SUBJECT INFORMATION AND CONSENT/ASSENT FORM AND AUTHORIZATION TO USE AND DISCLOSE PERSONAL HEALTH INFORMATION FOR RESEARCH
(for subjects aged 12 and older)

Name of Research Study: A Longitudinal, Case-Control Study to Collect Medical and Epidemiological Data and Blood Samples for Research Into the Causes of Multiple Sclerosis and Selected Demyelinating Diseases

Protocol #: ACP-001

Sponsor: Accelerated Cure Project for Multiple Sclerosis

Principal Investigator: **«FirstName» «MiddleName» «LastName» «Suffix»**

Address(es):

Daytime telephone number(s): «Phone»

24-hour contact number(s): «Phone2»

This Subject Information and Consent Form has been developed for use in a research study that may involve some subjects who do not have the legal capacity to consent to their participation. Accordingly, when the subject cannot legally consent to take part, the pronouns "you" and "your" should be read as referring to the subject rather than the legally authorized representative who is signing the form to give consent for the subject to take part in the research study.

Purpose of the Subject Information and Consent Form

This Subject Information and Consent Form may contain words you do not understand. Please ask the study doctor or the study staff to explain any words or procedures that you do not clearly understand.

The purpose of this form is to give you information about the research study and, if signed, will give your permission to take part in the study. The form describes the purpose, procedures, benefits, risks, discomforts and precautions of the research study. You should take part in the study only if you want to do so. You may refuse to take part or withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled. Please read this Subject Information and Consent Form and ask as many questions as needed. You should not sign this form if you have any questions that have not been answered to your satisfaction.

Your study doctor will be paid by the sponsor to conduct this research study.

Subject's Initials____
Parent/Guardian's Initials____

What is the purpose of this study?

The purpose of this study is to establish a collection of blood samples and associated data from approximately 10,000 people, some of whom have experienced at least one CNS demyelinating event characteristic of Multiple Sclerosis (MS), Transverse Myelitis (TM), Acute Disseminated Encephalomyelitis (ADEM), Neuromyelitis Optica (NMO) or Optic Neuritis (ON), their blood relatives (those who have and have not experienced at least one CNS demyelinating event), and unrelated subjects who have not experienced at least one CNS demyelinating event and who are suitable controls (relatives or non-relatives who have not experienced any central nervous system event). The samples and data will be made available to research scientists who are involved in the study of MS, TM, ADEM, NMO, and/or ON, and in particular, studies involved in determining the causes of these syndromes/diseases.

Why was I asked to participate in this study?

You have been asked to participate in this study because either you have experienced at least one CNS demyelinating event associated with one of the specified diseases (MS, TM, ADEM, NMO, ON) and meet the criteria to be a case for this study, or you do not have one of these demyelinating diseases and meet the criteria to be a control for this study. Your participation in this study is voluntary. This study will be conducted in five or more medical institutions. Approximately 10,000 subjects will participate in this study.

Who is sponsoring this study?

The Sponsor of this study is Accelerated Cure Project for Multiple Sclerosis, a national nonprofit organization dedicated to curing MS by determining its causes. Accelerated Cure Project believes that determining the causes of MS and other demyelinating diseases can be accelerated by organizing the research process and by encouraging collaboration between research organizations and clinicians. Accelerated Cure Project believes that establishing a large-scale, multidisciplinary blood and data bank will facilitate research most likely to reveal the causes of MS and other demyelinating diseases in the shortest time. The Sponsor is responsible for all collected samples and information and how they will be used.

Who is in charge of this study?

The person responsible for the conduct of this study is **«FirstName» «MiddleName» «LastName», «Suffix»** who can be reached at **«Company»**, telephone **«Phone» «Phone2»**. **«FirstName» «MiddleName» «LastName», «Suffix»** should be contacted if you have questions or concerns.

What is going to happen and how long will it take?

This study will be conducted in a confidential manner. If, after learning about this study to your satisfaction, you agree to participate, you will be asked to sign and date this consent form. If you are unable to sign this consent, you may have a witness sign the consent for you. You will be given a copy of the signed and dated consent to take home with you.

If you agree to participate, you will be interviewed and the interviewer will fill out a questionnaire (which includes questions about your lifestyle, environment, geographic [like: date of birth, and state where you were born], medical history, and health status) and then review your medical record to verify clinical information. Nothing you say during this interview will be entered into your medical record. Once this questionnaire is complete, it will be sent to a data management vendor chosen by the Sponsor.

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Then, up to 110 ml (approximately 7.4 tablespoons) of blood will be taken from a vein in your arm using a small needle. This blood will be sent to a laboratory chosen by the Sponsor. The interview and blood sampling should take approximately 1 ½ to 2 hours.

For identification purposes, you will be assigned a unique barcode, which will be placed on all the material that is sent to the laboratory or data management vendor. Materials used in this study such as your blood samples, medical records and questionnaire will be identified using this barcode, not by your name.

The interviewer will also complete a contact form that will have your name, address and other contact information. This will allow the Sponsor to have your study doctor contact you every year or two to update information about you, ask new questions related to your life style (for example, questions about dietary habits) or current health status, and perhaps ask for another blood sample similar to the one done during your initial interview. These contacts and blood sampling through your study doctor will continue over your life span. At any time, you can refuse additional interviews and blood sampling. This will not affect your ongoing care. The Sponsor will periodically send you mail for the purpose of allowing you to provide updated contact information.

If you have experienced a demyelinating event characteristic of MS or one of the other demyelinating diseases specified, you will be asked to speak with certain types of family members and friends who may wish to participate in this study. The Sponsor is especially interested in enrolling family members (with or without a demyelinating disease). Friends with or without a demyelinating disease may also be eligible for this study. The study doctor will inform you of which types of friends and family members are of interest. If they choose to contact the study doctor, the doctor will decide whether that person meets the requirements of the study.

Relationships between you and any family members, or friends, whom you ask to participate in the study, will be described on a form using the assigned barcodes. This will allow researchers to know how samples are related without knowing individual names.

Will I be contacted again?

Yes, you will be contacted again. Approximately once a year or every other year, you will be asked to be interviewed to collect new information, update your medical information, and/or collect additional blood samples. You may also be asked to be interviewed or provide additional samples at the time of doctor's appointments for relapses, changes in medication, etc. You may refuse to participate in any of these follow-ups without leaving the study.

You will also be offered the opportunity to sign up for a free quarterly newsletter from the Sponsor. Your decision of whether or not to receive this newsletter has no bearing on your participation in the study.

In addition, you will be offered the opportunity to receive a free Accelerated Cure Project t-shirt from the Sponsor. Your decision of whether or not to receive this t-shirt has no bearing on your participation in the study.

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What are the risks of participating?
There is a risk of the potential loss of confidentiality of your personal health information. There are minor risks and discomforts associated with blood sampling. This includes mild pain and possibly bleeding and a bruise at the needle site. Occasionally a person feels faint or light headed when their blood is drawn. An infection at the site of the blood draw rarely occurs.

Will I benefit by participating in this study?
There will be no direct medical benefit to you. Since it is possible that the causes of one, some or all of the specified demyelinating diseases (MS, TM, ADEM, NMO, ON) could be determined because of research using your samples, someone may benefit in the future.

What if I have questions or am injured because of my participation?
You may call your study doctor if you have any questions about the study, the blood collection, or if you believe you have a research-related injury. Your study doctor will provide immediate medical care as needed. Your study doctor's contact information is listed on the front page of this consent.

Legal Rights
You do not waive any legal rights by signing this Subject Information and Consent Form.

Payment for Participation
You will not be paid to participate in this study, however, you will receive $XX.00 to cover the cost of XX (INSERT site specific expenses that will be covered).

Will this cost me anything?
No. There is no cost to you to take part in this study.

What are my alternatives to participating in this study?
Your only alternative is to not participate. Your current or future medical care with the hospital or doctor's office will continue as usual.

Will my specimen be stored for future use?
Yes, your blood specimen will be evaluated by research scientists studying MS, TM, ADEM, NMO and/or ON, as well as other diseases if you agree. Some portion may be frozen or stored indefinitely for future use. Stored specimens may be analyzed in the future using additional technologies without you being asked to sign another consent form.

Will my samples be used to study any other diseases besides the specified demyelinating diseases (MS, TM, ADEM, NMO, ON)?
An important part of this research is to allow for associations to be made between MS, the other demyelinating diseases specified in this consent (TM, ADEM, NMO, ON) and other diseases (demyelinating and non-demyelinating), which may provide important information about MS, TM, ADEM, NMO or ON. Your sample may be used for research to investigate other disease states, if and only if the research will add to the knowledge of MS, TM, ADEM, NMO and/or ON.

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Will my sample be used for genetic research?

Yes. Genetic research is an important part of the investigation into the causes of these diseases. The demyelinating diseases specified (MS, TM, ADEM, NMO, ON) are complicated diseases with no known cures. The causes of these diseases are believed to be the result of combinations of inherited genes and possible various exposures to the environment.

What will happen to my sample and data if Accelerated Cure Project ceases to exist as an independent business entity?

If Accelerated Cure Project were combined with or absorbed by another business entity, your sample and associated data would continue to be used precisely in the manner spelled out in this document.

If Accelerated Cure Project were to cease to exist (and were **not** combined with another entity), every effort would be made to transfer your sample and associated data to another entity that would agree to and be bound to utilize your sample and data in precisely the manner spelled out in this document. If no such entity could be identified, your sample and data would be destroyed. However, specimens that have been already used for research, as well as any results or information already obtained cannot be destroyed.

What is the process for determining which researchers will have access to my sample?

Requests for samples from researchers will be reviewed by a scientific steering committee. The members of this committee may consist of Accelerated Cure Project staff, representatives from participating collection sites, members of Accelerated Cure Project's Scientific Advisory Board and others. Researchers will be required to follow specific guidelines for proposal submission. Proposals will be assessed based on a variety of factors including, among others, the scientific merit of the proposed research, its ability to increase the knowledge of the specified demyelinating diseases, the IRB approval status of the research, its adherence to this consent, etc. The submission and decision making process is currently under development and will be made publicly available.

Will Accelerated Cure Project send me the results of any research that uses my sample?

No. Accelerated Cure Project will not provide findings specific to you, but we will report progress of studies through a free quarterly newsletter that you may subscribe to if you agree.

What if I don't want to do this?

You are free to choose not to take part in this study. If you choose not to participate, your medical care and treatment at the hospital or doctor's office will not be affected.

Can I change my mind after I have given blood?

Yes. You may withdraw your consent by contacting your study doctor, whose phone number is on the first page of this consent. However, specimens that have been already used for research, as well as any results or information already obtained prior to withdrawal from the study, cannot be destroyed. Refusal to participate in the future will not affect your current or future medical care in any way. If you withdraw from this study at any time, you will not be contacted again.

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Is there a commercial use for the results of this study?
It is possible that the Sponsor or other researchers may make money from commercial application of research results. There is no provision for you to receive any financial benefit that might come from the research.

Contact for Questions
If you have any questions about your participation in this research study contact:

Principal Investigator: **«FirstName» «MiddleName» «LastName» «Suffix»**

Daytime telephone number(s): «Phone»

24-hour contact number(s): «Phone2»

If you have questions about your rights as a research subject, you may contact <Name of IRB> at <IRB Contact Number>. An Independent Review Board is a group of scientific and non-scientific individuals who perform the initial and ongoing ethical review of the research study with the study subject's safety and welfare in mind. If you have study-related comments, complaints or concerns, you should first contact the study investigator. Please call the IRB if you want to talk to someone other than the study investigator or have difficulty reaching the study investigator.

How will my privacy be protected?
Accelerated Cure Project will keep your name and contact information in a separate, secure database. This information will be used by Accelerated Cure Project to allow your study doctor to contact you in the future. It will also be used to send you mail in order to keep contact information up to date.

U.S. Federal Privacy Regulations require that you authorize the release of any health information that may reveal your identity. Your medical records and health information will be used and disclosed for this study. Your records may include, but may not be limited to, information about your blood samples, physical examinations, medical history, and other data collected or reviewed during the course of the study as described in this consent. This information cannot be used or disclosed without your signature.

For the purpose of this study as described in the consent, your medical records may be reviewed by the following:

- Study doctor(s) and staff
- Accelerated Cure Project, the sponsor
- Theorem Clinical Research, an agent for the sponsor
- Regulatory and governmental agencies
- <Name of IRB>

Most personally identifiable information will be removed from the copies of your medical reports and tests before being sent to the data management vendor, which will limit the

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information available to the sponsor, Theorem Clinical Research and other agencies. However, the town in which you live, the date of the interview, and dates of medical tests or procedures will be given to the data management vendor and these items could potentially identify you.

The laboratory will receive your blood samples labeled with your barcode, but without your name. The data management vendor will receive your questionnaire information labeled with your barcode, but without your name.

Absolute confidentiality cannot be guaranteed. It is possible your identity may become known in conjunction with your medical data. Accelerated Cure Project will take all possible steps to protect your confidentiality. Your specimens will be processed and compared to clinical information only by the use of a barcode. Accelerated Cure Project will hold your contact information in a separate secure location. If you withdraw from the study and withdraw your Authorization, no new information will be collected for study purposes unless the information concerns an adverse event (a bad effect) related to the study. If an adverse event occurs, your entire medical record may be reviewed.

Scientists who use your sample will not know your identity, but will be given information about your age, sex, race, medical history, etc. Publications resulting from research using your sample will not identify you.

Your authorization for the use and/or disclosure of your health information as described above has no expiration date.

If you do not sign this Authorization, you cannot participate in this research study. If you withdraw this Authorization in the future, you will no longer be able to participate in this study. Your decision to withdraw your Authorization or not to participate will not involve any penalty or loss of access to treatment or other benefits to which you are entitled.

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EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

Any person who is requested to consent to participate as a subject in a research study involving a medical experiment, or who is requested to consent on behalf of another, has the right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be used.

3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.

4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.

6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

7. Be given an opportunity to ask any questions concerning the experiment or the procedures involved.

8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time, and the subject may discontinue participation in the medical experiment without prejudice.

9. Be given a copy of a signed and dated written consent form when one is required.

10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

_____

Signature of Subject Date

Subject's Statement of Consent

A Longitudinal, Case-Control Study to Collect Medical and Epidemiological Data and Blood Samples for Research Into the Causes of Multiple Sclerosis and Selected Demyelinating Diseases

I have been told that my participation is voluntary and I may withdraw from the study at any time without prejudice or loss of benefits to which I am otherwise entitled. I have been told that I will receive a signed and dated copy of this consent form and I am aware that the study doctor will also retain a copy for his or her files.

I have been told that I do not have to sign this consent form if I do not want to participate in this research study or authorize the release my medical records or information.

Please indicate below if you wish to receive the free quarterly newsletter.

☐ Yes, I wish to receive the newsletter.

☐ No, I do not wish to receive the newsletter.

Please indicate below if you wish to receive a free Accelerated Cure Project t-shirt.

☐ Yes, I wish to receive a free Accelerated Cure Project t-shirt.
Indicate size desired:
MEN'S: XL ____ Large ____ Medium ____ Small ____
WOMEN'S: XL ____ Large ____ Medium ____ Small ____
CHILDREN'S: Med:___Small:___XS:___Sz 5/6:___Sz 4:___Sz 2:___

☐ No, I do not wish to receive a t-shirt.

_____
Subject's Name (please print)

_____ _____
Subject's Signature Date

_____
Legal Representative's Name, where applicable by law (please print)

_____ _____
Legal Representative's Signature Date

_____
Name of Person Obtaining Consent (please print)

_____ _____
Signature of Person Obtaining Consent Date

_____ _____
Witness signature, if necessary Date

_____
Witness name (please print)

SUBJECT'S STATEMENT OF ASSENT

I have read this consent form and my parent and/or legal guardian agrees that I can participate in this study. My parent and/or legal guardian has been given a signed and dated copy of this consent form.

I have asked any questions I have about the study and my questions have been answered.

_____
Child's Name (*please print*)

_____ _____
Signature of Child Date

_____ _____
Signature of Parent/Legal Guardian Date

_____ _____
Signature of Investigator/Person Explaining Consent Form Date

_____
Witness name (please print)

_____ _____
Witness signature, if necessary Date