

## RESEARCH CONSENT FORM Adult Version

H-27897- IMMUNIZATIONS IN PATIENTS WITH MITOCHONDRIAL DISORDERS

---

### Background

Mitochondrial disorders are rare but serious chronic diseases that usually affect lots of different parts of the body. The most common symptoms are in body parts that need a lot of energy like the brain and muscle, and heart. Often these symptoms appear to worsen after or are reaction to an infection, such as a cough or cold, or diarrhea. In more rare cases of mitochondrial disorder, the symptoms appear to worsen after a reaction to a shot.

Your doctor is asking you to participate because you have a mitochondrial disorder or dysfunction. We would like to look at your medical records and vaccine history. They may help us to learn more about mitochondrial disorder and its relationship to different sicknesses and vaccines.

### Purpose

To study a group of children with mitochondrial disease or suspected mitochondrial disease and understand the relationship between their disease and response to vaccinations.

### What Happens In This Research Study

You will be one of approximately 200 subjects to be asked to participate in this study.

All or part of the research in this study will take place at Boston University Medical Center.

If you agree to take part in this study:

1. We will ask you some questions about your health and past medical history and about any vaccines you have received and about your mitochondrial disorder.
2. We will ask you for permission to obtain and review your medical records from doctors and hospitals.

### Risks and Discomforts

Facts about you such as your race, ethnicity and sex will be part of the information we collect. These facts may help us figure out if the factors that cause side effects of the vaccine are the same in men and women and in people of different racial and ethnic backgrounds. Findings that come from this study could help people of the same race, ethnicity and sex as you. However, it may be possible, in some cases, through this kind of study that harmful stereotypes could be reinforced. There are no other foreseeable risks, discomforts, or inconveniences to the subject except a breach of confidentiality. However, we will keep information about you confidential.

Study staff will update you in a timely way on any new information that may affect your health, welfare, or decision to stay in this study.

### Potential Benefits

You will receive no direct benefit from your participation in this study. However, your participation may help the investigators better understand more about mitochondrial disorders/dysfunction in the future. The stored medical data will be of no benefit to you. However, they may be used in future research to understand the connection between mitochondrial disease and vaccines. .

### Alternatives

Your alternative is to not participate in the study.

## RESEARCH CONSENT FORM Adult Version

H-27897- IMMUNIZATIONS IN PATIENTS WITH MITOCHONDRIAL DISORDERS

---

### Subject Costs and Payments

There are no costs to you or your doctor for participating in this research study. The aim of this research is to improve public health. You will not be paid to participate in this research study.

### Confidentiality

Information from this study and from your medical record may be reviewed and photocopied by the Food and Drug Administration (FDA) and/or state and federal regulatory agencies such as the Office of Human Research Protection as applicable, and the Institutional Review Board of Boston University Medical Center. Information from this study and from your medical record may be used for research purposes and may be published; however, your name will not be used in any publications. All your medical data will be stored on a computer. This computer is located at Boston University Medical Center at the site of the research doctor who is providing the medical review of your case. Your name will be connected to your medical data only at the site of the research doctor. Your name will be removed from your data before it is entered in the computer. This is done in order to keep your data private. We will keep filed that link your name to your code number in a locked cabinet. Only the study staff at the study site will be allowed to look at these files. Data obtained from this study may be published. However, we would not publish your name or other data that would identify you. The research data will be stored indefinitely.

### Subject's Rights

By consenting to participate in this study you do not waive any of your legal rights. Giving consent means that you have heard or read the information about this study and that you agree to participate. You will be given a copy of this form to keep.

If at any time you withdraw from this study you will not suffer any penalty or lose any benefits to which you are entitled.

You may obtain further information about your rights as a research subject by calling the Office of the Institutional Review Board of Boston University Medical Center at 617-638-7207.

The investigator or a member of the research team will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury while participating in this research, contact COLIN MARCHANT at 617-414-5195 during the day or you may page Dr. Marchant at 1-800-329-8797 after hours.

### Right to Refuse or Withdraw

Taking part in this study is voluntary. You have the right to refuse to take part in this study. If you decide to be in the study and then change your mind, you can withdraw from the research. Your participation is completely up to you. Your decision will not affect your being able to get health care at this institution or payment for your health care. It will not affect your enrollment in any health plan or benefits you can get.

If you choose to take part, you have the right to stop at any time. If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them as soon as possible.

**RESEARCH CONSENT FORM**  
**Adult Version**

H-27897- IMMUNIZATIONS IN PATIENTS WITH MITOCHONDRIAL DISORDERS

---

The investigator may decide to discontinue your participation without your permission because he/she may decide that staying in the study will be bad for you, or the sponsor may stop the study.

**Protection of Subject Health Information**

You have certain rights related to your health information. These include the right to know who will get your health information and why they will get it. If you choose to be in this research study, we will get information about you as explained below.

HEALTH INFORMATION ABOUT YOU THAT MIGHT BE USED OR GIVEN OUT DURING THIS RESEARCH:

- Information from your hospital or office health records at BUMC/BMC or elsewhere. This information is reasonably related to the conduct and oversight of the research study. If health information is needed from your doctors or hospitals outside of BUMC/BMC, you will be asked to give permission for these records to be sent to the researcher.
- New health information from tests, procedures, visits, interviews, or forms filled out as part of this research study.

WHY HEALTH INFORMATION ABOUT YOU MIGHT BE USED OR GIVEN OUT TO OTHERS

The reasons we might use or share your health information are:

- To do the research described here
- To make sure we do the research according to certain standard set by ethics, law, and quality groups

PEOPLE AND GROUPS THAT MAY USE OR GIVE OUT YOUR HEALTH INFORMATION

**1. PEOPLE OR GROUPS WITHIN BUMC/BMC**

- Researchers involved in this research study
- The BUMC Institutional Review Board that oversees this research

**2. PEOPLE OR GROUPS OUTSIDE BUMC/BMC**

- People or groups that we hire to do certain work for us, such as data storage companies, or laboratories.

## RESEARCH CONSENT FORM Adult Version

H-27897- IMMUNIZATIONS IN PATIENTS WITH MITOCHONDRIAL DISORDERS

---

- Federal and state agencies if they are required by law or involved in research oversight. Such agencies may include the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, the Massachusetts Department of Public Health.
- Organizations that make sure hospital standards are met
- The sponsor(s) of the research study, and people or groups it hires to help them do the research
- Other researchers that are part of this research study
- A group that oversees the research information and safety of this study
- Other:

Some people or groups who get your health information might not have to follow the same privacy rules that we follow. We share your health information only when we must. We ask anyone who gets it from us to protect your privacy. However, once the information leaves BUMC, we cannot promise that it will be kept private.

In most cases any health data that is being given out to others is identified by a unique study number and not with your name. So, although in some cases it is possible to link your name to the study data, this is not usually done.

### TIME PERIOD FOR USING OR GIVING OUT YOUR HEALTH INFORMATION

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

### YOUR PRIVACY RIGHTS

- You have the right not to sign this form that allows us to use and give out your health information for research. If you don't sign this form, you can't be in the research. This is because we need to use the health information to do the research.
- You have the right to withdraw your permission to use or share your health information in this research study. If you want to withdraw your permission, you must write a letter to the researchers in charge of this research study.

If you withdraw your permission, you will not be able to take back information that has already been used or shared with others. This includes information used or shared to do the research study or to be sure the research is safe and of high quality.

**RESEARCH CONSENT FORM**  
**Adult Version**

H-27897- IMMUNIZATIONS IN PATIENTS WITH MITOCHONDRIAL DISORDERS

---

If you withdraw your permission, you cannot continue to be in the study.

- You have the right to see and get a copy of your health information that is used or shared for research. However, you may only get this after the research is finished. To ask for this information, please contact the person in charge of this research study.

**IF RESEARCH RESULTS ARE PUBLISHED OR USED TO TEACH OTHERS**

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifying information will not be used for these purposes without your specific permission.

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

\_\_\_\_\_  
Subject (Signature and Printed Name)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Person Obtaining Consent (Signature and Printed Name)

\_\_\_\_\_  
Date

**RESEARCH CONSENT FORM**  
**Parent/Guardian Consent Form**

H-27897- IMMUNIZATIONS IN PATIENTS WITH MITOCHONDRIAL DISORDERS

---

**Background**

Mitochondrial disorders are rare but serious chronic diseases that usually affect lots of different parts of the body. The most common symptoms are in body parts that need a lot of energy like the brain and muscle, and heart. Often these symptoms appear to worsen after or are reaction to an infection, such as a cough or cold, or diarrhea. In more rare cases of mitochondrial disorder, the symptoms appear to worsen after a reaction to a shot.

Your child's doctor is asking your child to participate because your child has a mitochondrial disorder or dysfunction. We would like to look at your child's medical records and vaccine history. They may help us to learn more about mitochondrial disorder and its relationship to different sicknesses and vaccines.

**Purpose**

To study a group of children with mitochondrial disease or suspected mitochondrial disease and understand the relationship between their disease and response to vaccinations.

**What Happens In This Research Study**

Your child will be one of approximately 200 subjects to be asked to participate in this study.

All or part of the research in this study will take place at Boston University Medical Center.

If your child agree to take part in this study:

1. We will ask your child some questions about his/her health and past medical history and about any vaccines your child have received and about his/her mitochondrial disorder.
2. We will ask your child for permission to obtain and his/her medical records from doctors and hospitals.

**Risks and Discomforts**

Facts about your child such as your child's race, ethnicity and sex will be part of the information we collect. These facts may help us figure out if the factors that cause side effects of the vaccine are the same in men and women and in people of different racial and ethnic backgrounds. Findings that come from this study could help people of the same race, ethnicity and sex as your child. However, it may be possible, in some cases, through this kind of study that harmful stereotypes could be reinforced. Facts about you such as your race, ethnicity and sex will be part of the information we collect. These facts may help us figure out if the factors that cause side effects of the vaccine are the same in men and women and in people of different racial and ethnic backgrounds. Findings that come from this study could help people of the same race, ethnicity and sex as you. However, it may be possible, in some cases, through this kind of study that harmful stereotypes could be reinforced. There are no other foreseeable risks, discomforts, or inconveniences to the subject except a breach of confidentiality, which is highly unlikely.

Study staff will update you in a timely way on any new information that may affect your child's health, welfare, or decision to stay in this study.

**Potential Benefits**

Your child will receive no direct benefit from your participation in this study. However, your child's participation may help the investigators better understand more about mitochondrial

**RESEARCH CONSENT FORM**  
**Parent/Guardian Consent Form**

H-27897- IMMUNIZATIONS IN PATIENTS WITH MITOCHONDRIAL DISORDERS

---

disorders/dysfunction in the future. The stored medical data will be of no benefit to your child. However, they may be used in future research to understand the connection between mitochondrial disorder/dysfunction and vaccines. .

**Alternatives**

Your alternative is for your child to not participate in the study.

**Subject Costs and Payments**

There are no costs to your child for participating in this research study. Your child will not be paid to participate in this research study.

**Confidentiality**

Information from this study and from your child's medical record may be reviewed and photocopied by the Food and Drug Administration (FDA) and/or state and federal regulatory agencies such as the Office of Human Research Protection as applicable, and the Institutional Review Board of Boston University Medical Center. Information from this study and from your child's medical record may be used for research purposes and may be published; however, your child's name will not be used in any publications.

**Subject's Rights**

By consenting for your child to participate in this study you do not waive any of your child's legal rights. Giving consent means that you have heard or read the information about this study and that you agree for your child to participate.

If at any time you withdraw your child from this study your child will not suffer any penalty or lose any benefits to which he/she is entitled.

You may obtain further information about your child's rights as a research subject by calling the Office of the Institutional Review Board of Boston University Medical Center at 617-638-7207.

The investigator or a member of the research team will try to answer all of your questions. If you have questions or concerns at any time, contact COLIN MARCHANT at 617-414-5195 during the day or you may page Dr. Marchant at 1-800-329-8797 after hours.

**Right to Refuse or Withdraw**

Taking part in this study is voluntary. You have the right to refuse for your child to take part in this study. If you decide to be in the study and then change your mind, you can withdraw your child from the research. Your decision will not affect your child's being able to get health care at this institution or payment for your child's health care. It will not affect your child's enrollment in any health plan or benefits your child can get.

If you choose for your child to take part, you have the right to stop at any time. If there are any new findings during the study that may affect whether you want your child to continue to take part, you will be told about them as soon as possible.

**RESEARCH CONSENT FORM**  
**Parent/Guardian Consent Form**

H-27897- IMMUNIZATIONS IN PATIENTS WITH MITOCHONDRIAL DISORDERS

---

The investigator may decide to discontinue your child's participation without your permission because he/she may decide that staying in the study will be bad for your child, or the sponsor may stop the study.

**Protection of Subject Health Information**

Your child have certain rights related to your child's health information. These include the right to know who will get your child's health information and why they will get it. If your child chooses to be in this research study, we will get information about you/your child as explained below.

HEALTH INFORMATION ABOUT YOUR CHILD THAT MIGHT BE USED OR GIVEN OUT DURING THIS RESEARCH:

- Information from your child's hospital or office health records at BUMC/BMC or elsewhere. This information is reasonably related to the conduct and oversight of the research study. If health information is needed from your child's doctors or hospitals outside of BUMC/BMC, your child will be asked to give permission for these records to be sent to the researcher.
- New health information from tests, procedures, visits, interviews, or forms filled out as part of this research study.

WHY HEALTH INFORMATION ABOUT YOUR CHILD MIGHT BE USED OR GIVEN OUT TO OTHERS

The reasons we might use or share your health information are:

- To do the research described here
- To make sure we do the research according to certain standard set by ethics, law, and quality groups

PEOPLE AND GROUPS THAT MAY USE OR GIVE OUT YOUR HEALTH INFORMATION

**1. PEOPLE OR GROUPS WITHIN BUMC/BMC**

- Researchers involved in this research study
- The BUMC Institutional Review Board that oversees this research

**2. PEOPLE OR GROUPS OUTSIDE BUMC/BMC**

- People or groups that we hire to do certain work for us, such as data storage companies, or laboratories.

**RESEARCH CONSENT FORM**  
**Parent/Guardian Consent Form**

H-27897- IMMUNIZATIONS IN PATIENTS WITH MITOCHONDRIAL DISORDERS

---

- Federal and state agencies if they are required by law or involved in research oversight. Such agencies may include the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, the Massachusetts Department of Public Health.
- Organizations that make sure hospital standards are met
- The sponsor(s) of the research study, and people or groups it hires to help them do the research
- Other researchers that are part of this research study
- A group that oversees the research information and safety of this study
- Other:

Some people or groups who get your child's health information might not have to follow the same privacy rules that we follow. We share your child's health information only when we must. We ask anyone who gets it from us to protect your child's privacy. However, once the information leaves BUMC, we cannot promise that it will be kept private.

In most cases any health data that is being given out to others is identified by a unique study number and not with your child's name. So, although in some cases it is possible to link your child's name to the study data, this is not usually done.

**TIME PERIOD FOR USING OR GIVING OUT YOUR HEALTH INFORMATION**

Because research is an ongoing process, we cannot give your child an exact date when we will either destroy or stop using or sharing your child's health information.

**YOUR PRIVACY RIGHTS**

- You have the right not to sign this form that allows us to use and give out your child's health information for research. If you don't sign this form, your child can't be in the research. This is because we need to use the health information to do the research.
- You/your child have the right to withdraw his/her permission to use or his/her health information in this research study. If you/your child want to withdraw your/his/her permission, you/your child must write a letter to the researchers in charge of this research study.

If you/your child withdraw your permission, you/your child will not be able to take back information that has already been used or shared with others. This includes information used or shared to do the

**RESEARCH CONSENT FORM**  
**Parent/Guardian Consent Form**

H-27897- IMMUNIZATIONS IN PATIENTS WITH MITOCHONDRIAL DISORDERS

---

research study or to be sure the research is safe and of high quality.

If you/your child withdraw your/your child's permission, your child cannot continue to be in the study.

- You/your child have the right to see and get a copy of your child's health information that is used or shared for research. However, you/your child may only get this after the research is finished. To ask for this information, please contact the person in charge of this research study.

**IF RESEARCH RESULTS ARE PUBLISHED OR USED TO TEACH OTHERS**

The results of this research study may be published in a medical book or journal, or used to teach others. However, your child's name or other identifying information will not be used for these purposes without your child's specific permission.

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

\_\_\_\_\_  
Person Obtaining Consent (Signature and Printed Name)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Parent/Legal Guardian (signature and printed name)

\_\_\_\_\_  
Date

## RESEARCH CONSENT FORM

### **12-17 years old ASSENT; and, VERBAL ASSENT for 7-11 year olds (If decisionally competent)**

H-27897- IMMUNIZATIONS IN PATIENTS WITH MITOCHONDRIAL DISORDERS

---

#### **Background**

Mitochondrial disorders are rare sicknesses that usually affect lots of different parts of the body. The most common problems are in body parts that need a lot of energy like the brain and muscle, and heart. Often these problems appear to get worse after an infection, such as a cough or cold, or diarrhea. In more rare cases of mitochondrial disorder, the problems appear to worsen after a reaction to a shot.

Your doctor is asking you to participate because you have a mitochondrial disorder. We would like to look at your medical records and vaccine history. They may help us to learn more about mitochondrial disorder and its relationship to different sicknesses and vaccines.

#### **Purpose**

To investigate a group of children with mitochondrial disease to better understand what happens to these children.

#### **What Happens In This Research Study**

All of the research in this study will take place at Boston University Medical Center.

If you agree to take part in this study, we will ask you some questions about your body. You can say no to answering questions.

#### **Risks and Discomforts**

There are no foreseeable risks, discomforts, or inconveniences to the subject except a breach of confidentiality and this is highly unlikely.

#### **Potential Benefits**

You will receive no direct benefit from your participation in this study. However, your participation may help the investigators better understand mitochondrial disorders and vaccines..

#### **Alternatives**

Your alternative is to not participate in the study.

#### **Subject Costs and Payments**

There are no costs to you for participating in this research study. You will not be paid to participate in this research study.

#### **Confidentiality**

Information from this study and from your medical record may be reviewed and photocopied by the Food and Drug Administration (FDA) and/or state and federal regulatory agencies such as the Office of Human Research Protection as applicable, and the Institutional Review Board of Boston University Medical Center. Information from this study and from your medical record may be used for research purposes and may be published; however, your name will not be used in any publications.

**RESEARCH CONSENT FORM**

**12-17 years old ASSENT; and, VERBAL ASSENT for 7-11 year olds (If decisionally competent)**

H-27897- IMMUNIZATIONS IN PATIENTS WITH MITOCHONDRIAL DISORDERS

---

**Subject's Rights**

Giving assent means that you have heard or read the information about this study and that you agree to participate.

A member of the research team will try to answer all of your questions. If you have questions at any time, contact COLIN MARCHANT at 617-414-5195 during the day or you may page Dr. Marchant at 1-800-329-8797 after hours.

**Right to Refuse or Withdraw**

Taking part in this study is voluntary. You have the right to say that you don't want to take part in this study. If you decide to be in the study and then change your mind, you can stop at any time.

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

\_\_\_\_\_  
Child assent (Signature and Printed Name)

\_\_\_\_\_  
Date