



# The North American Malignant Hyperthermia Registry of MHAUS

UPMC Mercy, Building B (Ermire), 8th Floor, Room 8522-3, 1400 Locust Street, Pittsburgh, PA 15219

## CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH REGISTRY

### TITLE: NORTH AMERICAN MALIGNANT HYPERTHERMIA REGISTRY

Tel: 1-888-274-7899

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Sponsor: Malignant Hyperthermia Association of the United States



### ***What is the purpose of the North American Malignant Hyperthermia Registry?***

Many advances in medicine have resulted from research involving the collection and analysis of the medical record information of patients with a certain disease or condition. Because you, or one of your relatives, has experienced Malignant Hyperthermia (MH), we are asking for your permission to allow us to place your past, current and future medical record information into the North American Malignant Hyperthermia Registry. By placing the medical record information of many patients such as you into a research registry, researchers will be able to conduct research studies directed at increasing our knowledge about this disease, Malignant Hyperthermia.

It is anticipated that the North American Malignant Hyperthermia Registry (NAMHR) will assist our investigators in two important ways.

First, it will allow researchers to review and study the medical records of many individuals to answer questions about MH and its treatment.

Second, it will help researchers identify and recruit patients who are eligible for participation in future research studies. If you agree to participate in the NAMHR, restricted parts of your medical information may be reviewed by physicians and researchers to determine if you might qualify for various future research studies. The parts of your record that researchers may review will not include any identifying information.

### ***Who is being asked to take part in the North American MH Registry?***

You, or someone in your family who has experienced an episode of MH, are being asked to take part in the NAMHR because your history suggests that you may be likely to experience this serious complication of anesthesia. We also ask people who have been proven NOT to be MH by normal muscle contracture test (CHCT) results, to join the NAMHR. These are very important control subjects.

### ***What is involved with my participation in the North American MH Registry?***

If you agree to be included in the NAMHR, you are allowing us to record basic personal information (name, address, phone number, etc.) about you and information regarding your health that is on the form submitted to the NAMHR. Your physician may complete this form without your help, but your personal information will not be recorded in the NAMHR unless you agree to this. The information about your anesthetic history, your general health and that of your family, and the results of muscle biopsy contracture tests may be reported without identifying you as an individual. Similarly, no information that identifies your adult relatives will be entered into the NAMHR unless there is a consent form, just like this one, signed by that individual relative. You may be contacted yearly by the NAMHR staff to check for changes in your address.

### ***What procedures will be performed for research purposes?***

**If you agree to be included in the NAMHR it does not mean that you are obligated to be in any future research studies, but it gives the NAMHR staff the ability to invite you to join a new study.**

If you are interested in participating in a particular research study, you will be asked to sign a separate consent form specific for that research study. This separate consent form will outline in detail the procedures, risks and benefits, etc. associated with participation in that research study. The NAMHR office and Principle Investigator of a study will be available to discuss any questions that you may have.

### ***What are the possible risks of participating in the NAMH Registry?***

There are no physical risks associated with agreeing to participate in the NAMH Registry.

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University Of Pittsburgh  
Institutional Review Board

Approval Date: 5/13/2015  
Renewal Date: 5/12/2016

IRB #: IRB000944

***What are the possible risks of participating in the NAMH Registry?***

There are no physical risks associated with agreeing to participate in the NAMH Registry.

The confidentiality of your records is important. Some people who are MH susceptible have had difficulty obtaining medical insurance. Some people who are MH susceptible may be denied having training in the military. These decisions are due to MH susceptibility, not to participation in the NAMH Registry.

There is a possibility of a breach of confidentiality of your medical record information, which is addressed in the Confidentiality section below. The Registry will try to avoid any such breach of confidentiality.

***What are the possible benefits of participating in the NAMH Registry?***

There are no direct benefits to participation in the registry. Collection of clinical information in this registry will permit research into the causes, manner of inheritance, and most effective treatment of MH, as well as the safest means for anesthetizing patients with MH.

***Will my insurance provider or I be charged for the costs of any part of this participation in the NAMH Registry?***

Neither you nor your insurance provider will be charged for the costs of participating in the NAMH Registry.

***Will I be paid if I take part in the NAMH Registry?***

You will not receive any payment for participating in this registry.

**CONFIDENTIALITY**

***Who will know about my participation in this registry?***

The Medical Director and staff of the NAMHR will know about your participation in this Registry. If you had a muscle biopsy and contracture test at a MH Diagnostic Center the Director and staff there may know about your participation in this Registry. All these individuals are expected to treat your participation in the NAMHR in a confidential (private) manner consistent with other hospital medical records.

***How will you protect my privacy and who will have access to my personal information?***

Paper records are kept in locked cabinets in rooms that are locked when no staff is present. You will not be identified by name or other personally identifying information in any publication or research results unless you sign a separate consent form giving your agreement to this.

In addition to the Medical Director, listed on the first page of this form, NAMHR staff, and Biopsy Center Directors, under the conditions described below, other individuals may have access to your private information included in the NAMH Registry.

Other investigators may request access to the NAMH Registry to identify subjects for their research studies. If the request is approved by the NAMHR advisory board and the Biopsy Center Directors, the NAMHR staff will search the database to identify potential subjects. A member of the NAMHR staff will then contact you to confirm your address and to inform you that you may be a possible candidate in a study. Your personal information will not be provided to an outside investigator by the NAMHR.



You will subsequently receive information about that study in the mail. You may then contact the investigator if you wish to join the study. You may also contact the NAMHR staff if you would like to obtain more information.

Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review information in the NAMHR (which may include your identifiable medical information) to ensure that the NAMHR adequately protects your privacy.

In unusual cases, the investigators may be required to release your identifiable medical record information from the NAMHR in response to an order from a court of law.

***For how long will my personal health information be placed in the NAMHR and for how long will this information be used for research purposes?***

Your health information contained within the NAMH Registry will be used for research purposes for an indefinite period of time.

***Is my participation in this research voluntary?***

Your participation in this registry is completely voluntary. You do not have to take part, and should you change your mind, you can withdraw at any time. Your current and future care and any other benefits for which you qualify will be the same whether you participate in this research study or not.

***May I withdraw, at a future date, my consent for participation in this study?***

You may withdraw, at any time, your consent for participation in the NAMHR. Then the NAMHR will not collect any additional information about you. Your personal information will not be used for the research purposes described above. However, any research use of your personal health information prior to the date that you formally withdraw your permission will not be destroyed.

To formally withdraw your permission for participation in the NAMH Registry you should provide a written and dated notice of this decision to the principal investigator of the NAMHR at the address listed on the first page of this consent form.



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**VOLUNTARY CONSENT:**

By signing this form I certify that I have read the preceding, or that it has been read to me, and I understand that I have agreed to have my medical information placed in this research registry. I agree to be contacted for future research studies about Malignant Hyperthermia and related conditions.

Any questions I have pertaining to the North American Malignant Hyperthermia Registry have been and will be answered by my Biopsy Center Director, the NAMHR Director, or one of the co-investigators listed on the front page. The toll free number for the NAMHR is: (888) 274-7899.

Any questions I have concerning my rights as a research subject will be answered by the Human Subject Protection Advocate, IRB Office, University of Pittsburgh, 1 (866) 212-2668

The IRB phone number associated with the North American Malignant Hyperthermia Registry is: (412) 383-1480.

The IRB phone number associated with my Biopsy Center, if I have one, is:

\_\_\_\_\_

A copy of this form will be given to me.

By signing this form, you agree to have your information placed in a research registry.

\_\_\_\_\_  
Print Subject(s) Name

\_\_\_\_\_  
Subject Phone Number

\_\_\_\_\_  
Subject Signature

\_\_\_\_\_  
Date

**CERTIFICATION OF INFORMED CONSENT:**

I certify that I have explained to the above individual the nature and purpose, the potential benefits, and possible risks associated with participating in this research registry and that any questions about this information have been answered. The principle investigator can be reached through the phone numbers listed on the first page of this form.

\_\_\_\_\_  
Printed Name of Investigator or Co-Investigator

\_\_\_\_\_  
Signature of Investigator or Co-Investigator

\_\_\_\_\_  
Date

