eConsent Form (form ICF)

Please complete the eConsent below.

Thank you!

ICF0 - INTRODUCTION

Thank you for taking your time to participate in the North American Malignant Hyperthermia Registry (NAMHR) of MHAUS. This Registry consist of 8 survey forms, as below. These forms are to be filled out by NAMHR participants AND their anesthesiologists/health care providers. The Registry is considered a Limited Data Set so date are okay to be entered.

- Informed Consent
- Participant Profile (form A)
- Participant Family Profile (form B)
- Biopsy Report (form C)
- DNA Test Results (form D)

Information about MH event will be collected in the Adverse Metabolic/Muscular Reaction to Anesthesia (AMRA) forms below:

- Clinical Information (form E)
- Before AMRA Episode (form F)
- During AMRA Episode (form G)
- After AMRA Episode (form H)

Instructions to complete the surveys:

1. To register a patient in the NAMHR Registry the first survey to be filled out will be the consent form below this introduction.

2. To be added anonymously click yes to the first question and that will end the consent survey and take you to the patient information survey.

3. To enter your name (or MH patient's name) with NAMHR, they will need to sign the consent form for release of information by you and your physician to NAMHR and for release of information by NAMHR to your future physicians. If both parents of a child who experienced an episode of MH wish to be registered, then separate consent forms must be signed for each parent and one for the child.

4. The first 4 surveys (form A, B, C, and D) are to collect information from the participants/patients regarding their history, biopsy information and genetic information; the following 4 surveys (form E, F, G, and H) pertain to clinical information about the MH event.

5. Survey form C can be filled out by either biopsy center staff or by participant's physicians/anesthesiologists; Survey form D can be filled out by either genetic test center staff or by participant's physicians/anesthesiologists.

6. Survey form E is recommended to be filled out by all participants' physicians/anesthesiologists. If a participant has ARMA episode, please also fill out survey forms, F, G, and H, in sequence.

7. You may need to consult with your anesthesiologist or other physicians responsible for diagnosing you as MH susceptible for assistance.

8. Information sent to the NAMHR will remain confidential. Any information released will only be released as a limited data set for research purposes and only with an IRB (ethics committee) review and approval.

9. For Healthcare Providers competing the registry information a 1 year membership to MHAUS will be given to you.

10. Once the surveys are submitted, all answers are final. Please download the completed form at end of survey for your reference. If you need to make changes, please contact the NAMHR office at:

The North American Malignant Hyperthermia Registry of MHAUS
University of Florida
Department of Anesthesiology
Communicore Building
1345 SW Center Drive, Room C2-22
PO Box 100254

08/10/2018 5:46pm
ICF0.1 - If you are a medical provider, you are encouraged to print and give this FAQ form to the patients. THANK YOU.

[Attachment: "FAQ.pdf"]

ICF0.2 - Would you like to submit a possible Malignant Hyperthermia case with NAMHR anonymously (previously called "AMRA Report")?

☐ Yes
☐ No

(if you click ‘Yes’, you will skip form ICF, and you should not provide patients’ personal information in the survey forms thereafter.)
### the Paper Informed Consent Form

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<td>ICF1.1 - If you have a signed paper Informed Consent Form, please scan and upload the form below.</td>
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<td>☐ Yes</td>
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<td>☐ No</td>
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<td>(if you click 'Yes', you will begin the survey shortly, and you could provide participant's personal information. If you don't have any consent form yet, please click 'No', you will soon continue with the eConsent process.)</td>
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Informed Consent Form 

If you are the parent/legally authorized representative for the subject, as you read the information in this Consent Form, you should put yourself in the subject’s place to decide whether or not to allow us to collect research information about the subject and to allow the subject to take part in this study. Therefore, for the rest of this form, the word “you” refers to the subject (child participant).

If you are an adult participant reading this form, the word “you” refers to you.

We the North American Malignant Hyperthermia Registry (NAMHR) are asking permission from you,

Printed name of study participant ("study subject")

to store some of your basic personal information and information regarding your health that is on the form submitted to the NAMHR in order to use it for future research.

The Principal Investigator (the person in charge of this research) or a representative of the Principal Investigator will describe this Malignant Hyperthermia (MH) registry databank to you and answer all of your questions. Your participation is entirely voluntary. Before you decide whether or not to take part, please read the information below and ask questions about anything you do not understand. If you choose not to participate in this study you will not be penalized or lose any benefits that you would otherwise be entitled to.

1. What are we asking to store?

If you agree, the following basic personal information will be collected and stored in the NAMHR databank:

- Name, address, birthday, phone number, and other information about you and your health
- Medical history about family members

IRB Project #: 201701821
IRB Version: 05/29/2014
PI Version: 08/29/2017
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2. Reason for Storing Your Information:

We wish to store your contact and medical information and potentially use it in future research and/or to contact you in the future to discuss possible participation in future research. Many different kinds of research uses medical information. Some researchers may develop new tests to find diseases. Others may develop new ways to treat or even cure diseases. In the future, some of the research may help to develop new products, such as tests and drugs. Some research looks at diseases that are passed on in families (called genetic research). Research done with your medical information may look for genetic causes and signs of disease.

Many medical problems may arise due to the environment or from genetic factors. Your medical condition may come from one or both of these causes. Genetic factors are those that people are born with and that can affect other family members. There may be genetic testing done in the future that would provide information about traits that were passed on to you from your parents or from you to your children. Because the nature and value of any future testing or research cannot be known at this time, this genetic information and any other results obtained from using your medical information may not be given to you or your doctor.

3. Can you change your mind?

If you decide that your information can be kept for future research but you later change your mind, you can contact Dr. Gravenstein at 352-494-4938 or the NAMHR office at 1-888-274-7899, and they will mark any of your medical information that is in the registry as withdrawn. To formally withdraw your permission for participation in the NAMHR, you should provide a written and dated notice of this decision to the principal investigator of the NAMHR. Following receipt of your request, the NAMHR will not collect any information from you and your personal information will no longer be used for research purposes above. However, any research use of your personal health information prior to the date that you formally withdraw your permission will not be destroyed. Otherwise, the data may be kept indefinitely, or until the University of Florida decides to destroy them. You have the right to see and copy the information that is collected from you and stored in the medical information bank. There will be no cost to you for any medical information collected and stored.

4. Where will your medical information be stored?

Your medical information will be kept in a secure location in a medical information databank called the North American Malignant Hyperthermia Registry (NAMHR) so that it may be used in future research to learn more about your medical condition and other medical problems. Once collected, you may be called from time to time to update information on your health that is necessary to keep the medical information current and to inquire about potential interest in future research.
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5. Are there any benefits to your participation in this medical information databank?

There is no direct benefit for your participation in this medical information databank. Even though the research that is done on your medical information cannot be used to help you, it might help other people who have a similar medical condition or other medical problems.

6. Are there any risks to your participation in this medical information databank?

There are no physical risks associated with agreeing to participate in the NAMHR. However, there is a possibility of a breach of confidentiality of your medical record information, which is addressed in the Confidentiality section to follow. The Registry follows procedures designed to avoid this.

Although every effort will be made to keep your information confidential, there is a small risk that an unauthorized person may obtain your information. Therefore, there is a very slight risk that a test result could be linked to your identity and inadvertently disclosed to a third party.

If you were to receive the result of a genetic test that indicated a problem, it could cause anxiety or other psychological distress. In addition, you might have to decide whether or not to discuss the findings with members of your family. If a third party learned the results, there is a risk of social stigma and of the unpredicted disclosure of this information to others.

There is a Federal law, called the Genetic Information Nondiscrimination Act (GINA) that makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. Additional information can be obtained at http://irb.ufl.edu/gina.html or call 1-800-669-3362. If you think this law has been violated, it will be up to you to pursue any compensation from the offending insurance company and/or employer.

7. Will your medical information be shared with others?

The NAMHR director, Dr. Gravenstein or his successors will be allowed to collect, use and/or give out your medical information tissue. They may give your medical information to other researchers whose research is approved by an Institutional Review Board (IRB) (An IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research). They may also give your medical information to a study sponsor, the Food and Drug Administration, the Department of Health and Human Services, the Office of Human Research Protections, or other Government agencies.

Your medical information may be shared with other research centers or private companies, in which case the University of Florida may charge the research center or private company a fee in order to recover the University of Florida’s costs of sharing your medical information. There is a risk that information received by these authorized persons or agencies could then be passed on to others beyond your authorization and not covered by the law.
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You have completed ... (of Form ICF - eConsent Form)
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Investigators may request access to the NAMHR to identify subjects for their research studies. If such a request is approved by the appropriate committees, the NAMHR staff will search the database to identify potential subjects. You will receive more information and a separate consent form for each new study. The NAMHR office and Principle Investigator of a study will be available to discuss any questions that you may have.

8. How will the researchers benefit?

In general, presenting research results helps the career of a scientist. Therefore, the Principal Investigator may benefit if the results of this study are presented at scientific meetings or in scientific journals. It is possible that new treatments, medicines, therapies or products could be created from studies that use your tissue or medical information. If that happens, the Principal Investigator and the University of Florida could receive significant financial benefits. You will not be offered any payment or any other financial benefit.
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9. Signatures:

As a representative of this study, the individual signing below has explained to the participant the purpose, the procedures, the possible benefits, and the risks of the collection, storage, and use of their medical information and how the participant’s protected health information will be collected used and shared with others:

Signature of Person Obtaining Consent and Authorization

Date

Consenting Adults: You have been informed about this study’s purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared with others. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask questions at any time.

Adult Consenting for Self. By signing this form, you voluntarily agree to participate in this study. You hereby authorize the collection, use and sharing of your protected health information as described in sections 17-21 above. By signing this form, you are not waiving any of your legal rights.

Signature of Adult Consenting & Authorizing for Self

Date

Parent/Adult Legally Representing the Subject. By signing this form, you voluntarily give your permission for the person named below to participate in this study. You hereby authorize the collection, use and sharing of protected health information for the person named below as described above. You are not waiving any legal rights for yourself or the person you are legally representing. After your signature, please print your name and your relationship to the subject.

Consent & Authorization Signature of Parent/Legal Representative

Date

Printed Name of Legal Representative

Relationship to Participant

Printed Name of Subject
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You have completed ... (of Form ICF - eConsent Form)

70%
Participants Who Cannot Consent But Can Read and/or Understand about the Study.

Although legally you cannot "consent" to be in this study, we need to know if you want to take part. If you decide to take part in this study, and your parent or the person legally responsible for you gives permission, you both need to sign. You signing below means that you agree to take part (assent). The signature of your parent/legal representative above means he or she gives permission (consent) for you to take part.

Assent Signature of Participant __________________________  Date ____________

Please click on Next Page to continue
e-ICF is available for download below

You have completed ... (of Form ICF - eConsent Form)
80%

ICF3.1 - Copy of Informed Consent for download.

Please click on the PDF document below to download and save to your computer.

[Attachment: "eConsent Form.pdf"]

ICF3.2 - If you would like to receive a copy of the Informed Consent by email, please enter your email address here:  

(Note: Your email address will NOT be used for any other purpose.)

Please click on Next Page to sign and consent to participate the registry.
**Please provide the following information and signature(s) to consent:**

**You have completed ... (of Form ICF - eConsent Form)**

90%

| ICF4.1 - Are you consenting for yourself or your minor child? | ☐ self  
| | ☐ child |
| ICF4.2 - Do you AGREE with the above e-Consent form and to participate in the registry? or do you AGREE with the above e-Consent form and to register your child, if you are consenting parent/guardian? | ☐ Yes  
| | ☐ No |
| ICF4.3 - Your first name: | ____________________________ |
| ICF4.4 - Your last name: | ____________________________ |
| ICF4.5 - Please click on the link below to add your signature. | ____________________________ |
| ICF4.6 - Date of Consent | ____________________________  
  *(for example, if Dec 25th, 2017, please type in 2017-12-25)* |
| ICF4.7 - what's your relationship to the child being registered? | ☐ mother  
| | ☐ father  
| | ☐ child  
| | ☐ brother/sister  
| | ☐ grandchild  
| | ☐ half-sibling  
| | ☐ niece/nephew  
| | ☐ grandparent (mother side)  
| | ☐ aunt/uncle (mother side)  
| | ☐ first cousin (mother side)  
| | ☐ second cousin (mother side)  
| | ☐ other (mother side)  
| | ☐ grandparent (father side)  
| | ☐ aunt/uncle (father side)  
| | ☐ first cousin (father side)  
| | ☐ second cousin (father side)  
| | ☐ other (father side)  
| | ☐ relative by marriage  
| | ☐ other blood relative |
| ICF4.8 - Your child’s first name | ____________________________ |
| ICF4.9 - Your child’s last name | ____________________________ |
ICF4.10 - Please click on the link below to add the signature of child (if 7 years of age or older)

__________________________________________  
(the minor child signs here)

Congratulations. You have completed ... (of Form ICF - eConsent Form)  
100%