CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

MEDICAL RECORD

• Adult Patient or • Parent, for Minor Patient

INSTITUTE: National Institute of Environmental Health Sciences

STUDY NUMBER: 11-E-0072 PRINCIPAL INVESTIGATOR: Frederick Miller, M.D., Ph.D.

STUDY TITLE: Environmental Risk Factors for the Anti-Synthetase Syndrome

Initial Review Approved by the IRB on 09/28/10
Amendment Approved by the IRB on 02/04/11 (A) Date Posted to Web: 02/10/11

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

If you are the parent of a child enrolling in the study you are reading this consent form for your child, who will be the participant in the study.

Researchers at the National Institute of Environmental Health Sciences (NIEHS), in collaboration with other researchers, are conducting a study to try to understand why some persons develop certain diseases while other persons do not. Scientists believe that differences in exposures, or people’s responses to certain exposures in the environment as a result of differences in the genetic makeup of the person, may determine who develops certain diseases.

You are being asked to enroll in this study because you either have recently developed a form of muscle disease called myositis or because you are healthy and have volunteered to be in a comparison group of people who do not have a form
of myositis or any other autoimmune disease. The information and samples from myositis patients cannot be analyzed or fully understood unless it is compared to similar information and samples from healthy people. The primary group being studied consists of persons with myositis who also produce a protein in the blood that reacts with the person’s tissues called an autoantibody. These autoantibodies bind to certain parts of the person’s own cells, called synthetases, that are involved in making new proteins. They are therefore called anti-synthetase autoantibodies. A syndrome called the anti-synthetase syndrome, which includes myositis and lung disease, is associated with having the anti-synthetase autoantibodies. This study is being conducted to determine if persons with the anti-synthetase syndrome have had different environmental exposures before disease onset compared to other patients with myositis who do not have these autoantibodies and compared to healthy individuals who do not have an autoimmune disease. About 150 myositis subjects with anti-synthetase syndrome will be compared to 150 matched persons who are their friends, cousins or other volunteers, who do not have myositis or another autoimmune disease. The same 150 myositis subjects with the anti-synthetase syndrome will also be compared to 150 myositis patients without the anti-synthetase syndrome.

You will not be in a treatment program for your medical conditions at 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.

**RESEARCH TESTS OR PROCEDURES FOR THIS STUDY**

If you agree to participate in this study, you will be enrolled by phone discussions with NIH researchers and by a visit to your local health care provider. This evaluation will first involve obtaining your medical records and answering questions about your medical history. If you qualify for the study, you will complete and sign a form, which gives us your contact information and permission to do these studies and assigns you an NIH number.

Then you will be mailed an enrollment kit that contains the consent form, written questionnaires house dust collection materials and blood tubes. You should read the consent carefully and ask the NIH researcher any questions you have about it. The NIH researcher will discuss the protocol and consent with you in detail and allow you to ask any questions. If you agree to enroll, then you will sign the consent with a witness present who will also sign the consent. You will then collect the dust sample with your vacuum cleaner, complete the questionnaires and take the signed consent and questionnaires, dust sample and blood tube kit to your local doctor. Your local doctor will perform a brief physical examination and complete the physician questionnaire and include copies of your records along with the blood tubes and possibly other clinical specimens for research purposes.

All this information, your signed consent, the questionnaires and your dust and blood samples will be returned to the NIH or its designees for processing. You will be given a copy of the consent to keep for your records. When we receive this kit, you and your local health care provider will each be paid $100 to compensate you for your time and expenses. The specific tests that you will have depend on whether you have myositis or are a volunteer without myositis or any other autoimmune disease.

**TESTS THAT ALL SUBJECTS WILL HAVE**

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

1) Allow us to obtain and review your past medical records from your doctors or other health care providers. The information from your records will be kept strictly confidential.

2) You will spend about 1-2 hours completing forms about your past medical history and the types of exposures you have had at work, at home and elsewhere. If you have myositis you will also be asked if you have had certain infections, engaged in heavy exercise or physical exertion, reacted to the sun in a particular way, used tobacco or alcohol, or
experienced stressful events in your life before the diagnosis of your disease. If you are a healthy volunteer you will be asked if you had the same exposures before the date of diagnosis of disease of the myositis subject to which you are matched, which will be printed on your questionnaire.

3) You will be given a kit that contains instructions and a filter to be put onto your vacuum cleaner to collect house dust in your bedroom that will be stored for possible future analyses of infectious or toxic agents based on the other results from the study.

4) You will undergo a medical history and physical examination by your physician who will also complete 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 these illnesses. 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.

5) If you are an adult you will have about 8 tablespoons (120 milliliters) of blood collected for a number of clinical and research tests. If the subject is a child the amount of blood drawn will be less and will depend on the size of the child. 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.

The following tests will be performed on the blood samples:

a) To confirm that you do not have certain diseases or medical problems that you are unaware of, a blood specimen will be collected for routine clinical chemistry and other blood studies, including tests for autoantibodies found in patients with rheumatic diseases.

b) Because certain environmental exposures may cause certain diseases, we will 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.

c) The blood testing you will undergo includes tests of muscle enzymes and other blood chemistries that may reflect ongoing inflammation.

d) 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.

e) The hereditary factors that determine many of our physical characteristics and may predispose to disease are called genes. To identify which genes may be related to disease, DNA, the chemical substance that contains the genes, is extracted from blood or tissues from healthy persons and from those with disease and compared using statistical methods. We will be testing your blood for the genes for human leukocyte antigens (HLA) and for other genes that may be important in regulating the immune system. This will allow us to determine if certain forms of these genes are more common in patients with the anti-synthetase syndrome.

f) We will be comparing the metabolism in your blood cells with the metabolism in blood cells from other groups of subjects to see if persons with the anti-synthetase syndrome have a different metabolism. The metabolism in your blood cells is controlled by how some genes are activated (turned on) and some are deactivated (turned off) and this determines which proteins are made. Because this pattern of proteins and gene activation may help us
g) We are asking you to let us have samples of your blood and urine to store for future research on the causes of autoimmune diseases and their complications. We will also ask to collect any past blood or tissue biopsy specimens that are no longer needed for your clinical care, for research purposes. Your blood samples will be processed in the NIH and by our contractors for testing and for storage in freezers. We will store all your samples with a code and not with your name. 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 described in this consent form by investigators involved in this protocol.

The investigators conducting this study do not plan to provide you with the results of the research tests mentioned above because further research may be necessary before the results are meaningful. If meaningful information is developed from this study that may become important for your health, however, 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 Drs. Frederick Miller or Lisa Rider.

**TESTS THAT ONLY MYOSITIS SUBJECTS WILL HAVE**

If you have myositis and your doctor believes additional tests are needed to better understand your disease and determine your treatment, you may have some of the tests listed below. You or your insurance company will need to pay for these tests but their results will be sent to the study investigators:

**Electrocardiogram:** This is a test measuring the electrical activity of your heart. Wires are attached to the chest wall, arms and legs using a sticky paste which takes only a few minutes. There is no discomfort from this procedure. If the electrocardiogram shows any abnormalities, an echocardiogram, or sound-wave study of your heart function would also be done. No harmful consequences of this procedure are known.

**Pulmonary Function Tests:** Your lung function and breathing would be assessed by a pulmonary function test if you are having any difficulties with breathing. You would have to blow into a tube for a few seconds. If this test shows abnormalities, a chest x-ray or chest CT scan would also be done.

**Chest X-ray:** This test will be done only if your doctor decides it is needed for your care. A chest X-ray uses a small amount of radiation to determine if there are any abnormalities in your lungs or other chest tissues. Please, however, notify your doctor if you have had any other recent x-ray studies since effects of radiation can be additive. If you are pregnant you will not be permitted to participate in this aspect of the study since it is best to avoid radiation to the human embryo, so if you are a woman of child-bearing potential please talk with your doctor to see if you need to have a pregnancy test before any x-rays.

**Chest CT scan:** If your doctor decides it is needed for your care because your chest x-ray is abnormal or you have significant breathing problems that need further evaluation, you may have a CT scan of the chest. This test involves having you lie on a padded table, which is slowly moved into a large tube inside the machine where multiple X-rays will be taken. Please notify your doctor, however, if you have had any other recent x-ray studies because the effects of radiation can be additive. If you are pregnant you will not be permitted to participate in this aspect of the study because it is best to avoid radiation to the human embryo, so if you are a woman of child-bearing potential please talk with your doctor to see if you need to have a pregnancy test before any x-rays.
Magnetic Resonance Imaging Scan of the Lower Extremities: This study produces a picture of your muscles or the tissue under the skin (subcutaneous tissue) using magnetism. The test involves having you lie on a padded table, which is slowly moved into a large tube inside the machine where there is a powerful magnet. Watches, keys, coins, bank and credit cards, and certain types of jewelry cannot be brought into the room with the machine because of the power of the magnet. You will have to lie very still for the test, approximately 30 minutes. This test involves no x-rays and there are no known risks from the test, although some people may feel claustrophobic. You can communicate with the MRI technician during this test and the procedure will be stopped if you cannot tolerate it. If you are unable to lie still for 30 minutes for this test, you will not be able to undergo this evaluation, but may participate in other aspects of the study. You will sign a separate consent form for the MRI that will explain that you cannot have this procedure if you have a pacemaker, defibrillator, certain ear implants, or some types of clips used on brain aneurysms.

Other Procedures: When clinically indicated, additional testing may be recommended for you, including an electromyography study or a muscle or lung biopsy. These procedures require separate informed consent and will be further explained to you if they are recommended. Also, because the risk of cancer is increased in adults with myositis, if you have myositis it is important for you to be carefully evaluated for cancer. 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, stool tests to look for blood or an abdominal CT scan similar to the chest CT scan above to evaluate cancers in the abdomen or pelvis. Children may rarely undergo other recommended tests to check for cancer.

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, hobbies, other activities, 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.

You or your doctor may be also contacted in the future for additional information or to give additional blood samples, and you may be asked to consider participating in future studies. Your participation in this and all future studies is completely voluntary. You may withdraw from this study at any time, and you may decline to participate in any follow-up studies without in any way affecting your eligibility for participation in future research at the NIH.

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

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.

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.
The researchers will learn new medical information about you from the testing as well as new details about your cells and your DNA, and it is possible that this information, or the changes seen in your blood samples, may be associated with a specific 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. However, as explained below, a new 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.

**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, but 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. 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 to your doctor if needed. If you have myositis, you may potentially 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 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.

**WHAT WILL HAPPEN TO THE SAMPLES OR INFORMATION THAT ARE COLLECTED FROM THIS STUDY?**

Your DNA/blood/cell/other samples/study records will remain stored indefinitely in order to allow for the studies to be completed and to allow for retesting of your samples as necessary. Your DNA/blood/cell/and other 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. The reason for duplication of long-term storage is to insure against accidental loss of frozen samples. All stored DNA/blood/cell samples and information generated from this study will be identified by a code and not your name. This code will be kept secure in a locked area or in computer files that only Dr. Miller and a few specific investigators or their designees in this study can access with a password.

As part of this protocol, some of the data are stored coded in controlled access databases in which protocol investigators with approval have access to the data; however, your information is coded and you cannot be personally identified. When data are transferred to investigators with approved projects no identifying information about you will be provided to these investigators. Your coded information or samples may be sent to other investigators involved in this protocol for research purposes, as defined in this protocol. These investigators will not know your name and will not know which samples are yours.

The collaborating investigators may also collect information and samples from study subjects and are located at: the National Institutes of Health in Bethesda, MD and Research Triangle Park, NC; the Johns Hopkins University, Baltimore, MD; the Brigham and Women's Hospital, Boston, MA; the Medical University of South Carolina, Charleston, SC; the University of Pittsburgh, Pittsburgh, PA; and The Mayo Clinic, Rochester, MN.

Your samples will not be available for routine care or commercial diagnostic testing. It is possible that your samples or study records may be shared anonymously with other investigators for other research use beyond the scope of this study.
Such usage will be strictly anonymous, in that no identifying information about you, including your name, will be provided to the researcher, and there will be no way for the researchers to link these samples back to you.

**WHAT TO DO IF YOU DECIDE TO WITHDRAW FROM THIS STUDY**

You may withdraw from this study at any time by providing written notification to your primary NIH doctor. You may ask to no longer be contacted by us. In this case, we will no longer contact you by phone or mail. 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.

**COMPENSATION**

You and your referring health care provider will each be paid $100, for the time, expense and inconvenience involved in participation, after your enrollment into the study. 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 and your local health care provider will again each be paid $100.

**CONFLICT OF INTEREST STATEMENT**


2. This protocol has investigators(s) who are not NIH employees. They are expected to comply with their Institution’s conflict of interest policies.
CONSENT TO STORE YOUR INFORMATION AND SAMPLES FROZEN FOR POSSIBLE FUTURE RESEARCH

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. Your information and frozen samples will be stored under a number code. Only the NIH study researchers will be able to match this code with your name. The remainder of your coded information and specimens may be used for additional studies of autoimmune diseases and their causes. Your remaining coded information and samples may also be used to study disorders unrelated to the diseases being studied in this research. The researchers will not have access to your name or any identifying information about you.

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

☐ I DO NOT agree to this

____________________________________________         ___________________
Signature of Adult Patient/Parent/Legal Representative             Date

____________________________________________         ___________________
Signature of Witness                                                                  Date

____________________________________________         ___________________
Signature of Investigator                                                                  Date
CONSENT TO USE YOUR SAMPLES FOR GENOMIC RESEARCH

The researchers would like permission to use you DNA samples for more extensive genetic testing called genome-wide association studies that are trying to determine the genetic risk and protective factors for myositis. This test analyzes a large number of parts of your DNA and allows researchers to see if genes not previously known to be associated with disease are important in developing some diseases. We are also asking your permission to put your coded information from your DNA testing and certain medical record information in a government health research database, available on the internet. Aggregate data that combines all participants in this study would be available to anyone on the internet. Your individual coded medical information and information from more detailed analyses of the coded samples will be put in a controlled-access database. The information in this database will be available in a secured manner only to qualified researchers who have received approval from an NIH Data Access Committee. Please note that traditionally-used identifying information about you, such as your name, address, telephone number, or social security number, will not be put into the public genetic databases for this project and will also not be available to these approved researchers.

Your privacy is very important to us and we will use many safety measures to protect your privacy. However, in spite of all of the safety measures that we will use, we cannot guarantee that your identity will never become known. Under Federal law, anyone has a right to request the release of an individual's coded data (data that does not contain personally identifiable information) from the genome-wide database, including members of the public, insurers, employers and law enforcement agencies. NIH would take a legal position that this data is not releasable, but it is unclear that this would be upheld in court. Although your genetic information is unique to you, you share some genetic information with your children, brothers, sisters, and other blood relatives. Consequently, it may be possible that genetic information from them could be used to help identify you. Similarly, it may be possible that genetic information from you could be used to help identify them. While the public genetic databases developed for this project will not contain information that is traditionally used to identify you, such as your name, address, telephone number, or social security number, it is possible using sophisticated laboratory techniques to link your genetic information in these databases back to you. For example, someone could compare information in these genetic databases with information from you (or a blood relative) in another database and be able to identify you (or your blood relative).

Since some genetic variations can help to predict the future health problems of yourself and your blood relatives, this information might be of interest to employers, health providers, insurance companies, and others. Patterns of genetic variation also can be used by law enforcement agencies to identify a person or his/her blood relatives. Therefore, your genetic information potentially could be used in ways that could cause you or your family distress, such as by revealing that you (or a blood relative) carry a genetic disease. It also is possible that there could be violations to the security of the computer systems used to store the codes linking the genetic and medical information to you. There also may be other privacy risks that we have not foreseen. While we believe that the risks to you and your family are very low, we are unable to tell you exactly what all of the risks are.

A new 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). Be aware that this new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.
The following link contains details on this policy: [http://www.genome.gov/Pages/PolicyEthics/GeneticDiscrimination/GINAInfoDoc.pdf](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.

We believe that the benefits of learning more about myositis outweigh these potential risks. There is a great potential for researchers and health professionals to learn a great deal about the causes of these diseases and from that, to develop better ways to prevent, detect, treat, and cure these illnesses. We will make every attempt to protect your confidentiality and to make sure that your personal identity does not become known.

You may still participate in the study even if you do not choose to have genome-wide testing and allow your health information to be placed in the government database.

- [ ] I AGREE to genome-wide association studies of my DNA and inclusion of the results into a government database

- [ ] I DO NOT agree to this

____________________________________________      ___________________
Signature of Adult Patient/Parent/Legal Representative          Date

____________________________________________     ___________________
Signature of Witness                                                                Date

____________________________________________     ___________________
Signature of Investigator                             Date
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, Telephone: 301-451-6273 or toll free at 888-271-3207. Other researchers you may call at 888-271-3207 are: Dr. Lisa Rider, Dr. Irene Whitt or 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:

#### 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.

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#### 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.)

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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.

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### THIS CONSENT DOCUMENT HAS BEEN APPROVED FOR USE FROM SEPTEMBER 28, 2010 THROUGH SEPTEMBER 27, 2011.

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