

**PARENTAL PERMISSION FOR CHILD TO PARTICIPATE IN A RESEARCH
STUDY AND AUTHORIZATION TO USE AND DISCLOSE PERSONAL
HEALTH INFORMATION FOR RESEARCH**

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 Name:

Research Site Address(es):

Daytime telephone number(s):

24-hour contact number(s):

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 for your child to take part in the study. The form describes the purpose, procedures, benefits, risks, discomforts and precautions of the research study. You should give your permission for your child to take part in the study only if you want to do so. You may refuse to give your permission for your child to take part or withdraw your child from this study at any time without penalty or loss of benefits to which your child is otherwise entitled. Please read this Parental Permission 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 child's study doctor will be paid by the sponsor to conduct this research study.

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 my child asked to participate in this study?

Your child has been asked to participate in this study because either your child has experienced at least one CNS demyelinating event associated with one of the specified diseases (MS, TM, ADEM, NMO, ON) and meets the criteria to be a case for this study, or your child does not have one of these demyelinating diseases and meets the criteria to be a control for this study. Your child's 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 (INSERT PI NAME) who can be reached at (INSERT NAME OF INSTITUTION), telephone (INSERT PHONE NUMBER). (INSERT PI NAME) 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 give your permission for your child to participate, you will be asked to sign and date this permission form. If you are unable to sign this permission form, you may have a witness sign the form for you. You will be given a copy of the signed and dated permission form to take home with you.

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

Then, up to 50 ml of blood will be taken from a vein in your child's 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, your child 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 child's blood samples, medical records and questionnaire will be identified using this barcode, not by your child's name.

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

If your child has 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 your child 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 my child be contacted again?

Yes, your child will be contacted again. Approximately once a year or every other year, the study doctor will ask to interview your child to collect new information, update your child's medical information, and/or collect additional blood samples. Your child 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 give permission for your child to participate in any of these follow-ups without your child leaving the study.

When your child is 18 years old (or of legal age where state law may differ), your child will be presented with the informed consent to give his/her own consent at that time.

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

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

What are the risks of participating?

There is a risk of the potential loss of confidentiality of your child's personal health information. There are minor risks and discomforts associated with blood sampling. These include 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 my child benefit by participating in this study?

There will be no direct medical benefit to your child. 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 child's samples, someone may benefit in the future.

What if my child or I have questions or if my child is injured because of my child's participation?

You or your child may call your child's study doctor if you or your child has any questions about the study, the blood collection, or if you or your child believes your child has a research-related injury. Your child's study doctor will provide immediate medical care as needed. Your child's study doctor's contact information is listed on the front page of this permission form.

Legal Rights

You do not waive any of your or your child's legal rights by signing this Subject Information and Permission Form.

Payment for Participation

Your child will not be paid to participate in this study, however, you will receive \$XX (INSERT site specific) to cover the cost of XX (INSERT site specific expenses that will be covered). Additionally, your child will receive \$XX (INSERT site specific) in the form of a XX (INSERT site specific).

Will this cost me anything?

No. There is no cost to you to take part in this study.

What are my alternatives to giving permission for my child to participate in this study?

Your only alternative is to not give permission for your child to participate. Your child's current or future medical care with the hospital or doctor's office will continue as usual.

Will my child's specimen be stored for future use?

Yes, your child's 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 permission form.

Will my child's 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 child's 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.

Will my child's 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 child's sample and data if Accelerated Cure Project ceases to exist as an independent business entity?

If Accelerated Cure Project were to be combined with or absorbed by another business entity, your child's 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 child's sample and associated data to another entity that would agree to and be bound to utilize your child's sample and data in precisely the manner spelled out in this document. If no such entity could be identified, your child's 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 child's 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 child's sample?

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

What if I don't want my child to do this?

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

Can I change my mind after my child has given blood?

Yes. You may withdraw your permission by contacting your child's study doctor, whose phone number is on the first page of this permission form. 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 allow your child to participate in the future will not affect your child's current or future medical care in any way. If you withdraw your permission for your child to participate in this study at any time, you and your child will not be contacted again.

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 or your child to receive any financial benefit that might come from the research.

Contact for Questions

If you have any questions about your child's participation in this research study contact:

Investigator Name:

Telephone contact number(s):

24-hour contact number(s):

If you have questions about your child's rights as a research subject, you may contact the <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 child's privacy be protected?

Accelerated Cure Project will keep your child's name and contact information in a separate, secure database. This information will be used by Accelerated Cure Project to allow your child's study doctor to contact your child in the future. It will also be used to send your child 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 child's identity. Your child's medical records and

health information will be used and disclosed for this study. Your child's records may include, but may not be limited to, information about your child's blood samples, physical examinations, medical history, and other data collected or reviewed during the course of the study as described in this consent. If you agree to allow your child to take part in this research, you will be giving your permission to let researchers and others described in this form to use and share your child's protected health information. This information cannot be used or disclosed without your signature.

For the purpose of this study as described in the consent, your child's 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 child's medical reports and tests before being sent to the data management vendor, which will limit the information available to the sponsor, Theorem Clinical Research and other agencies. However, the town in which your child lives, 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 your child.

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

Absolute confidentiality cannot be guaranteed. It is possible your child's identity may become known in conjunction with your child's medical data. Accelerated Cure Project will take all possible steps to protect your child's confidentiality. Your child's specimens will be processed and compared to clinical information only by the use of a barcode. Accelerated Cure Project will hold your child's contact information in a separate secure location. If your child withdraws from the study, 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 child's entire medical record may be reviewed.

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

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

If you do not sign this Authorization, your child cannot participate in this research study. If you withdraw this Authorization in the future, your child will no longer be able to

participate in this study. Your decision to withdraw your Authorization or to not allow your child to participate will not involve any penalty or loss of access to treatment or other benefits to which your child is entitled

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 give permission 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 Parent/Legal Guardian

Date

PARENT/GUARDIAN PERMISSION STATEMENT

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 know that taking part in this research study is my child’s choice. My child may choose to leave this study at any time, for any reason, or for no reason. If my child decides not to stay in the study, I shall tell the study doctor of this decision. I freely give my permission to have my child take part in this research study conducted under the supervision of <INSERT PI NAME>. I know there may be some risks or discomforts to my child. I have read about these risks in this form and they have been carefully explained to me. My child’s participation in this research has been clearly explained to me. My child and I have had the opportunity to ask questions about the study and have had time to decide to participate. Our questions have been answered to our satisfaction. I know we are free to ask further questions about the study at any time. I have been told about the materials and procedures used in this study. I know what my child is supposed to do in this research study. I have been told I will receive a copy of this permission form.

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 your child 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 my child to receive a t-shirt.

Subject’s Name (please print)

Parent/Legal Guardian’s Name (please print)

Parent/Legal Guardian’s Signature

Date

Name of Person Obtaining Consent (please print)

Signature of Person Obtaining Consent

Date

Witness name (please print)

Witness signature, if necessary

Date