

**Office of Institutional Board of Research Associates
NYU School of Medicine**

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Program Director: Jill P. Buyon, M.D.

INFORMED CONSENT FORM TO PARTICIPATE AND AUTHORIZATION FOR RESEARCH

TITLE OF RESEARCH: RESEARCH REGISTRY FOR NEONATAL LUPUS (RRNL)

A. PURPOSE OF THE STUDY:

You are being invited to participate in the Research Registry for Neonatal Lupus (*RRNL*). The *RRNL*, was initiated at the Hospital for Joint Diseases (HJD) and relocated to the New York University Hospitals Center (NYULMC), with the support of the National Institutes of Health (*NIH*) through funding from the National Institute of Arthritis and Musculoskeletal and Skin Diseases (*NIAMS*).

The purpose of this research is to gather information on as many cases as possible in order to facilitate research in a disease called Neonatal Lupus (*NL*). This disease is rare and affects babies during pregnancy and afterwards. The mothers of the babies have antibodies to certain proteins called SSA/Ro and SSB/La. These autoantibodies may be present in a woman who appears to be totally healthy or in association with diseases such as systemic lupus erythematosus or Sjogren's Syndrome.

During pregnancy these autoantibodies are transported across the placenta (tissue that provides food for an unborn baby) to the growing fetus along with normal antibodies (substances that help fight infection). The most serious problem that can occur in the baby, if a mother has these autoantibodies, is congenital heart block (CHB). This is a condition in which the heart beats abnormally slowly, due to a blockage of the normal signal sent from the top of the heart to the middle. The heart block is almost always permanent, and in most cases, use of a life-long pacemaker is needed.

Another problem that can be part of *NL* is a skin rash, which may appear after birth. This rash is usually made worse by exposure to sunlight and disappears at about six months of age. Other less common problems that can occur in *NL* can be low blood counts and liver abnormalities. In summary, some babies with *NL* have only CHB, some have only skin rashes, some have only blood or liver problems and some babies have two or more of these problems.

As a candidate for enrollment you fall into one of the following three categories:

- You are the sibling (sister or brother) of a woman who has a child/children with any problem of *NL*.
- You are the maternal grandmother of a child/children with any problem of *NL*.
- You are the maternal grandfather of a child/children with any problem of *NL*.

Everyone enrolled in the *RRNL* will be asked to donate blood so we can isolate your DNA. In certain instances, we **may** test your blood for SSA/Ro and SSB/La antibodies. In the case of patients who decline donating blood, they will be asked to donate saliva samples and DNA will be isolated from those samples. All donated samples are for use by Dr. Jill Buyon and her research team, as well as other investigators with approved research protocols to the *RRNL*.

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Subject's Initials: _____ Date: _____

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The eventual hope is that by enrolling individuals, reviewing medical records and collecting additional blood for antibody testing and isolating DNA from blood and saliva for the ongoing research, we will find ways to prevent and treat NL.

B. SUBJECT PARTICIPATION:

We estimate that a total of approximately **459** families will have enrolled in the *RRNL* by the end of the current contract period.

SUBJECT PARTICIPATION:

- Inpatient
- Outpatient
- Other - Participation involves signing consent forms, completing an enrollment questionnaire, signing requests for the release of medical records and returning these documents to Dr. Buyon by mail, and providing blood for testing of antibodies and isolation of DNA from blood and saliva samples.

Siblings of women with anti-Ro/La antibodies who have a child/children with NL. Your participation will involve:

- Reading and signing a Consent Form;
- Completing an Enrollment Questionnaire (demographic and general questions about your health).
- Donating blood for the isolation of DNA and in some instances, serological testing for SSA/Ro and SSB/La antibodies. The antibody testing of your blood and isolation of DNA will be performed at the *HJD* Clinical Immunology Lab and the research laboratory of Dr. Jill Buyon respectively.
- In lieu of a blood sample, donating a saliva sample from which we will isolate DNA in the research laboratory of Dr. Jill Buyon.
- Results of the DNA testing will be accumulated over the duration of the grant. Any resulting publications in scientific journals will be shared with everyone enrolled in the grant. DNA results will **NOT** be available on an individual basis.

Maternal grandmothers/grandfathers of NL-affected child/children. Your participation will involve:

- Reading and signing a Consent Form;
- Completing an Enrollment Questionnaire (demographic and general questions about your health).
- Donating blood for the isolation of DNA and in some instances, serological testing for SSA/Ro and SSB/La antibodies. The antibody testing of your blood and isolation of DNA will be performed at the *HJD* Clinical Immunology Lab and the research laboratory of Dr. Jill Buyon respectively.
- In lieu of a blood sample, donating a saliva sample from which we will isolate DNA in the research laboratory of Dr. Jill Buyon.
- Results of the DNA testing will be accumulated over the duration of the grant. Any resulting publications in scientific journals will be shared with everyone enrolled in the grant. DNA results will **NOT** be available on an individual basis.

Each single request for the donation of blood will be for the following quantities:

- Any adult enrolled in the *RRNL* will be asked to donate 27 ml (**5.4 teaspoons**).

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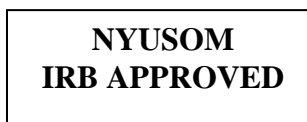
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Each single request for the donation of saliva will be for the following quantities:

- One 2ml container (< 1 teaspoon) or saliva (or)
- Five saliva sponges cut into a kit and sealed to preserve the DNA and prevent bacterial growth.

Specimen kits for the collection of blood for antibody testing and the isolation of DNA or saliva collection kits for the isolation of DNA will be mailed to your home. We will also provide return postage for the kits to be shipped to Dr. Buyon's attention at the *NYULMC*. We may request additional blood and DNA samples over the remaining performance period of the grant. One complete kit contains **3** small tubes: 2-red top tubes (10 ml each) and 1-lavender top tube (7ml) (DNA samples). The saliva collection kits will either be a saliva collection container (2ml) or five saliva collection sponges. Your participation will involve **0** visits to the host medical facility (*HJD*). Donating blood for antibody testing and the isolation of DNA will necessitate a brief visit (approximately **15-20 minutes**) to your primary care physician. Donating a saliva sample using either a collection cup or five saliva sponges should take less than **10-15 minutes**. It should take less than **30 minutes** to read the consent form, complete the enrollment questionnaire.

C. DESCRIPTION OF THE RESEARCH:

Dr. Buyon and her research staff will recruit and enroll anti-SSA/Ro and/or anti-SSB/La positive mothers and their *NL*-affected children, fathers, unaffected siblings, maternal aunts and uncles and maternal grandparents of *NL* affected children for the *RRNL*. Patients are referred to the *RRNL* by physicians who are currently treating them or their *NL*-affected child. Patients also contact the *RRNL* staff after learning about the *RRNL* from an independent source.

Participation will involve several steps:

Siblings of women with anti-Ro/La antibodies who have a child/children with NL. Your participation will involve:

- Reading and signing a Consent Form;
- Completing an Enrollment Questionnaire (demographic and general questions about your health).
- Donating blood for antibody testing and for the isolation of DNA. The antibody testing of your blood and isolation of DNA will be performed at the *HJD* Clinical Immunology Lab and the research laboratory of Dr. Jill Buyon.
- In lieu of a blood sample, donating a saliva sample from which we will isolate DNA in the research laboratory of Dr. Jill Buyon.
- Results of the DNA testing will be accumulated over the duration of the grant. Any resulting publications in scientific journals will be shared with everyone enrolled in the grant. DNA results will **NOT** be available on an individual basis.

Maternal grandmothers/grandfathers of NL-affected child/children. Your participation will involve:

- Reading and signing a Consent Form;
- Completing an Enrollment Questionnaire (demographic and general questions about your health).

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- Donating blood for antibody testing and for the isolation of DNA. The antibody testing of your blood and isolation of DNA will be performed at the *HJD* Clinical Immunology Lab and the research laboratory of Dr. Jill Buyon.
- In lieu of a blood sample, donating a saliva sample from which we will isolate DNA in the research laboratory of Dr. Jill Buyon.
- Results of the DNA testing will be accumulated over the duration of the grant. Any resulting publications in scientific journals will be shared with everyone enrolled in the grant. DNA results will **NOT** be available on an individual basis.

Applicable to Everyone enrolled in the RRNL who donates blood samples:

- Donated blood and saliva samples will be processed by Dr. Buyon’s research team as follows:
 - A small portion of the samples will be tested for the presence of anti-SSA/Ro and anti-SSB/La autoantibodies.
 - DNA will be extracted from a small portion of the blood or saliva samples and stored for future genetic evaluation. A Research Protocol to the *RRNL* proposes to develop a ranking for evaluation of 100 candidate genes potentially involved in *NL*–Heart Block. Genes will be added or deleted from the list as warranted and the ranking of genes to be investigated will constantly be revised, particularly according to the interests and progress of Dr. Buyon’s research group and other collaborators and investigators in the field of *NL*.
 - A permanent resource of cells (also called a permanent cell line) from donated blood and saliva samples will be established and may be used for other studies at a later time.
 - The remaining quantity of blood and/or saliva donated for research will be aliquoted (divided) into very small quantities and stored for future use. The *RRNL* maintains a specimen bank of sera, plasma and DNA samples. The samples are stored with a confidential code, but not with your name or any other unique identifying information.
- By participating in the *NYULMC/NIAMS RRNL*, you are agreeing to allow blood, DNA samples and health information on you to be shared with researchers across the country. Part of the *RRNL* contract with the *NIH* states that coded specimens and coded health information be made available to researchers at facilities other than *NYULMC*. These outside researchers formally apply to use the collected resources of the *RRNL* for research projects concerning *NL*. Formal applications are submitted to Dr. Buyon for initial review and then to a special Review committee to determine if the proposed research will likely yield information that will be helpful to patients and families with *NL*. Investigators applying to use the *RRNL* resources are experts in many medical specialties including pediatric cardiology (doctors who study and take care of children’s hearts), electrophysiology (scientists who study electronic pacing and monitoring of the heart) and developmental biology of the heart (doctors and medical researchers who understand how the heart tissue grows during a pregnancy). Other researchers are specialists in the field of rheumatology, including autoimmunity (how the human body deals with infections but sometimes harms its own tissue and organs), genetics (pre-determined coding for how the human body will function), cell biology as it relates to inflammation (swelling) and organ repair, as well as pediatric and adult dermatologists (doctors who treat disorders of the skin).

For some research studies an investigator will need to obtain more information and/or blood samples for antibody testing and/or blood or saliva samples for the isolation of DNA from you. For these projects you will

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first be contacted in writing by Dr. Buyon explaining the exact nature of any special research studies. If you are then willing to participate, you will be sent the name, address, and phone number of the researcher who is performing that particular study. You will be asked to contact that researcher directly. Your name will not be given out; therefore the additional research will not involve you unless you contact the researcher. Signing this consent form does not obligate you to participate in such additional studies. Each such additional study, that involves more information than that contained in the *RRNL*, will provide its own consent form.

D. COSTS/REIMBURSEMENTS:

Expense to individuals enrolling in *RRNL*. - **NONE**

This study is being sponsored by a contract from the National Institutes of Health – National Institute of Arthritis, Musculoskeletal and Skin Diseases (*NIH-NIAMS*). Salary lines for the Registry Director, Dr. Jill Buyon, the Project Administrator and members of the *RRNL* staff are paid in whole or in part by this contract.

E. POTENTIAL RISKS AND DISCOMFORTS:

For subjects enrolled in the *RRNL* who are offering to donate blood samples, the potential risks of obtaining blood specimens are few, including local hematoma (bruising at the needle puncture site), pain, and rare syncope (fainting spell). In terms of blood drawing, standard procedures will be used to avoid hematoma. In cases where patients are apprehensive (afraid of needles or the sight of blood), venipuncture will be performed with the patient supine (lying on the back). Standard emergency trays are always on stand-by at blood drawing stations. For subjects donating saliva samples, there is no risk associated with this procedure.

For some people, learning certain types of genetic information can pose social or psychological risks. Perhaps they will be anxious about their future health or that of their children. It is possible that some types of genetic information may affect employability or insurability. The genetic testing we will perform is unlikely to involve such risks for the following various reasons:

- Samples will only be identified by code number, so that your identity will be kept confidential.
- At present, we do not know for certain if results of genetic testing will be clinically meaningful. At present, knowing the results of genetic tests will not affect assessment of your health. We will provide you with published, anonymous results of all genetic testing as well as the overall work of the *RRNL* in general. The actual results of genetic testing will **NOT** be given to anyone outside of Dr. Buyon's study staff. This means that it will not be made available to you, your family members, your private physician, your employer, your insurance company or any other party as allowed by law.
 - At present, your family is already known to be affected by and at risk for *NL*. We are trying to learn more about what makes *NL* happen. Since it already happened in your family, by studying your family's samples, we will learn if any particular gene appears more frequently than in the general population. In the future this particular gene might be considered to be a "risk factor."

F. POTENTIAL BENEFITS:

There may be no direct benefit expected from your participation in this study. It is hoped the knowledge gained will be of benefit to others in the future.

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The *RRNL* and approved Research Protocols from outside investigators are designed to investigate aspects of autoimmune-associated *NL*. Procedures have been in place since September 1994 to protect the confidentiality of enrolled patients. There are no medical interventions planned for subjects other than those prescribed by their primary care givers except for having samples of blood drawn.

The potential benefits to be gained through the research performed in these projects outweigh the minimal risk of drawing blood.

G. ALTERNATIVES TO PARTICIPATING IN THE STUDY

You are free to choose not to participate in the study and your medical care will not be affected.

H. CONFIDENTIALITY:

Private information about you that identifies you will be collected and stored in the *RRNL* database and known only to Dr. Buyon and her select members of her research staff. Any data or specimens shared with other investigators for the purposes of this research project will be coded with a unique identification number in order to protect your identity. This section of the consent/authorization form describes how your information will be used and shared in this research, and the ways in which New York University Langone Medical Center/New York University School of Medicine (*NYULMC/NYUSM*) will safeguard your privacy and confidentiality.

If you agree to be in this research program, Dr. Jill P. Buyon and her study team will ask you to authorize your treating physicians to release copies of certain medical records for her review. You will be asked to voluntarily donate samples of your blood for antibody testing and/or saliva for the isolation of DNA. Testing of these donated specimens will be used to complete this research. The results of serological tests and DNA will be kept in your *RRNL* file together with other documents you have signed or questionnaires you have completed. These files are kept secure in locked file cabinets within a locked office that is located in the laboratory of Dr. Buyon. Only Dr. Buyon and members of her research team have access to your file. In addition, you agree to have permanent cell lines established on all samples donated.

Other persons and organizations, including co-investigators, federal and state regulatory agencies, and the IRB(s) overseeing the research may receive your information (without identifiers) during the course of this study. Except when required by law, study information shared with persons and organizations outside of *NYULMC/NYUSM* will not identify you by name, social security number, address, telephone number, or any other direct personal identifier.

When your study information is disclosed outside of *NYULMC/NYUSM* as part of the research, the information that can identify you as listed above will be removed and your records will be assigned a unique code number. *NYULMC/NYUSM* will not disclose the code key, except as required by law.

Confidentiality of Your Medical Records

Your research file, including copies of certain medical records you have authorized us to obtain, will be kept in accordance with state and federal laws concerning the privacy and confidentiality of medical information. The confidentiality of your research record is also protected by federal privacy regulations, as described below.

Confidentiality of Your Study Information

Your study records include information that identifies you and that is kept in research files. We will try to keep this information confidential, but we cannot guarantee it. Files are kept in a locked room of Dr. Buyon's research area at *NYULMC*. The *RRNL* Database computer is used only by Dr. Buyon and the *RRNL* Project

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Administrator, and is kept in the same locked office as the *RRNL* files. If data from this study are to be published or presented, we will first take out the information that identifies you.

Retention of Your Study Information

The study results will be kept in your research record for at least six years or until after the study is completed, whichever is longer. At that time, either the research information not already in your medical record will be destroyed, or information identifying you will be removed from such study results at *NYULMC/NYUSM*. Any research information in your medical record will be kept indefinitely.

Your HIPAA Authorization

A new federal regulation, the federal medical Privacy Rule, has taken effect as required by the Health Insurance Portability and Accountability Act (*HIPAA*). Under the Privacy Rule, in most cases we must seek your written permission to use or disclose identifiable health information about you that we use or create [your "protected health information"] in connection with research involving your treatment or medical records. This permission is called an Authorization.

If you sign this form you are giving your Authorization for the uses and sharing of your protected health information described below. You have a right to refuse to sign this form. If you do not sign the form you may not be in the research program, but refusing to sign will not affect your health care (or payment for your health care) outside the study.

This Authorization will not expire unless you withdraw it in writing. You have the right to withdraw your authorization at any time, except to the extent that *NYULMC/NYUSM* has already relied upon it or must continue to use your information to complete data analysis or to report data for this study. The procedure for revoking your authorization is described below in Section K.

By signing this form you authorize the use and disclosure of the following information for this research:

- Upon enrollment you will sign Request for the Release of Medical Records forms. We **may** use these forms to request copies of certain portions of your medical records from your physician(s). Dr. Buyon will use the information from those records to verify medical information you provided when you completed certain research questionnaires.
- Your research record.
- If available, results of serological tests (copies are available to you and we offer to send the tests results to anyone you designate).
- Results of DNA testing accumulated over the duration of the grant.
- Abstractions of medical records, diagnosis and classification for the purposes of data input for the *RRNL* and research observations made during your participation in the *RRNL* and research protocols to the *RRNL*.

By signing this form you authorize the following persons and organizations to receive your protected health information for purposes related to this research. ***It must be noted that information concerning you will always be referred to by the unique identification number assigned upon enrollment.***

- The following research sponsors and the people and companies they use to oversee, administer, or conduct the research: **National Institutes of Health (NIH) -- National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS).**
- The members and staff of the *NYULMC/NYU* School of Medicine's affiliated Institutional Review Board

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- Principal Investigator: Dr. Jill P. Buyon
- Project Administrator/Research Associate: Zoey Smith
- Specimens/abstracts of medical information to investigators not located at *NYULMC/NYU School of Medicine* with approved Research Protocols to the *RRNL*.
- Members of Dr. Buyon's Research Team at *NYULMC*.

I. COMPENSATION/TREATMENT IN THE EVENT OF INJURY:

As a participant in the *RRNL*, you will receive no medical care or medical treatment and therefore are not entitled to any compensation from either the *New York University Langone Medical Center (NYULMC)* or the *National Institutes of Health*.

J. VOLUNTARY PARTICIPATION AND AUTHORIZATION:

Your decision as to whether or not to take part in this study is completely voluntary (of your free will). If you decide not to take part in this study it will not affect the care you receive and will not result in any loss of benefits to which you are otherwise entitled.

You will be told of any significant new findings developed during the course of the research that may influence your willingness to continue to participate in the research.

Your decision as to whether to give your Authorization for the use and disclosure of your protected health information for this study is also completely voluntary; however, if you decline to give your Authorization or if you withdraw your Authorization you may not participate in the study.

K. WITHDRAWAL FROM THE STUDY AND/OR WITHDRAWAL OF AUTHORIZATION:

If you decide to take part in the study, you may withdraw from participation at any time without penalty or loss of benefits to which you would otherwise be entitled. You may also withdraw your Authorization for us to use or disclose your protected health information for the study.

If you do decide to withdraw your consent, we ask that you contact Dr. Jill P. Buyon in writing and let her know that you are withdrawing from the study. Her mailing address is NYU Langone Medical Center, 560 First Avenue, TCH-407, New York, New York 10016. If you wish to withdraw your Authorization as well as your consent to be in the study, you must contact Dr. Buyon in writing.

Remember that withdrawing your Authorization only affects uses and sharing of information after your written request has been received, and you may not withdraw your Authorization for uses or disclosures that we have previously made or must continue to make to complete analyses or report data from the research.

The Principal Investigator or another member of the study team will discuss with you any considerations involved in discontinuing your participation in the study. You will be told how to withdraw from the study. For withdrawal of samples: If you agree to allow your tissue/blood/cells to be kept for research, you are free to change your mind at any time. We ask that you contact Dr. Jill P. Buyon, in writing and let her know you are withdrawing your permission for your blood/cells to be used for research. Her mailing address is NYU Langone Medical Center, 560 First Avenue, TCH-407, New York, New York 10016. Any unused tissue/blood/cells will have all identifying information removed that would link the sample to you. The sample may then be used for other research, but no one will be able to relate those research results to you.

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L. PERMISSION TO CONTACT YOU ABOUT FUTURE RESEARCH:

I authorize Dr. Buyon and her research staff to contact me about future research on *NL*, *Ro/La* antibodies and/or pregnancy as well as genetic studies. I understand that any future protocols for which I will be approached will have to be approved by the investigator's IRB as well as the *RRNL*'s Review/Advisory Committee. At that time, I can decide whether or not I am interested in participating. I will then have the opportunity to contact the researcher to be fully informed about the project.

I agree to be contacted by the Principal Investigator or Project Administrator of the research study titled: Research Registry for Neonatal Lupus (*RRNL*).

I **do not** want to be contacted by the Principal Investigator or Project Administrator of the research study titled: Research Registry for Neonatal Lupus (*RRNL*).

Signature of participant or legal representative

Date

Your permission to allow us to contact you about future research would be greatly appreciated, but it is completely voluntary. If you choose not to allow us to contact you, it will not affect your care at any of the NYUSM facilities. Please understand that giving your permission to do this is only for the purpose of helping us identify subjects who may qualify for one of our future research studies. It does not mean that you must join in any study.

M. CONTACT PERSON(S):

For further information about your rights as a research subject, or if you are not satisfied with the manner in which this study is being conducted and would like to discuss your participation with an institutional representative, who is not part of this study, please contact the Administrator, Institutional Board of Research Associates, Telephone No. 212-263-4110.

If you have any questions regarding your participation in the *RRNL* or any of the other projects of this program, please contact the Principal Investigator, Jill P. Buyon, M.D. at the following telephone number: (212)-263-0746.

AGREEMENT TO PARTICIPATE AND AUTHORIZATION FOR THE USE OR DISCLOSURE OF PROTECTED HEALTH INFORMATION:

Part of the consent process includes your Authorization to use Protected Health Information for the purposes of this study, as described above. If you do not want to authorize the use of this PHI, you should not agree to be in this study.

I have read this consent form

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or

it was read to me by: _____.

Any questions I had were answered by: Jill P. Buyon, M.D., Project Director

I am am not participating in another research project at this time.

(If yes, you should discuss this with your study doctor.)

I volunteer to participate and will enroll in the category I have checked off. I am:

- The adult sibling (sister/brother) of a woman with anti-Ro/La antibodies who has a child/children with *NL*.
- Maternal grandmother of and *NL*-affected child/children.
- Maternal grandfather of an *NL*-affected child/children.

I voluntarily agree to participate in this research program at:

The NYU Langone Medical Center

Other, please specify:

I understand that I am entitled to and will be given a copy of this signed Consent/Authorization Form.

By signing this Consent/Authorization form, I give my Authorization for the uses and disclosures of my protected health information as described above.

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WHEN THE SUBJECT IS AN ADULT:

[This section is to be completed if the subject is 18 years of age or older. If the subject is a child, the form "WHEN THE SUBJECT IS A CHILD" is to be completed and the "Adult" page deleted. If the study involves both adults and children, both pages are to be included.]

* For subjects who may not be capable of providing informed consent, the signature of a legal representative is required. For a valid HIPAA authorization, the "personal representative" must have authority under state law to make health care decisions for the subject.

Print Name of Participant
or Legal Representative* _____/_____
Signature of Participant Date
or Legal Representative*

Print Name of Person
Obtaining Consent _____/_____
Signature of Person Date
Obtaining Consent

[Use this section only when a witness is required.]

** When the elements of informed consent are presented orally to the subject or representative, a witness to the oral presentation is required. [NOTE: it is unclear whether HIPAA authorization may be presented orally – this might require an IRB waiver to permit alteration of the form of authorization]

Print Name of Witness** _____/_____
Signature of Witness** Date

11 of 12 Subject's Initials: _____ Date: _____

(IRB Official Use Only)

*This Consent Document is approved for use by the New York University's Institutional Review Board (IRB).
Only the IBRA-stamped approved form may be used.*

Approved: From: 2/11/11 To: 2/10/12
The study expiration date applies for this form
Template rev. date:6/9/2003 [Extended Family]-Version Date: 1/28/11]



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NYU School of Medicine

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WHEN THE SUBJECT IS A CHILD: ASSENT FORM

My parent/guardian knows about this research project and wants me to be in the research project if I want to. I do want to be in the research project, but I know that I can stop being in the research project any time I want to. I know that the project's Principle Investigator can talk about the study with my parent/guardian, but will not talk about it with anyone else who is not working on the study unless I and my parent/guardian say it is OK. I can call the research project's PI any time I have any questions.

Signature of Child _____ Date _____

I have solicited the assent of the child.

Signature of Person Obtaining Assent/Consent _____ Date _____

Consent of Parent or Guardian:

- I agree with the manner in which assent was solicited and given by my child and I agree to have my child participate in the study.
- Although my child did or could not give his/her assent, I agree to have my child participate in the study.
- I **have been given a copy** of this Consent Form.

Print Name of Parent(s) _____ Date _____

Signature of Parent(s) _____ Date _____

Print Name of Legal _____ Date _____

Signature of Legal Representative _____ Date _____

12 of 12 Subject's Initials: _____ Date: _____

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