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)

Dr Krista Vandenborne is asking permission from you/your child,

_____
Printed name of study participant ("study subject")

to store some of your blood, urine, saliva samples, and any MRI/MRS data.
The Principal Investigator (the person in charge of this research) or a representative of the Principal Investigator will describe this tissue and data bank 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 will be collected and stored in the tissue and data bank. We are requesting that blood, urine, saliva samples, and any MRI/MRS data taken as part of any ImagingDMD study be stored in the University of Florida Biorepository.

2. Reason for Storing Your Tissue and data:

We wish to store your blood, urine, saliva samples and MRI/MRS data and potentially use it in future research. 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 tissue and data may not be given to you or your doctor.

There are many different kinds of research uses for these samples and data. 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 blood, urine, saliva samples and MRI/MRS data 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 tissue and data may not be given to you or your doctor.

Tests done only for research purposes will not be evaluated or used to diagnose or treat any of your medical problems. This/these test(s) may need to be repeated if required for your medical care in the future.

3. Can you change your mind?

If you decide that your tissue and data can be kept for future research but you later change your mind, you can contact Dr Krista Vandenborne at 352-474-0329 or contact the research coordinator Claudia Senesac at 352-273-6453 who will remove and destroy any of your tissue samples and /or MRI/MRS data that he/she still has. Otherwise, the samples may be kept until they are used up, 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 tissue and data bank. There will be no cost to you for any tissue or MRI/MRS data collected and stored.

4. Where will your <medical information \ tissue \ blood sample> be stored?

Your tissue samples and MRI/MRS data will be kept in a secure location in a biorepository called Imaging Duchenne Muscular Dystrophy Biorepository 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 tissue and/or data.

5. Are there any benefits to your participation in this tissue and data bank?

There is no direct benefit for your participation in this tissue and data bank. Even though the research that is done on your tissue samples and/or MRI/MRS data 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 tissue and databank?

There are no known risks to storing your tissue samples and MRI/MRS data in the Biorepository. However the risks of drawing blood from a vein include discomfort at the site of puncture; possible bruising and swelling around the puncture site; rarely an infection; and, uncommonly faintness from the procedure. There are no known risks to collecting urine or saliva samples.

MRS and MRI are not known to harm living systems. Imaging is used routinely for medical care and is very safe for most people, but you will be monitored during the entire MR scan in case any problems occur. However, the possibility of unforeseen hazards cannot be ruled out. The risks of MRI are:

- The MRI scanner contains a very strong magnet. Therefore, you may not be able to have the MRI if you have any type of metal implanted in your body, for example, any pacing device (such as a heart pacer), any metal in your eyes, or certain types of heart valves or brain aneurysm clips. Someone will ask you questions about this before you have the MRI.
- There is not much room inside the MRI scanner. You may be uncomfortable if you do not like to be in close spaces ("claustrophobia"). During the procedure, you will be able to talk with the MRI staff through a speaker system, and, in the event of an emergency, you can tell them to stop the scan
- The MRI scanner produces a loud hammering noise, which has produced hearing loss in a very small number of patients. You will be given earplugs and a headphone set to reduce this risk.

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 tissue and data be shared with others?

Dr Krista Vandenborne and/or other research staff directly connected with this study or their successors will be allowed to collect, use and/or give out your tissue samples and MRI/MRS data. They may give your tissue and MRI/MRS data 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 \ tissue 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 blood, urine, saliva samples and MRI/MRS data 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 tissue and/ or MRI/MRS data. 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.

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.

9. If you choose to take part in this study, will it cost you anything?

Study Services

The Sponsor will pay for all services required as part of your participation in this study. There will be no cost to you. If you receive a bill related to this study, please contact Dr. Krista Vandenborne at 352-474-0329.

Items/Services Not Paid for by the Sponsor

All other medical services provided to you that are not directly required by this study will be billed to you or your insurance company in the usual manner.

10. What if you are injured because of the research study?

If you are injured as a direct result of your participation in this study, only the professional services that you receive from any University of Florida Health Science Center healthcare provider will be provided without charge. These healthcare providers include physicians, physician assistants, nurse practitioners, dentists or psychologists. Any other expenses, including Shands hospital expenses, will be billed to you or your insurance provider.

You will be responsible for any deductible, co-insurance, or co-payments. Some insurance companies may not cover costs associated with research studies or research-related injuries. Please contact your insurance company for additional information.

The Principal Investigator will determine whether your injury is related to your participation in this study.

No additional compensation is routinely offered. The Principal Investigator and others involved in this study may be University of Florida employees. As employees of the University, they are protected under state law, which limits financial recovery for negligence.

Please contact one of the research team members listed in question 3 of this form if you experience an injury or have questions about any discomforts that you experience while participating in this study.

11. Signatures:

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this research study; the alternatives to being in the study; and how privacy will be protected:

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Signature of Person Obtaining Consent 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 privacy will be protected. 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 other questions at any time.

Adult Consenting for Self. By signing this form, you voluntarily agree to participate in this study. By signing this form, you are not waiving any of your legal rights.

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Signature of Adult Consenting 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 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 Signature of Parent/Legal Representative Date

_____ _____

Print: Name of Legal Representative Print: Relationship to Participant:

_____

Print: Name of Subject:

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. Your 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