

### **Acute Flaccid Myelitis (AFM) Biorepository Adult Consent / Parent Permission / Assent 15-17 Years**

NOTE: Parents or legal guardians who are giving permission for a child's participation in the research, note that in the sections that follow the word 'you' refers to 'your child'.

#### **Key Information**

- We are asking for your consent/permission/assent to take part in a biorepository. Your participation is voluntary. Your alternative is not to take part.
- The purpose of this project is to collect samples to make sure samples are available for research.
- If you agree to take part, you will give samples when you are at the hospital. You will also give permission to keep for future use any leftover samples from those taken for diagnosis.
- You will also have blood samples taken about 4-8 weeks after you got symptoms.
- The risks for taking part in this project are minor possible effects of taking blood. More details are given further down in this form. There is a small possibility of loss of privacy.
- There is no direct benefit for participating however we hope to learn more about AFM to help treat or prevent this illness.

#### **Why am I being asked?**

You are being asked to take part in the Acute Flaccid Myelitis (AFM) Biorepository because doctors think you might have AFM. AFM is an uncommon illness and samples from people are a valuable source of information. A Biorepository is a place that gets and stores samples like blood and saliva. This Biorepository is being established and funded by the Centers for Disease Control and Prevention (CDC). We ask that you read this form and ask any questions you may have before agreeing to take part in the Biorepository. McKing is the company that was awarded a contract from the CDC to develop, facilitate, implement, and manage the Biorepository. The Biorepository Senior Scientist at McKing is Dr. Wendy E. Kaye.

Taking part in this AFM Biorepository is voluntary. You should feel free to ask any questions you may have. Your decision whether or not to take part will not affect your current or future relations with the CDC or your medical care. If you decide to take part you are free to withdraw at any time without affecting that relationship.

#### **What is the purpose of this AFM Biorepository?**

This Biorepository is being created to make sure samples are available for research, even when there are no new cases of AFM. The Biorepository aims to provide samples to be used in future studies to assess the cause and risk factors of AFM and to support the future development of AFM vaccines and medications.

It is unknown exactly how many people will take part. We think up to 200 people will be asked to contribute samples to the Biorepository each year.

#### **What are the procedures involved?**

You will have samples collected from you at two different times. The first time will be shortly after admission to the hospital. The second time will take place in your home or similar location about four to eight weeks after you got symptoms. Each sample collection should take about 30 minutes.

The first collection will include two tubes of blood, stool sample or rectal swab, nose or mouth swab, and any cerebrospinal fluid (CSF) left over from a procedure called a lumbar puncture (also called spinal tap) and will be coordinated with the collection of samples needed for the diagnosis of your illness. About 12mL of blood will be

collected (approximately 2.5 teaspoons) from children and 20mL (4 teaspoons) from those 18 years of age and older.

We are also asking for permission to keep any other samples leftover from those taken for diagnosis.

The second collection will include only two tubes of blood. About 12mL of blood will be collected (approximately 2.5 teaspoons) from children and 20mL (4 teaspoons) from those 18 years of age and older. We will make an appointment for someone to come to your location to collect the samples at a time that works for you.

After the second collection, your participation will end however we will keep your samples to do future studies.

### **Sample Storage**

The purpose of this Biorepository is to collect samples for future research related to AFM. Your samples will be stored with a number. No private information will be on the sample container.

Researchers can ask to use samples for research related to AFM. We do not know what types of research will be done. Researchers must provide a detailed plan of the study. This plan must be approved by a scientific review committee and the ethics committees at the researchers' institutions. Your samples along with others will be provided to approved researchers. These samples will not have your name on them. The samples might include information about you such as age or state where you lived. We will limit the amount of information about you to reduce the chances that you will be identified.

Results of research using these samples will be available on the CDC website.

### **What are some of the risks and discomforts that may happen to people who are in this Biorepository?**

The risks from taking blood include bruising where the blood is collected, discomfort, feeling lightheaded, rarely an infection, small clot, and fainting. The nose swabs or swabs collected from the back of the throat may be uncomfortable and painful. You may have a small nosebleed or feel like gagging. You may see small amount of blood after the swab is taken but this is normal. We will not do a spinal tap for the Biorepository. We will ask that a little extra be collected when they are collecting the sample for diagnostic purposes. Stool samples will be collected in a toilet hat or diaper and do not have risk associated with collection. The rectal swab may feel a little uncomfortable but does not carry a risk.

All attempts will be made to keep your information safe. There is a slight risk that someone could get access to the data we have stored about you. If information about you does leak out, the CDC and McKing cannot guarantee that it will be protected.

### **Are there benefits to taking part in this Biorepository?**

While you will not directly benefit from taking part, it is hoped that knowledge gained from this research may benefit others with AFM in the future by helping find ways to treat and prevent AFM.

### **What other options are there?**

You have the option to not take part in this Biorepository.

### **What about privacy and confidentiality?**

If you take part in the Biorepository, McKing and the CDC will not have access to your private medical records.

The people who will know that you are taking part in this Biorepository are members of the Biorepository team, and people collecting or processing your samples.

A possible risk of the Biorepository is that people outside of the Biorepository find out you are taking part in the Biorepository or learn information about you and your health. Your samples will be stored with a number. Your name will not be on the container.

When the results of the Biorepository are published or discussed at meetings, no information will be included that would reveal your identity.

Records with your name, like this form, will be kept as secure as possible. We will keep it in a locked file cabinet. There are some agencies, like the Institutional Review Board (IRB) and regulatory agencies that can review all the records to audit the project.

There is no plan to identify you from your DNA however it is possible to run your DNA in public databases and for your identity to be known.

**Will my family be told Biorepository results?**

Your family will not be personally told of any new findings that come to light during the course of using your samples. We will not tell you or your family any individual results from research studies. The CDC will post study results in aggregate (grouped, not individual) on their website and share new findings publicly through peer-reviewed papers posted in medical journals, with the media, and on websites for the public. We will make every effort not to reveal your identity.

**What are the costs for participating in this Biorepository?**

There is no cost to you for participating in this Biorepository. You will not be charged for any lab tests or sample collection for this project.

**Will I be reimbursed for any of my expenses or paid for my participation in this Biorepository?**

You will not be paid to take part in this Biorepository.

**Will my cells, tissues, blood, or other biological materials be used to develop commercial products?**

It is possible that a commercial product may be developed from the samples collected as part of this Biorepository. The nature of the research means that your sample is only one of many that will lead to this product and your sample will not have your name on it. You and your family will not profit financially from such a product. You will have no legal rights to any discovery or invention that either directly or indirectly results from the use of your samples, individual information, or information from your samples.

Cells obtained from your body may be used to establish a cell line which may be shared in the future with other researchers and which may be of commercial value. A cell line is one which will grow indefinitely in the laboratory. Cell lines may be useful because of the characteristics of the cells and/or the products they may produce. Your personal information will not be associated with this cell line.

**Can I withdraw from or be removed from the Biorepository?**

Taking part in this Biorepository is voluntary. If you choose not to take part or decide to withdraw your consent and stop taking part, there will be no penalty, this will not affect your relationship with CDC, your medical team or other benefits to which you are otherwise entitled.

You have the right to leave the Biorepository at any time without penalty. If you withdraw from the Biorepository, we will destroy any of your remaining samples. However, we will not be able to remove your samples that have already been used or shared with researchers.

**Who should I contact if I have questions regarding the Biorepository? Who should I contact if I wish to voice concerns or complaints? Who can I talk to about my rights or if I want to withdraw my samples?**

If you have questions, concerns, or complaints, think the Biorepository has hurt you or to report a project related harm, or if you want to withdraw your samples, you can talk to Wendy E. Kaye, Ph.D., McKing Senior Scientist or Laurie Wagner, MPH, McKing Consulting, Biorepository Coordinator at 1-855-874-6912.

If you want to speak with someone who is not directly involved in this Biorepository, or have questions about your rights as a research participant, or wish to voice questions or offer input, concerns or complaints, you may contact the Ethical and Independent Review Services, Institutional Review Board (IRB) at 1-800-472-3241 or by email at [subject@eandireview.com](mailto:subject@eandireview.com). Reference E&I project 20066.

**Remember**

Taking part in this Biorepository is voluntary. Your decision whether or not to take part will not affect your current or future relations with the CDC or your medical team. If you decide to take part, you are free to withdraw at any time without affecting that relationship.

**Participants' Rights:**

I have read the above information. I have discussed this Biorepository with the person obtaining consent, been given a chance to ask questions and my questions have been answered to my satisfaction. I agree to take part in this Biorepository and for my or my child's samples to be stored for future use for an indefinite time. I will be given a copy of this signed and dated consent/permission/assent form.

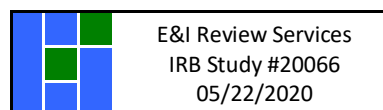
\_\_\_\_\_  
Print Participant Name

\_\_\_\_\_  
Signature of Participant                      Date

\_\_\_\_\_  
Signature of Parent or Guardian,      Date  
if participant is under 18 yrs. old

\_\_\_\_\_  
Printed name of Parent

\_\_\_\_\_  
Telephone number, for future contact



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*If the participant is physically unable to sign the consent form, please complete the following*

I, \_\_\_\_\_, witnessed that \_\_\_\_\_  
(witness printed name) (participant printed name)

was explained this consent form and has agreed to take part in this Biorepository. Due to the progression of the disease, the participant is physically unable to sign the consent form.

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Witness Signature

Date