

INSTITUTE: National Institute of Environmental Health Sciences

STUDY NUMBER: 13-E-0015 PRINCIPAL INVESTIGATOR: Frederick Miller, M.D., Ph.D.

STUDY TITLE: Environmental Risk Factors for Myositis in Military Personnel

Continuing Review Approved by the IRB on 01/27/15

Amendment Approved by the IRB on 11/18/14 (F)

Date Posted to Web: 03/21/15

Adult Patient or Control

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.

THE PURPOSE OF THIS STUDY

Researchers at the National Institute of Environmental Health Sciences (NIEHS), in collaboration with researchers from the Department of Defense (DoD), the Veterans Administration and Children's National Medical Center, Washington, DC, are conducting a study to try to understand why some people have developed myositis, an autoimmune disease of the muscles, while they were serving in the military, and other persons have not. An autoimmune disease is an illness that occurs when the body tissues are attacked by a person's own immune system. In the case of myositis, the immune system attacks muscle tissue.

Some scientists believe that differences in environmental exposures may determine who develops certain diseases. Some researchers also believe that differences in the genetic makeup of a person may affect how people respond to certain

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exposures and can determine who develops certain diseases. Because of these beliefs, both environmental and genetic information will be evaluated in this study.

You are being asked to enroll in this study because you either have: 1) developed a muscle disease called myositis while you were serving in the military; or 2) because you served in the military but are healthy and do not have myositis or any other autoimmune or muscle disease. Healthy controls are being enrolled in this study because the information from myositis patients cannot be fully understood unless they are compared to similar information from healthy people.

You will **not** be in a treatment program for your medical conditions at the NIH in this study, but we will report laboratory and other results that may be important to your health to you and your health care provider.

THE INFORMATION YOU PROVIDE WILL NOT BE USED TO DETERMINE YOUR FITNESS FOR MILITARY SERVICE OR YOUR MILITARY BENEFITS.

For this study, 150 myositis patients will be compared to 150 matched healthy volunteers, who do not have myositis or another autoimmune or muscle disease. The healthy volunteers will come from the same clinics as the myositis patients when possible, and will have served in the military during a similar time period as the patients with myositis. You will be considered enrolled once you, your witness, and somebody from the study team sign the consent document.

Participation in this study involves your doctor taking a medical history and performing a physical examination. You will also donate blood samples and complete a survey. The survey asks about information on your family, your education, your work history, your supplement use, your health conditions, and your stressful experiences. We will connect your survey with other data, including Department of Defense medical and other military records and results of blood tests performed by the NIH.

RESEARCH TESTS OR PROCEDURES FOR THIS STUDY

First, all subjects or their health care providers will complete a screening evaluation form to determine if they are qualified for enrollment in this study. This often requires review of portions of your medical records, particularly the results of any muscle testing, such as a muscle biopsy.

For NIH Onsite Participants:

If you agree to participate in this study, doctors involved in this protocol will see you at the NIH Clinical Center in Bethesda, MD where you will have a medical evaluation. This evaluation will involve obtaining and reviewing your medical records, answering questions about your medical history, and completing written or online questionnaires. You will also have a physical examination and you will donate blood. The specific tests that you will have depend on whether you have myositis or are a volunteer without myositis or any other autoimmune disease.

For NIH Offsite Participants (Not Enrolling at the NIH Clinical Research Center in Bethesda, MD):

If you agree to participate in this study, you will be enrolled through your doctors in military treatment facilities or Veteran's Affairs (VA) clinics. Alternatively you can also enroll through the NIH by phone discussions with NIH researchers and by a visit to the NIEHS Clinical Research Unit in Research Triangle Park, NC, or to your local health care provider. The evaluation will first involve obtaining your medical records, if available, and answering questions about your medical history. If you qualify for the study, you will complete, sign and return a NIH admissions form, which gives us your contact information and permission to do these studies. If you enroll through the NIEHS Clinical Research Unit or by your local health care provider, the NIH researcher will discuss the protocol and send you this consent so it can be discussed with

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you in detail and you can ask any questions. If you agree to enroll, then you will sign this consent form with a witness present who will also sign this consent form.

Then you will be mailed an enrollment kit that contains the written questionnaires, information about accessing the secure and password-protected online questionnaires if you wish to complete these via the internet, and blood tubes. You will then complete the questionnaires and take the signed consent and questionnaires and enrollment kit to your local doctor or to the NIEHS Clinical Research Unit. Your local doctor will perform a brief physical examination and complete the physician questionnaire and include copies of your medical records. You will then have blood drawn into the blood tubes in the kit. Your local doctor will then send all of the enrollment kit containing your signed consent form, the questionnaires and your blood samples to the processing center following the enclosed express mail instructions. For participants enrolling at off-site locations, we will do our best to offer additional assistance and support in completing study procedures.

PROCEDURES AND TESTING FOR ALL SUBJECTS

All subjects will be asked to do the following in this study, which should take about three to four hours:

- 1) The researchers will review your past medical records previously obtained from your health care providers. The information from your records will be kept strictly confidential.
- 2) You will spend about one to two hours completing forms about your past medical history and the types of exposures you have had, particularly while serving in the military. You will also be asked if you have had certain infections, which vaccines you received, which medications or supplements you have taken, how you reacted to the sun, whether you used tobacco, or if you experienced stressful events in your life, and when these events occurred. You will also be asked about your occupations while you served in the military and your deployments. You will be asked questions about your family background, educational history, health conditions, and symptoms of autoimmune disease.
- 3) You will undergo a medical history and physical examination by your physician who will also complete physician forms describing the findings from this evaluation. This evaluation is performed to document what features of myositis you have or to confirm that you do not have myositis or other autoimmune diseases. If any abnormalities or diseases are detected that your health care provider did not previously identify, additional testing may be performed or recommended for clinical care purposes only.
- 4) Once you have become an active participant in the study by signing the study consent, some of your health information may be accessible in military databases. This would include information about your health, including any autoimmune or other major illnesses that you have, medications you have been taking, and vaccines you received. It would also include information about your deployments and their locations and military occupations. In order to do this search in the military databases, you will have to provide your social security number and date of birth in the questionnaires, as well as your gender, name and branch of military service. Once the search of your military records is complete, your social security number, name and date of birth will be removed from the records of the investigators conducting the search of the military databases and your data will be de-identified.
- 5) You will have about 3 tablespoons (46 milliliters) of blood collected for a number of research tests. Blood drawing involves cleaning the skin of the arm with alcohol. A needle is then inserted into the vein. Blood is then quickly withdrawn using a special tube or syringe.

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The following tests will be performed on the blood samples:

- a) Because certain environmental exposures may cause certain diseases, based on the results of the questionnaires, we may be testing your blood for evidence of past exposures and if you have had certain infections. The NIH laboratories will perform some of these tests but our collaborators will also perform some of these tests in their laboratories.
 - b) We will examine selected parts of your DNA or genes to see if they have differences in spelling (called polymorphisms) or mistakes in their spelling (called mutations). For this study, we plan to look at only genes that control how you respond to environmental factors that we think are important based on the questionnaires or that have something to do with the development of myositis or other autoimmune diseases.
 - c) We will test your blood to see if there are differences in the levels of certain molecules called RNA, which is made from DNA, and controls how proteins inside your cells are made.
 - d) We also will look at how the genes get turned on or off by different processes or may be chemically changed (called epigenetic changes).
 - e) Some of your samples and data will be stored and may be used for future research. Any sample/data used for possible future research related to this protocol will be coded. Any sample/data used for possible future research outside the scope of this protocol will be anonymized.
- 6) For subjects enrolling through the NIH- either at the NIH Clinical Research Center in Bethesda, or through the NIEHS Clinical Research Unit in North Carolina, or their own physician's office, we will draw an extra 2 tablespoons (30 ml) of blood. We will be testing your blood for your white and red blood cell counts, levels of electrolytes and other chemicals, autoantibodies found in certain autoimmune diseases as well as the genes for human leukocyte antigens (HLA) that may be important in regulating the immune system or responding to certain environmental agents.

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 still 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.

The investigators conducting this study do not plan to provide you with the results of the research tests mentioned above because further study may be necessary before the results are meaningful. However, if meaningful information is developed from this study that may be important for your health, you and your health care provider will be informed when it becomes available. 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. Frederick Miller.

ADDITIONAL PROCEDURES AND TESTING THAT SUBJECTS WITH MYOSITIS MAY HAVE

Myositis patients will also complete a questionnaire about how active their disease is at present, how much damage the myositis has caused, and how they can perform daily life functions.

We will also ask to collect any past tissue biopsy specimens, which are no longer needed for your clinical care, for research purposes. We would particularly like to study muscle biopsies, but we could study other tissues as well. The

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

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muscle tissue samples, when available, will also be studied for the epigenetic changes (chemical changes to the DNA structure) and metabolic changes, similar to the changes we plan to examine in your blood sample.

If you have myositis and your NIH study doctor believes that additional tests are needed to understand your disease and determine your best treatment, you may have some of the tests listed below if you enroll at the NIH Clinical Center in Bethesda, Maryland (and as clinically indicated by your own doctor at other enrolling sites):

Up to 1.5 tablespoons (23 milliliters) of additional blood may be drawn for certain tests. The blood testing you will undergo includes tests of muscle enzymes and other blood chemistries and blood count tests (hematology/immunology) that may reflect ongoing muscle inflammation. A urine sample may be tested.

Additional testing may be recommended for you and the results may be used in the research that is part of this study. This may include a physical therapy assessment of your muscle strength. To see if the electrical activity of your muscles is abnormal, an electromyography (EMG) test may be performed. A magnetic resonance imaging (MRI) scan of the lower extremities may also be recommended in patients with myositis. This study produces a picture of your muscles using magnetism, and requires you to lie still on a padded table for 30-60 minutes while a powerful magnet takes pictures of your muscles. Also, studies to test your heart or lung function, such as an electrocardiogram (ECG), an echocardiogram (heart echo), a chest x-ray (CXR), pulmonary function testing, computerized tomography (CT) scan of the chest may be recommended. Some of these procedures may require separate informed consent and will be further explained to you if they are recommended.

Also, because the risk of cancer is increased with myositis, if you have myositis it is important for you to be carefully evaluated for cancer, especially in the first two years of your illness. Therefore, you may have additional testing for cancer, if clinically indicated, based on your age, sex or other risk factors. These tests could include certain blood tests to assess the possibility of prostate cancer, a pelvic exam to assess the possibility of cervical or other pelvic cancer, a mammogram to test for breast cancer, stool tests to look for blood, or an abdominal computerized tomography (CT) scan similar to the chest (CT) scan above to look for cancers in the abdomen or pelvis.

Muscle Biopsy

Subjects seen at the NIH and Walter Reed National Military Medical Center may be asked to have a muscle biopsy if needed for their clinical care and to donate some of this tissue to the research study. The purpose of the biopsy is to confirm the diagnosis and extent of disease activity. Subjects without myositis, who are having a procedure involving removal of muscle tissue for another reason, may also be requested to donate a piece of their muscle tissue for this research study. If a muscle biopsy or muscle tissue removal is needed for your care, we will ask to obtain small pieces of muscle tissue so that researchers can study the metabolism of your tissues. The muscle cells will also be cultured when the samples are obtained fresh so that studies of the changes in your genes, their chemistry and their expression may be performed.

A surgeon experienced in muscle biopsies will perform the biopsy or tissue removal. The surface of the skin over the affected muscle, an area the size of a quarter, will be numbed by injecting a medication called lidocaine. A small incision (about one quarter inch long) will be made and several small pieces of the muscle (each the size of a pea) will be removed. In some cases you may be given medication by vein just before the biopsy to decrease your pain and make you less aware of the procedure. This will require you to not eat or drink after midnight on the night before the biopsy. In this situation, an anesthesiologist would consult with you before the muscle biopsy procedure to determine the best medications to be used for your particular situation. After the biopsy is taken, antibacterial ointment (to reduce the risk of infection) and steri-strips (small tape like band aids) or dermabond (a glue-like material) will be applied to the muscle biopsy site and this will be covered with a bandage and an elastic wrap. An ice pack will be applied after the biopsy. You

PATIENT IDENTIFICATION**CONTINUATION SHEET for either:**

NIH-2514-1 (10-84)

NIH-2514-2 (10-84)

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will be given instructions about how to care for the biopsy site. Some patients may experience pain after the biopsy and pain medication will be available.

QUESTIONNAIRES AND FOLLOW-UP CONTACTS

In order to determine if you have had certain exposures in the past, we will ask about your past occupations in the military, deployments, infections, stressful life events, and other exposures of interest to the study by having you complete questionnaires. Depending on the answers to these questions, you may be contacted by phone by persons involved in this study to clarify certain answers and to obtain more detailed information about your occupations or if additional samples or information is needed in future aspects of the study.

Your doctor may also be contacted in the future for additional information or to obtain additional blood samples from you. You also may be asked to consider participating in future studies. Your participation in this and all future studies is completely voluntary.

RISKS OR DISCOMFORTS TO YOU IF YOU TAKE PART IN THIS STUDY

Your participation in this study is VOLUNTARY. If you do not participate, there will be no penalty, and you will lose no benefits to which you are otherwise entitled. Even if you participate, you may choose to not answer any question on the survey that you are uncomfortable answering. Maximum participation, however, will help the researchers better understand the health issues being studied.

You may reasonably expect to experience the following risks and/or discomforts. The major risks of blood drawing involve the pain of the needle puncturing the skin and the risk of getting a bruise. There is also a small chance of infection or bleeding around the spot where the blood was drawn and a very few persons may faint during blood drawing. You will receive appropriate treatment for any complications of this sort.

If you have a muscle biopsy, you may expect to have discomfort and/or pain, bruising at the time of the biopsy and persistent soreness for the next several days. There is also the unlikely possibility of bleeding and infection and a scar after the biopsy is healed. In rare cases a thick, irregular skin scar called a keloid may form. This is caused by excessive tissue growth at the site of the incision. If medications by vein are administered before the procedure for sedation, some of these medications may cause side effects. These side effects include drowsiness that would occur in most cases, nausea or vomiting in 5-10% of cases, decreased breathing or decreased heart function in 1-5% of cases, dizziness for several hours after the biopsy in 5-10% of cases, or other unpredictable reactions to the medication. You will be closely monitored for any problems by the anesthesiologist who administers these medications. These medicines may also affect your memory of the procedure. If some of the tissue from the muscle biopsy is taken for research purposes you may have slightly more pain or a small chance of additional bleeding when the research pieces are removed.

Some people are concerned that research about genetic causes of illness may give information that is not only about themselves, but also about their relatives and other groups of people who are like them. Because the diseases we are studying result from many genes and exposures, it is unlikely, although possible, that we will learn genetic information in this study that can be used to diagnose or predict autoimmune diseases in you or your family.

It is possible that while completing the questionnaire you may experience emotional distress in recalling stressful experiences. Another risk associated with this study is the inadvertent disclosure of personal information, however, safeguards are in place to minimize the possibility of this happening. Your information will be delivered to NIH investigators or their contractors by FAX, by encrypted email, or by overnight courier (using a sealed envelope).

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The researchers will learn new medical information about you from the testing, as well as new details about your autoantibodies and your DNA, and it is possible that this information, or the changes seen in your blood samples, may be associated with a specific type of disease and this could affect your ability to obtain health insurance in the future. NIH and the Clinical Center, like other hospitals, may be required to release such information to insurance companies if you have signed a release of information form. 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. According to this law, health insurance companies or group health plans (as of May 21, 2010) cannot request your genetic information or use it to make decisions about your eligibility or premiums; and employers cannot use it in deciding to hire, promote, or fire you, or in setting the terms of your employment (as of Nov 21, 2009).

The following link contains details on this policy:

<http://www.genome.gov/Pages/PolicyEthics/GeneticDiscrimination/GINAInfoDoc.pdf>. You may ask your research team for additional information or a copy of The Genetic Information Nondiscrimination Act of 2008 informational document.

Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

BENEFITS TO YOU OF TAKING PART IN THIS STUDY

This is a research study. By donating information about your health and exposures, as well as your blood or biopsy samples, you may not personally benefit from this study. However, you may be helping scientists discover genetic differences in our cells that make some people more sensitive to environmental factors or in understanding which environmental exposures may be related to disease. While there may be no direct benefit to you from participation, the military is expected to benefit from better knowledge about health problems of patients who have developed an autoimmune muscle disease while serving in the military.

The physicians involved in your care at the NIH will not take over your clinical care. We will, however, work with your referring physician and make treatment recommendations if needed. If you have myositis, you may benefit directly from participation in this study by undergoing a thorough clinical evaluation, the results of which will be shared with your doctor in order to help them plan the most appropriate treatments for you. If you do not have myositis, you still may benefit from participation by a thorough clinical evaluation to rule out autoimmune or muscle disease. If we discover any new information during the study that might affect your health, we will notify you and your health care provider immediately.

WHAT OTHER CHOICES YOU HAVE BESIDES TAKING PART IN THIS STUDY

You have the alternative of not participating in this study.

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RESEARCH USE AND DISPOSITION OF HUMAN SAMPLES AND DATA

YOUR INDIVIDUAL SURVEY DATA WILL BE CONFIDENTIALLY MAINTAINED AND WILL NOT BE SHARED WITH STAFF WHO ARE NOT ACTIVELY PARTICIPATING IN THIS STUDY.

Your blood samples will be processed in the NIH and by NIH contractors for testing and kept for indefinite storage in freezers. Your samples will be stored at two sites: in the laboratory of Dr. Frederick Miller in Bethesda, MD, and in the repository of the National Institute of Environmental Health Sciences in Research Triangle Park, NC. The reason for duplication of long-term storage at different locations is to ensure against accidental loss of frozen samples if an electrical or mechanical failure occurs at one of the sites.

We will store all your samples with a code rather than your name. This code will be kept secure in a locked area or in computer files that only a few investigators or their designees in this study can access with a password. Coding is done to protect your identity and only those researchers closely involved with the progress of the study will have access to the locked files that can link the code to your name or other private information. These coded samples will be used to complete studies by investigators involved in this protocol. When data are transferred to investigators with approved projects, no identifying information about you will be provided to these investigators. These investigators will not know your name and will not know which samples are yours.

As part of this protocol, you have sent information that will help us to identify you in the military databases. This information (such as your social security number, gender, date of birth, name, and branch of military service) will be retained only until you can be located in these databases by the people with access to them, and then your social security number, name and date of birth will be removed from the records of the investigators by the military researchers who are working with these databases.

As the study is funded by the Department of Defense (DoD), representatives from the DoD are eligible to review research records as part of their responsibility to protect subjects in DoD funded studies.

WHAT TO DO IF YOU DECIDE TO WITHDRAW FROM THIS STUDY

You may withdraw from this study at any time by providing signed and written notification to your NIH doctor or to the health care provider who enrolled you into this study. You may ask to no longer be contacted by us and to not return to the NIH. In this case, we will no longer contact you by phone, email or mail. If you withdraw from the study, however, your samples and data will still be maintained for study purposes until the end of the study. If you decide to withdraw from this study, it will not in any way affect your eligibility for medical care or participation in future research at the NIH.

If you withdraw, upon your written request, we will remove any of your identifying information from your stored samples. If you withdraw and state that you wish your samples to be destroyed, we would destroy the original donated samples, but not the data or research materials derived from the original samples. Also we would not destroy the information collected about you in your forms, tests and questionnaires. We would, however, remove any of your identifying information from these materials so they could not be traced to you. For samples that have already been distributed to approved researchers, an attempt will be made to have these samples destroyed, consistent with your wishes. We will not be able to retract analyses or publications that used your information prior to your written request.

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COMPENSATION

Once you have enrolled in the study and we have obtained all your questionnaires and samples, you and your referring healthcare provider (who has completed the study questionnaire) will each be paid \$100 for the time, expense and inconvenience involved in participation. In some cases you may be asked to return for one or more additional visits to repeat some of the research tests and, if this occurs, you will be paid an additional \$100 for each return visit. If you are asked to return to see your local health care provider to obtain additional samples, your health care provider will be paid \$100 for each visit. Patients who contribute a new muscle biopsy specimen for the research as part of their participation in this study will be paid an additional \$100.

Please note that under 24 USC 30 payments to Federal Employees and Active Duty military personnel for participation in research while on active duty is limited to blood donation and may not exceed \$50 per blood draw. You may not receive any other payment or non-monetary compensation for participation in a research study unless you are off duty or on leave during the time you are participating

CONFLICT OF INTEREST STATEMENT

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 has investigators(s) who are not NIH employees. They are expected to comply with their Institution's conflict of interest policies.

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CONSENT FOR LONG-TERM STORAGE OF YOUR INFORMATION AND SAMPLES FROZEN FOR POSSIBLE FUTURE RESEARCH THAT MAY BE EITHER RELATED OR UNRELATED TO THIS PROJECT

Thank you for agreeing to participate in this study. Now we would like your permission for the NIH to store the remainder of your blood and other samples, as well as your coded information, for possible future research. . Possible areas of future research that we may use your samples for include testing for new autoantibodies not yet identified, testing for certain infectious or non-infectious agents, or genes or their modifications found to be associated with autoimmune disease, which are discovered after all subjects are enrolled in this study.

We will store all your samples with a code rather than your name. This code will be kept secure in a locked area or in computer files that only a few investigators or their designees in this study can access with a password. Coding is done to protect your identity and only those researchers closely involved with the progress of the study will have access to the locked files that can link the code to your name or other private information.

Your remaining coded information and samples may be used to study other questions about the causes of autoimmune diseases or to study disorders unrelated to the diseases being studied in this research. Your coded information and samples will be anonymized prior to being used to study diseases or disorders unrelated to the purposes of this research protocol.

Your consent to frozen storage of your samples does not affect your ability to participate in this study.

_____ **I AGREE to frozen storage of my samples and information for possible future research.**
(Initial)

_____ **I DO NOT agree to this.**
(Initial)

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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 authorized hospital accreditation organizations.

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. Reimbursement of travel and subsistence will be offered consistent with NIH guidelines.

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. Frederick W. Miller; NIH Building 10, Room 4-2330, Bethesda, MD 20892, Telephone: 301-451-6273 or toll free at 888-271-3207. Other researchers you may call at 888-271-3207 are Dr. Adam Schiffenbauer, Dr. Lisa Rider or Ms. Anna Jansen.

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:

<p>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.</p> <p>_____ Signature of Adult Patient/Legal Representative _____ Date</p> <p>_____ Print Name</p>	<p>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.)</p> <p>_____ Signature of Parent(s)/Guardian _____ Date</p> <p>_____ Print Name</p>
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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 _____
Print Name

**THIS CONSENT DOCUMENT HAS BEEN APPROVED FOR USE
FROM JANUARY 27, 2015 THROUGH JANUARY 26, 2016.**

<p>_____ Signature of Investigator _____ Date</p> <p>_____ Print Name</p>	<p>_____ Signature of Witness _____ Date</p> <p>_____ Print Name</p>
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PATIENT IDENTIFICATION

CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY (Continuation Sheet)

• Adult Patient or • Parent, for Minor Patient
NIH-2514-1 (07-09)
P.A.: 09-25-0099
File in Section 4: Protocol Consent