UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM
to Participate in Research, and

AUTHORIZATION
to Collect, Use, and Disclose Protected Health Information (PHI)

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

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 use 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.

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.

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. **I**t 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.

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 \ tissue 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

_____

Your Contact number:

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