INSTITUTE: NCI-Frederick

STUDY NUMBER: OH99-C-N046 PRINCIPAL INVESTIGATOR: Michael Dean, Ph.D.

STUDY TITLE: Collection and Distribution of Samples from Healthy Donors for In Vitro Use at NCI-Frederick

Latest IRB Review: Continuing Review 9/25/06
Latest Amendment Approved: Amend A 3/11/03

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.

Description of the Research Study

In order to perform research related to human health and disease, investigators at the NIH, including those at the National Cancer Institute's Frederick Cancer Research and Development Center (NCI-FCRDC), need to use human samples from healthy, normal donors in their experiments. The goal of this research study is to collect samples, primarily blood, but occasionally buccal mucosal [cheek] cells, semen, urine, and nail clippings from paid, healthy volunteer donors for use by FCRDC investigators. Blood collected as part of your participation in this Research Donor Program (RDP) will be used strictly for laboratory experiments and will not be used for transfusion or other purposes.

The types of research experiments that your samples may be used in range over a broad area of medical investigation, and include but not be limited to: use in making vaccines against bacteria and viruses; use in screening new drugs for effectiveness against cancer, immune disorders and infections; use in development of methods and quality control of reagents; use in determining the structure and function of blood cells. You will not be contacted about the outcome of any results from the research.

Eligibility

To participate in the Research Donor Program, you must be 18 years of age or older, must weigh more than 110 pounds, must be in excellent health without known heart, lung, kidney, bleeding disorders, infectious disease or other chronic illnesses. To determine eligibility, prospective new participants in the Research Donor Program will be evaluated at a "pre-donation assessment" visit. A brief health questionnaire, examination of blood pressure and heart rate, evaluation of arm veins, and blood tests to determine blood counts will be conducted at this assessment visit. You will be notified of the results of this assessment and any clinically relevant findings, e.g. anemia, within a few days. In addition, OHS staff may monitor your blood counts before every blood donation. Lowered blood cell counts could require temporary interruption of your participation in the Research Donor Program.

If you meet other eligibility criteria and agree to participate in the study, a sample of blood for testing for exposure to HIV, HTLV and Hepatitis C virus and for infection with Hepatitis B virus will be taken at the time of your first donation. You will be notified of results from these tests within two weeks. A positive result on any of these tests will make you ineligible to participate. You will receive appropriate counseling concerning positive results and be able to ask questions. You will also be referred for medical treatment. These tests will be required every six months of your participation in the study.

MALES ONLY: To donate semen, you must NOT have knowingly had any injury, infection, or treatment performed that renders you incapable of producing sperm.

Study Design

If you are added to the donor pool, you will be assigned a number. To ensure fairness of selection, donors will be called to donate in numerical order. A unique number, but not your name, will be placed on each sample released for research use. Only Occupational Health Services staff members assisting with the Research Donor Program will be able to trace the number on a sample and link it with your name. Under no circumstances will they release your identity to investigators who have received your sample.

In the case that an Investigator requires donors with specific characteristics, donors meeting those requirements will also be called in numerical order. If an investigator does find your blood or other sample is particularly helpful to their research, you should be aware that this in no way indicates that you are carrying a disease or an increased susceptibility to disease. However, researchers may request that we recruit you as a donor specifically so that their laboratories can test your samples on repeated occasions. As long as you are interested in continuing your participation in the Research Donor Program, we will try to comply with these research requests.

It is possible that your blood or other sample may be used in experiments resulting in the discovery or development of major new diagnostic tests, vaccines, or drugs, and that use of your sample will lead to submission of government patents for products from which commercial gain or profit is eventually realized. Because you have donated your sample, you will not be informed if a commercial product is developed as a result of the use of your sample in the laboratory.

Although it is not the purpose of this study to screen for genes or conditions of known clinical relevance, it is possible that research testing of your samples could reveal an unexpected medical condition, such as an increased susceptibility to an inherited or other disease, that may affect you and your family. In this unlikely event, the NCI's institutional Review Board will be informed and may decide that it is in your best interest to inform you of the findings.

In compensation for the time, discomfort, and inconvenience, which the research donation may have caused, you will be given financial compensation based on the volume of blood donated, as follows:

001 – 100ml (6.7 Tbsp) donation = $20.00
101 – 200ml (13.4 Tbsp) donation = $30.00
201 – 300ml (20 Tbsp) donation = $40.00
301-- 400ml (26.7 Tbsp) donation = $45.00
Compensation for buccal cell samples, urine, nail clippings will be $20.00
Compensation for semen donation will be $40.00

Procedures

1. Blood donation: Although the uses of donated blood through the Research Donor Program are experimental, the techniques used to draw blood from donors are well-established medical techniques. If you choose to participate in the Research Donor Program, your blood will be drawn by trained medical staff at Occupational Health Services (OHS) using standard medical procedures used by blood banks and in diagnostic medicine. Before each donation, you will be asked questions about your general health and recent medical history. You may be asked to have a type of blood count that involves a finger prick with a sterile instrument or portion of the donated blood sample may be used for blood cell counts, if you do not have a current blood count on file, if there is concern that you may be anemic, or if you will be or have recently donated 100 ml or more of blood. Every six months, a small portion of your blood donation will be used to test for transfusion-transmissible diseases, including HIV, HTLV and hepatitis B and C. You will be asked to sit in the venipuncture chair, a needle will be placed using sterile techniques into a vein in the bend of your elbow, or other forearm vein or hand vein. Between 3 and 400 ml (30 tablespoons) of blood will be withdrawn into either a plastic bag, or into multiple syringes or tubes. The entire process takes about 10-15 minutes. You will be allowed to donate up to 500 ml of blood in an eight week period. Following donations of 100 ml or greater, you will be asked to relax under observation for 10-15 minutes and have some refreshments and juice.

2. Buccal mucosal [cheek] cell donation: A buccal sample is obtained by either gently brushing the inside of your mouth with a soft brush or swab or by having you swish approximately one tablespoon of mouthwash inside your mouth and then expectorate it into a collection container. You may be asked to provide up to three buccal samples in a single visit. The donation procedure is expected to take less than 10 minutes

3. Urine or nail clippings: OHS will provide a container for collection, which may be done at the OHS or in the privacy of your own home.

[MALES ONLY, if meeting eligibility requirement] 4. Semen donation: Forty-eight hours prior to donation you will receive from OHS a specimen cup, insulated transport container and instructions]. Specimen collection should take place at the your home on the morning of the specified date with delivery to OHS no later than 9:30 the same morning. The entire ejaculate should be collected into the vessel, capped and stored out of the light at room temperature in the insulated transport container. Considering the intended use of the sample, it is important that the specimen not come in contact with foreign matter such as any discharge or cellular debris from a second individual. Therefore, the most effective method is for you to produce a specimen by self-masturbation, without the use of any substance that might jeopardize the viability of the specimen. To maximize the number of viable cells it is suggested that you abstain from particular sexual activities [resulting in ejaculation] for at least 24 hours prior to donation.

Alternative Approaches or Treatments

You may choose not to participate in this study.
If you do wish to participate in the Research Donor Program, be aware that there is no alternative procedure available for the withdrawal of blood from a human donor that is equally devoid of risk and personal discomfort as venipuncture of the forearm vein.

Risks or Discomforts of Participation

1. Blood donation: Whole blood donations are generally very safe and side effects are rare. Pain and bruising may occur at the needle placement sites. As with other kinds of blood drawing, temporary lowering of the blood pressure may develop, and lightheadedness, dizziness and even fainting may result. Sterilized, single-use equipment is used to draw blood is and disposed of following a donation procedure. Blood drawing equipment is never in contact with blood from another individual. No blood products are given during these procedures. Occupational Health Services medical staff is available at all times during the donation procedure to provide short term medical care for complications or reactions resulting from the donation procedures.

2. Buccal mucosal cell, urine, nail clippings, semen donations: There are no known physical risks associated with the buccal cell, semen, urine and nail clipping collection procedures.

NIH researchers do not plan to provide you with the results of any laboratory investigations involving use of your samples, or any other research data or results. These results will, in general, be preliminary. Further, this study is not designed to determine information about you with known clinical importance. In many cases, additional research may be necessary to determine whether these results are meaningful in terms of health and disease. You will, of course, be contacted about the outcome of medical tests you undergo as part of the eligibility assessment.

At least every six months, a sample of your blood will be tested for certain blood-borne viruses. These include HIV, hepatitis B, hepatitis C, and HTLV. The hepatitis viruses may cause liver inflammation and more rarely, cirrhosis. HTLV is associated with a rare form of paralysis and leukemia. If your blood is found to contain any of these viruses, you will not be permitted to participate in this protocol. You will be counseled by an OHS health care professional on the implications of the virus to your health and lifestyle, and if you wish, you will be referred for a consultation with an NIH expert in the treatment of the viral infection.

Although it is not the purpose of this study to screen for genes or conditions of known clinical relevance, it is possible that research testing of your blood samples could reveal an unexpected medical condition, such as an increased susceptibility to an inherited or other disease, that may affect you and your family. In this unlikely event, the NCI's institutional Review Board will be informed and may decide that it is in your best interest to inform you of the findings. It is possible that knowledge of these results might affect your social or psychological well being, and might even lead to discrimination, stigmatization, or difficulties with insurability. As stated above, under no circumstances will we ever release your identity to an NIH investigator who has received your blood, without your advance approval.

Extensive records are kept by OHS in connection with research blood donations. These records are maintained in accordance with the Privacy Act and are kept confidential to the extent permitted by law. By agreeing to participate in this study, you do not waive any rights that you may have regarding access to and disclosure of your own records.

OHS health care providers are available for consultation at all times. Should you note any side effects or reactions after leaving the donor blood-drawing area, you may contact OHS at (301) 846-1096.

Potential Benefits of Participation

You or your family will receive no direct health benefits for participating in this study.

Research Subject's Rights

You should know that the following general principles apply to all participants in this study: 1) participation is strictly voluntary; 2) you may withdraw your consent and discontinue participation at any time without prejudice to yourself; 3) all questions you have concerning participation will be answered.

Please check if willing to donate:

☐ – buccal [cheek] cells ☐ – urine ☐ – nail clippings (**males only**) - ☐ – semen

As part of your participation in this study, it will be necessary to test your blood for the presence of antibodies to the Human Immunodeficiency Virus (HIV), the virus that causes Acquired Immune Deficiency Syndrome (AIDS). In order to perform the test, a small amount of blood (approximately 2 teaspoons) will be withdrawn from one of your arms with a needle. You may experience some slight discomfort at the needle entry site and there may be some bruising. In addition, there is a very small risk of you fainting or of infection at the needle entry site. If your test results are found to be positive, or if you are otherwise diagnosed as having AIDS, you should be aware of the following Clinical Center HIV Testing Policy:

1. Your physician will notify you promptly of the HIV test results.

2. Your physician and/or the Clinical Center HIV counselor will offer you, and any current and/or ongoing sexual partner(s) (spouses are generally considered to be current or ongoing sexual partners) or needle-sharing partner(s) you identify, information on the meaning of the test results and how to prevent the spread of the infection.

3. Because the virus may be transmitted in several ways, it is important that you inform sexual and/or needle-sharing partner(s) that any, or all, of them may have been exposed to the HIV virus and encourage them to be tested. If you request it, staff at the Clinical Center will assist you in notifying your partner(s) and arrange counseling for them through an HIV counselor.

4. The results of your HIV test and/or documentation of the diagnosis of AIDS will become a part of your Clinical Center medical record and, as such, will be protected from unauthorized disclosure by the Federal Privacy Act of 1974. In general, access to your medical record will be restricted to those health care professionals directly involved in your care or in the conduct of ongoing biomedical research, and information is not usually released to other third parties without your permission or that of your designated representative. However, there are some particular routine uses of such information of which you should be aware.

   a. If you are unwilling or unable to notify your partner(s), the Clinical Center is responsible for attempting to contact and inform them of their possible exposure to the virus. Reasonable attempts will be made to protect your identity including withholding your name when notifying any partner(s) of their possible exposure. Some notification or counseling of current and/or ongoing partners may be carried out through arrangements with, or referral to, local public health agencies.

   b. A summary of your care at the Clinical Center will be sent to the physician who referred you here for treatment.

   c. The Clinical Center may report certain communicable diseases, such as HIV infection, to appropriate State and Federal government agencies.

      i. For Clinical Center patients who are Maryland residents, the Clinical Center reports by “Patient Unique Identifier Number” (rather than by name) newly obtained HIV-positive results from its laboratory to the Maryland Department of Health and Mental Hygiene. Patient Unique Identifier Number is: last four digits of social security number, birth month, birth day, birth year, race and gender.

      ii. For Clinical Center patients who are Maryland residents, the Clinical Center reports by name new cases of AIDS to the Maryland Department of Health and Mental Hygiene.

      iii. For Clinical Center patients who are not Maryland residents, the Clinical Center reports HIV-positive results and/or AIDS to the patient’s primary care/referring physician.

If you have any questions regarding the HIV testing or the information provided above, you are encouraged to discuss them with your physician and/or a Clinical Center HIV counselor: (301) 496-2381.

OTHER PERTINENT INFORMATION

1. Confidentiality. When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

The Federal Privacy Act protects the confidentiality of your NIH medical records. However, you should know that the Act allows release of some information from your medical record without your permission, for example, if it is required by the Food and Drug Administration (FDA), members of Congress, law enforcement officials, or other authorized people.

2. Policy Regarding Research-Related Injuries. The Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the National Institutes of Health, the Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

3. Payments. The amount of payment to research volunteers is guided by the National Institutes of Health policies. In general, patients are not paid for taking part in research studies at the National Institutes of Health.

4. Problems or Questions. If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, Dr. Michael Dean; Building 560, Room 21-18, Telephone: (301) 846-5931. Other researchers you may call are: Dr. Janelle Cortner, Building 427, Room 11, Telephone: (301) 846-5712

You may also call the Clinical Center Patient Representative at 301-496-2626.

5. Consent Document. Please keep a copy of this document in case you want to read it again.

COMPLETE APPROPRIATE ITEM(S) BELOW:	
A. Adult Patient's Consent I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby consent to take part in this study. Signature of Adult Patient/Legal Representative — Date	**B. Parent's Permission for Minor Patient.** I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby give permission for my child to take part in this study. (Attach NIH 2514-2, Minor's Assent, if applicable.) Signature of Parent(s)/Guardian — Date
C. Child's Verbal Assent (If Applicable) The information in the above consent was described to my child and my child agrees to participate in the study. Signature of Parent(s)/Guardian — Date	
THIS CONSENT DOCUMENT HAS BEEN APPROVED FOR USE FROM SEPTEMBER 25, 2006 THROUGH SEPTEMBER 24, 2007.	
Signature of Investigator — Date	Signature of Witness — Date