

CHILDREN'S ASSENT FORM
(for subjects aged 7-11 years old)

STUDY TITLE: 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 MS

INVESTIGATOR:

You are being asked to take part in a research study because you have a particular disease (Multiple Sclerosis (MS), Transverse Myelitis (TM), Acute Disseminated Encephalomyelitis (ADEM), Neuromyelitis Optica (NMO) or Optic Neuritis (ON)), or because you don't have one of these diseases but are related to or like someone who does . Before you decide to take part in this study, we want to tell you about the study so you can ask questions.

WHY IS THE STUDY BEING DONE?

The purpose of this study is to collect blood and information from people with MS, TM, ADEM, NMO, or ON, their relatives, and some unrelated people. The blood and information will then be made available to scientists looking for what causes these diseases.

WHAT WILL I BE ASKED TO DO?

For the first visit, you will have blood taken from a vein in your arm, and you will answer some questions about you and your family, your health, what you like to do, and other things. If you have one of the diseases mentioned above, the doctor doing this study will review your medical records and will enter some information from your records into a form on a computer.

Then, every 1-2 years for the rest of your lifetime, the study doctor may contact you again and see if you would like to come in for another visit. During that visit, you may be asked to give more blood, and/or to answer more questions. You can say no to any of those future visits and still be part of the study.

For this first visit, here's what will happen:

1. The doctor and staff will make sure that you and your parent understand the study and what will happen. If both you and your parent agree you want to participate you will sign this form before anything else happens in this study. Some blood (about 1 ½ ounces) will be taken from a vein in your arm. The tubes of blood will be marked with a special barcode (some letters and numbers) instead of your name.

2. You will be asked some questions about you, your interests, your health, and your family. The answers you give will be entered into a form on a computer. When the data is stored, it will be stored under the same barcode that is on your tubes of blood. Again, the data won't be stored under your name.
3. If you have one of the diseases being studied, the study doctor will review your medical records and also enter some information from your records into the form on the computer. This information will be stored under the same barcode mentioned above.
4. You or your parent will be asked for your address and phone number so that the doctor can contact you again to see if you want to come in for future visits.
5. You or your parent will be asked to suggest other family members or friends who might want to participate in the study.
6. You'll be asked if you want to receive a free newsletter and/or a free t-shirt from the people who are sponsoring the study (Accelerated Cure Project for Multiple Sclerosis). You can say no to the newsletter and/or the t-shirt and still be part of the study.

CAN BAD THINGS HAPPEN TO ME BY BEING IN THE STUDY?

Risks and discomforts associated with drawing blood samples from your arm may include pain, bruising, lightheadedness, and on rare occasions, infection. Care will be taken to avoid these difficulties.

Your data and blood will have a barcode, not your name on them so the researchers who use them to study diseases won't know who you are. There is a chance, though, that somehow your name could become connected with your blood and/or data.

WHAT HELP MIGHT I GET FROM BEING IN THE STUDY?

You won't get any direct help from being in the study. It's possible that the people using your blood and data to study the diseases mentioned may learn something about the causes of one or more of the diseases. This means that other persons may be helped in the future.

CAN I REFUSE TO BE IN THE STUDY?

You do not have to be in the study and can stop at any time. Stopping or not being in the study will not make anyone upset with you. If you have one of the diseases mentioned and you don't want to be in the study, nothing will change about how your doctor treats you.

Please let your parents, study doctor or the staff know about any unpleasant parts of the study. The study doctor or the staff will answer any questions you have at any time about the study.

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