to get this information. We will also ask you to sign a separate form if we need information from other hospitals where you have been treated.

III. What are the risks of taking part in this research study?

There may be some risks and discomforts in taking part in a research study. We know that these risks and discomforts may happen during this research study:

Investigational Agent: One of the purposes of this study is to determine the side effects of 3BNC117. This drug, 3BNC117, has been tested in a small group of humans and to date, it has been safe and well tolerated. However, side-effects such as those listed below are

possible with the administration of a monoclonal antibody:

- Infusion of monoclonal antibodies may lead to pain or burning at the place where the plastic tube enters the skin.

- People can be allergic to many things including antibodies. An allergic reaction means that the body is very sensitive to something. If you are allergic to any part of the antibody or to the liquid used to mix them, you may develop a rash on your skin, fever, chills or trouble breathing. Very rarely, severe allergic reactions may result in a severe reaction or even death. The severe reaction is called "anaphylaxis".

- Monoclonal antibodies activate a part of the immune system called complement. Activation of complement may cause body aches, sore muscles, fever, chills, shakes, pain in the stomach, or pain in the back.

- By joining with other substances in your body, monoclonal antibodies can form something called immune complexes. This happens when the antibody and parts of the HIV or something like the HIV virus become linked. These complexes can get deposited in the kidneys. If this happens you can get blood or protein in the urine. Sometimes this can also affect permanently how well your kidneys work.

- 3BNC117's target is the HIV virus, however when it was tested on different human tissues outside the body, it was found that 3BNC117 can bind to cells in the conjunctival tissue (the lining that covers the inside of the eyelids and the white part of the eyes). This binding could lead to inflammation of the eyes, although volunteers that have received 3BNC117 to date have not developed symptoms suggestive of conjunctival inflammation.

- To avoid these problems your study team will see you very frequently during the study and talk to you about how you feel. If you develop eye complaints, you will be referred for evaluation by an ophthalmologist. This will be performed at no cost to you. Your research team will also examine you and take blood and urine tests. You will be told the results of the tests to make sure that you are not having side effects from the monoclonal antibody infusion.

- HIV strains (viruses) in your body that are "resistant" to (not blocked by) 3BNC117 could become detectable in your blood after the infusion of 3BNC117. However, 3BNC117 does not interfere with approved antiretroviral medications (ART). Standard ART should be able to control the growth of these viruses. If resistance develops, this may limit your future use of 3BNC117, if it is licensed for clinical use by the FDA.
- With any new medicine or monoclonal antibody, there is a possibility of totally unexpected side effects. The Rockefeller University Hospital inpatient unit is

equipped for providing emergency medical interventions in the unlikely event of a severe allergic or other reaction. In case of an emergency, after you are stabilized you will be transferred to the New York Presbyterian Hospital (Cornell) for specialized medical care.

- We don't know how 3BNC117 would affect your baby or your unborn child. If you are a woman who can become pregnant, or a male participating in sexual activity that could lead to pregnancy, you must agree to practice an effective form of birth control before receiving the first 3BNC117 infusion and until the end of the study, even after you restart your HIV medication. If you think that you or your partner is pregnant, you should tell your study doctor or nurse at once. If you are a man who has sex with men you must use condoms for all sexual activity.

Effective forms of birth control for a female include:

- Abstinence
- Intrauterine device (IUD)
- Hormonal [birth control pills, injections, or implants]
- Tubal ligation

If you are a sexually active male participating in sexual activity that could lead to pregnancy and you have not had a vasectomy you must agree to use an effective method of contraception from screening until your 'End of Study' clinic visit.

<u>Pausing your HIV Medication:</u>

- There is the chance that your HIV viral load will increase when you pause your HIV medications. If this happens, your CD4 cell counts might drop. However you will be followed very closely and your HIV medications will be restarted if your HIV viral load increases to more than 200 copies/ml or if your CD4 count cell drops to less than 350 cells/μl, two weeks in a row. Should your HIV medications be restarted within the first three weeks of the study you will not receive the second infusion of 3BNC117.

- Should you become pregnant while pausing your HIV medications the study doctors will ask you to restart your medications immediately because there is a chance that you could transmit HIV to your unborn child while you are off your medications.

- When your HIV medications are paused, you might experience symptoms similar to when you first got HIV, such as fever, rash, swollen glands, headache, sore throat, nausea, vomiting. If you develop these symptoms, the study doctors will evaluate you and your HIV medications will be resumed if the symptoms are believed to be

due to increased HIV levels.

- Resistance to your HIV meds might occur, since your HIV pills will be paused for about 3 months. In order to decrease that risk, you will be asked to restart your HIV pills if your viral load increases to ≥ 200 copies/ml (confirmed by a repeat measurement) or ≥ 10,000 copies/ml at any time.

- While you are off your HIV medications, you are at increased risk of transmitting HIV to a sexual partner and at increased risk of HIV "superinfection" from an HIV-infected partner. Therefore you are asked to use male or female condoms during the study, particularly while off your HIV medications. If you feel you have been exposed to HIV while off your HIV medications, you may restart your medication if your HIV primary care physician recommends this.

Blood draw: the risks associated with a blood draw are generally minor. They are mild pain at the needle site (common), local bruising at needle site (rare), infection and fainting (extremely rare).

Privacy and Confidentiality Risks: There is the risk that there could be computer security breaches which could reveal your identity. There may be the risk that data about you may become public, and could be used by employers or law enforcement agencies. These privacy risks are described in greater detail below.

There may be other risks and discomforts that we do not know about now, but we will tell you any new information discovered which might affect your decision to participate or remain in the study.

IV. What are the alternatives to participating in this research study?

You do not have to participate in this research to receive treatment for your HIV infection. There are drugs approved for use in the treatment of HIV infection. You may get these drugs from your primary care physician.

V. What are the benefits of taking part in this research study?

You are unlikely to have any direct benefits from participating in this study. It is possible that 3BNC117 will lead to better control of HIV infection, and it may improve the treatment of patients with HIV in the future.

VI. Who will be able to see the information learned about you in this research study?

We will protect your personal information and will do our best to keep this information confidential. We will listen to what you say we may do with this information, and we will follow the law. For example, by New York State law hospitals must inform the New York State Department of Health if we find that you have a reportable communicable disease(s), such as sexually transmittable diseases like chlamydia, hepatitis, gonorrhea or syphilis. Also, the researchers must report to the authorities if they believe that child abuse or neglect has happened, or to prevent serious harm to you or others.

Whenever possible, data about you will be unlinked from your name and identified by a code. Sponsors receive your data linked only to a code. However, auditors and regulators from government agencies that oversee research, and people at the Rockefeller University Hospital and at Rockefeller University may see your information in the course of their duties.

We will share information about you only with the government agency that oversees this research, and the people at the Hospital and the Rockefeller University in connection with their duties.

During the research study, only the researchers will know that your samples came from you, because your stored samples will be identified only by a special code instead of your name. As a result, the others who study your samples will not know that they came from you and will not be able to figure out that they came from you.

If the researchers publish the results of this study, they will not mention your name or other information that could identify you.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time."

Genetic Information Nondiscrimination Act

A Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. Additional information is available in the outpatient or inpatient information handbook.

VII. What are the payment arrangements?

There is no cost to you for being in this research study.

Payment will be made to participants who fill out a form from The Rockefeller University Finance Office and are eligible for and want to receive payment.

There will be no compensation for the screening visit. Each study volunteer will be paid $200 for each 3BNC117 infusion study visit. You will receive an additional $60 for each follow up study visit after the infusion, up to and including week 12. You will receive $100 for the week 14 and 24 visits and the final study visit. If you complete all of the study visits, you will be eligible to receive $1,360 in total compensation.

If your HIV viral load remains suppressed by week 12 and you choose to remain off your HIV medications, you will return to the clinic every week for follow up after week 12. You will be compensated $50 for each of these additional visits. In total, you may receive up to $2,260 if you remain off ART until the final study visit at week 36.

If the study doctors ask that you return for an unscheduled visit, you will be compensated $25 each time.

Compensation is provided to help cover your travel expenses, as well as child care and time lost from gainful employment. If you stop participating in the study before the last study visit, you will be paid for the portion of the study you completed.

Dr. Nussenzweig and Dr. Scheid, co-investigators on this study, are inventors of the study drug and are named on a patent application for their invention. Dr. Nussenzweig holds equity in Celldex, the manufacturer of the study drug. Dr. Nussenzweig, Dr. Scheid, the Rockefeller University, and Celldex may benefit financially if the study drug is licensed to a third-party pharmaceutical company.

If research using your samples helps develop a drug or another product that is sold to the public, the drug company, the University and the researchers may share in some of the profits. For example, a cell line from your samples could be used to make a product for sale. There are no plans to pay you any money resulting from such discoveries. However, by signing this form, you do not give up any rights you may have.

VIII. What happens if you don't want to stay in this study or your participation is ended?

You can choose if you want or do not want to be part of this study. If you do not join, there is no penalty and no one will hold this against you. If you decide to join this study, you may change your mind and stop taking part in this study at any time, and this will not be held against you. Information about you up to that time may stay a part of the study.

During this study, the researchers may learn new information that might make you change your mind about whether you want to stay in the study. You will be given that information promptly.

If you decide to join this study but later want to stop, you should let the researchers know. The study team would still like to follow all volunteers who received the study drug for safety reasons.

The researchers also may stop you from taking part in this study, even if you do not choose to stop being in it. You may be asked to leave the study if:

- You fail to keep appointments
- The research study is terminated or canceled by the investigator, the FDA or the Rockefeller University Institutional review Board (RU IRB)
- There is a significant adverse event to you or other participants in the study

IX. Consent to the use, storage and sharing of your samples or data for separate research studies

The scientific value of your samples and the information obtained from them is greatly increased if we can share them with other scientists at universities, pharmaceutical and technology companies worldwide. May we store, use and share your blood/or tissue samples and data with other investigators at the Rockefeller and elsewhere for separate studies for many years? Your samples will either be stripped of information identifying them as yours or coded (we will hold the key to the code) so that they cannot be identified as having come from you. Other data related to your sample, but that does not identify you may accompany your samples.

Any time in the future, you may withdraw your consent to use any samples that have not already been used in research or shared. If you withdraw your consent, the remaining unused samples will be destroyed, unless the samples cannot be identified as having come from you.

Would you like us to store, use and share your blood/or tissue samples/associated data as described above?

Yes_____ No_____

If you say "no" to this question, this will not affect your participation in this study.

X. Who do you call if a medical problem results from this research study?

If you believe that this study has led to a medical problem, you should call the researcher listed below right away. The investigator will help you to get the appropriate, available

medical care.

Name: Marina Caskey, MD
Phone: 212-327-7396
Fax: 212-327-7234
E-mail: mcaskey@rockefeller.edu

The Rockefeller University does not plan to pay for medical care that you may have as a result of taking part in a research study at The Rockefeller University Hospital. However, you do not give up any rights you may have to seek compensation by signing this form.

XI. Who do you contact if you have questions about the research study?

Please ask as many questions as you want about this research study and this consent form. If you agree to take part in this study and have questions later on, you may contact the following researcher:

Name: Noreen Buckley, NP
Phone: 212-327-7394
Fax: 212-327-7234
E-mail: nbuckley@rockefeller.edu

If you have any concerns about your experience while taking part in this research study, you may contact The Rockefeller University Institutional Review Board (IRB) Office at (212) 327-8410, or the Office of Clinical Research at (212) 327-8408.

XII. May we have permission to contact you about future studies?

May we contact you by phone to find out if you are interested in hearing about new research studies? Contact would be made by the Rockefeller staff of the Clinical Research Support Office for Recruitment. If you decide at any time that you no longer want to be contacted, please tell us, and we will stop calling you.

Would you like us to contact you about future research studies?

Yes _____ No _____

If you say "no" to this question, this will not affect your participation in this study.

AGREEMENT TO PARTICIPATE -- SIGNATURES REQUIRED

I have read this consent form, and my questions have been answered.

A copy of this consent form will be given to you. Please keep a copy of the form as it contains important information that you may wish to refer to during the research study and thereafter.

I hereby voluntarily consent to take part in this research study.

Name of the Study Participant (Print) _____

_____	_____
Signature of Study Participant	**Date (To Be Filled in by Study Participant)**

Signature of the Person Conducting the Informed Consent Discussion

I have explained the research protocol and this consent form to the participant and have answered the participant's questions about this research study and/or the consent process.

Name of Person (Print) _____

_____	_____
Signature of Person Discussing Consent	**Date (To Be Filled in by Person Discussing Consent)**