CONSENT FORM FOR PARTICIPATION IN A NEUROMUSCULAR RESEARCH STUDY

INTRODUCTION

You/your child are being invited to be in an experimental research study because you have/your child has a muscle disease. Please ask us about anything in this document or that we tell you that you do not understand.

PURPOSE

The purpose of the study is as follows:

1. To study the hereditary makeup of the muscle in patients suffering from neuromuscular disorders, by analyzing the DNA, RNA (inherited family features) and proteins (an essential chemical blend) in muscle biopsy specimens.
2. To establish cell appearances, muscle cells removed from you/your child during the muscle biopsy will be placed in a special solution in tubes/flasks and allowed to multiply and grow outside the body from muscle biopsy specimens.

PROCEDURES

1. During the process of performing surgery to attempt to improve the symptoms of the underlying muscle disease (requested by your treating physician), some of muscle tissue that has to be removed and would otherwise be discarded will be used for the research studies. The DNA and RNA (inherited family features) removed from the muscle will be studied at once or stored for study at a later date. The tests will help us better understand which hereditary factors may be responsible for different neuromuscular diseases and the role of other factors that may be produced by these hereditary factors.

2. The small sample removed will be shared with other researchers who will grow cells obtained from your muscle sample in a test tube to look for hereditary factors (genes) that may be associated with neuromuscular diseases.

3. The samples will be identified only by a code number and the other researchers will not know your identity.

4. Your/your child's active participation in this study will last until the specimen has been collected.

5. If you approve, a member of the clinical staff will draw 10 – 30 ml (2 - 6 teaspoons) of blood from your/your child's arm.

RISKS

There is no extra from using for research purposes some of the removed muscle that would otherwise be discarded. This surgery was recommended by your/your child's treating physician for the best care of your/your child's muscle disease. You/your child may experience the risks and complications of muscle surgery: bleeding, pain, scar or allergic reaction to local anesthetic agent and delayed wound healing.

For the blood donation, what we know about the risk for giving blood is that there might be a small amount of pain for a short time and a very small chance of infection.

BENEFITS

You/your child will not receive any direct benefit from participating in this study. We do hope to learn information that may benefit others in the future from this research.

ALTERNATIVES

The alternative is to not participate in this study.

COSTS

You/your child will not be charged for additional tests and procedures which are performed only because you/your child are participating in this research. Your/your child's responsibility to pay for other medical treatment will not be changed by you/your child's participation in this research project.

In the case of injury of illness resulting from your/your child's participation in this study, medical treatment is available to you/your child at the NAME OF MEDICAL CENTER. You/your child will be charged the usual and customary charges for any such treatment you receive.

COMPENSATION

You/your child will not be paid for your/your child's participation in this study.

VOLUNTARY PARTICIPATON

Your/your child participation is voluntary. If you/your child decide not to participate in this study you/your child will not suffer a penalty or loss of benefits to which you/your child are otherwise entitled. If you/your child decide to participate in this study you/your child may discontinue your/your child's participation at any time, without penalty or loss of benefits and it will have not effect on the quality of your/your child's medical care. If you/your child do not sign this consent document you/your child will not be enrolled in the study.

Signed copies of this consent document will be:

1. retained on file by the Principal Investigator,
2. given to you/your child to keep,
3. included in your/your child's medical records.

WITHDRAWAL

You/your child may choose to stop your/your child's participation in this study and withdraw at any time. If you/your child decide to withdraw the information already collected about you/your child may still be used in this study. Your/your child's decision to stop your/your child's participation will have no effect on the quality of medical care.

NEW INFORMATION

You/your child will be told of any information we learn during your/your child's participation in this study that may affect your/your child's willingness to participate.

CONFIDENTIALITY

Study information will be kept private. Study records may be reviewed by the Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), and the NAME OF MEDICAL SCHOOL Institutional Review Board (IRB) and Office of Compliance. You/your child will not be identified in reports or publications of this study.

PROTECTED HEALTH INFORMATION

Protected health information is any personal health information through which you/your child can be identified. The data collected in this study includes: initials, date of birth, brief medical history. A decision to participate in this research means that you/your child agree to use of your/your child's health information for the study described in this form. The information will not be released beyond the purposes of conducting this study. The information collected in this study will be kept indefinitely. While this study is ongoing you/your child may not have access to the research information, but you/your child may request it after the research is completed.

NUMBER OF PARTICIPANTS

We expect XXX participants to enroll in this study here.

QUESTIONS

If you have any questions about this study or need to report any problems, side effects or injuries, please call the Principal Investigator, Dr. NAME, whose phone number is XXX and the hospital telephone operator can page the doctor on call.

You may discuss your/your child's rights as a research participant with the Chairman of the Institutional Review Board, NAME, ADDRESS, AND PHONE NUMBER OF THE MEDICAL CENTER. The Institutional Review Board is a group of people not involved with this study who have reviewed the study to protect your/your child's rights.

STATEMENT OF PARTICIPATION IN THE MUSCLE TISSUE PART OF THIS STUDY

I/my child have been told about this study and the possible risks and benefits. My/my child's participation in allowing some of the surgically removed muscle tissue to be used for research is voluntary and I/my child may withdraw at any time without any penalty or loss of benefits to which I/my child am entitled, including medical care at the NAME OF MEDICAL CENTER.

By signing this form I/my child am not giving up any legal rights I/my child may have.

Participant (Print Name)	Date
Participant's Signature	Date
Assent of Minor Participant	Date
Signature of Minor Participant's Parent or Legally Authorized Representative and Relationship to Minor	Date

Person Obtaining Consent Name (Print)	Signature	Date

I acknowledge that the participant identified above has been entered into this study, which properly obtained informed consent.

Investigator's Name (Print)	Signature	Date

STATEMENT OF PARTICIPATION IN THE BLOOD DONATION PART OF THIS STUDY

I/my child have been told about this study and the possible risks and benefits. I/my child I voluntarily consent to donate blood for use in research as described in this document.

By signing this form I/my child am not giving up any legal rights I/my child may have.

Participant (Print Name)	Date
Participant's Signature	Date
Assent of Minor Participant	Date
Signature of Minor Participant's Parent or Legally Authorized Representative and Relationship to Minor	Date

Person Obtaining Consent Name (Print)	Signature	Date

I acknowledge that the participant identified above has been entered into this study, which properly obtained informed consent.

Investigator's Name (Print)	Signature	Date