

Informed Consent Form
To Participate in Research, and
Authorization
To Collect, Use, and Disclose Protected Health Information (PHI)

If you are a parent or legally authorized representative for the child, as you read the information in this Consent Form, you should put yourself in your child's place to decide whether or not to allow your child to take part in this study. Therefore, for the rest of the form, the word "you" refers to your child.

If you are an adult, child, or adolescent reading this form, the word "you" refers to you.

We, on behalf of principal investigator (PI) Dr. Jennifer Fishe, (904-244-4986 – primary, 904-633-0990 - secondary) are asking permission from you:

Printed name of legal guardian (if applicable)

on behalf of the study subject:

Printed name of study participant ("study subject")

To store some of the study subject's clinical data, tissue, and/or DNA samples in order to use it for future research. We may store information about you such as your name, medical record number, or dates associated with your healthcare. All this information and samples is called protected health information (PHI). We will not release this information unless the request is approved by an institutional review board (IRB) and the study PI. An IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research.

The Principal Investigator (Dr. Jennifer Fishe – the person in charge of this research) or a representative of the Principal Investigator will describe this tissue, DNA, and data bank to you and answer all of your questions. Your participation is entirely voluntary.

Before you decide whether or not you will take part, please read the information below and ask questions about anything you do not understand. If you choose to not participate in this study, you will not be penalized or lose any benefits that you would otherwise be entitled to. Funding for this project is provided by the University of Florida and through a grant from the National Institutes of Health – National Center for Advancing Translational Sciences (NCATS) and through the Scott R. MacKenzie Foundation.

1. What are we asking to store?

If you agree, the following tissue, data, and contact information will be collected from you and stored in the medical information / tissue / DNA / saliva bank: RePEAT Tissue/DNA/Saliva Samples; your name, telephone number, mailing address, and email address. Your health and medical records may also be accessed for future research purposes.

2. Reason for Storing Your Tissue / DNA / saliva sample, and Data

We wish to store your tissue, DNA/saliva sample, and data to potentially use it in future research. Many different kinds of research use tissue, DNA, and saliva samples. 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 data, and tissue / DNA / saliva sample 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 / tissue may not be given to you or your doctor.

If you agree, we will also store your contact information in order to contact you for future research studies that you may wish to participate in.

3. Can you change your mind?

If you decide that your data, and tissue / DNA / saliva sample can be kept for future research but you later change your mind, you can contact the Principal Investigator Jennifer Fishe at 904-244-4986 or Jennifer.Fishe@jax.ufl.edu who will remove and destroy any of your data, and tissue / DNA / saliva sample that 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 medical information / tissue bank. There

will be no cost to you for any data, and tissue / DNA / saliva sample collected and stored.

4. Where will your data, and tissue / DNA / saliva sample be stored?

Your data, including PHI, will be kept on a secure, password-protected server that is only accessible by a password protected computer kept in a locked office for the PI and IRB-authorized study team. Tissue / DNA / saliva sample will be kept in a secure location at the University of Florida College of Medicine – Jacksonville biorepository so that it may be used in future research to learn more about childrens' medical conditions 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 / tissue bank / blood sample current.

5. Are there any benefits to your participation in this data, and tissue / DNA / saliva sample bank?

There is no direct benefit for your participation in this data, and tissue / DNA / saliva sample bank. Even though the research that is done on your medical information / tissue 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 data, and tissue / DNA / saliva sample bank?

- You may experience minor discomfort when the saliva sample is collected
- There is less than minimal risk of bleeding or infection with the saliva sample collection

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.

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 data, and tissue / DNA / saliva sample be shared with others?

The Principal Investigator listed at the beginning of this consent form or their successors will be allowed to collect, use and/or give out your de-identified medical information / tissue. They may give your de-identified medical information / tissue 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 de-identified

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. Information gathered from your coded samples and your coded (i.e., deidentified) medical information may be put into a controlled-access database along with information from other research participants. These databases may be accessible through the Internet. The information in this database will be available only to the researchers who have received approval from the National Institutes of Health (NIH) Data Access Committee. The federal government requires this for research funded by American taxpayers. Please note that identifying information about you, such as your name, address, telephone number, or social security number, will NOT be put into these databases for this project.

Your deidentified data, and tissue / DNA / saliva sample 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 data, and tissue / DNA / saliva sample. 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.

If you agree to share your genetic information specifically with the National Institutes of Health's database of genotypes and phenotypes (dbGaP) by signing the second addendum below, the study coordinator will communicate to the laboratory that your de-identified data may be submitted to dbGaP. Your PHI will not be provided to dbGaP, only the result of their genetic test and their non-identifiable demographic information. If you have any questions about what will be shared with dbGaP please ask one of the research study staff listed in question 1 of the "Consent Addendum" attached.

Your PHI will be used and shared with others until the end of the study, unless you decide to have your information stored in dbGaP. Information stored in dbGaP will be used/shared with others indefinitely.

Once this research study is completed, any information that could identify you **might** be removed from any identifiable private information or identifiable biospecimens collected and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

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.

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 alternative to being in the study; 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 other 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 above. By signing this form, you are not waiving any of your legal rights.

I agree that my tissue/DNA/saliva samples can be stored. Yes No

I agree that my contact information can be stored. Yes No

Please review the statement below and initial by your choice:

I agree to have my de-identified genetic data shared with the NIH databank (dbGaP) to be used for future unknown research.

Initials _____

YES

Initials _____

NO

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

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

Consent to Collect and Store Your Genetic Data for Future Research Consent Addendum

As part of the research project the study staff are seeking your consent to store your genetic data.

Reason for Storing Your Data:

You have recently agreed to participate in the research study listed above, which is funded by the National Institutes of Health (NIH). That research study involves determining certain genetic information about you. The NIH has a policy of sharing genetic information with other researchers to help further new discoveries on disease treatment and cures. Genetic factors are those that people are born with and that can affect other family members. Your genetic information that will be stored in this federal data bank (dbGaP), will be determined by the research study you have already agreed to.

The person in charge of the research project you agreed to (also known as the Principal Investigator) or a representative of the Principal Investigator will describe this data sharing to you and answer all of your questions. Your participation in allowing your data to be shared and stored in this NIH data bank is entirely voluntary. Before you decide whether or not to take part, read the information below and ask questions about anything you do not understand. If you choose not to participate in this data banking and data sharing study you will not be penalized or lose any benefits that you would otherwise be entitled to.

What will Happen to Your Genetic Data:

If you agree to this data banking and data sharing study, your genetic data and any other data that is collected in the study will be placed into a secure location (a large computer) at the University of Florida (UF). Once the other study you agreed to (listed above) is completed, your genetic data and other data collected on you during that study will have all identifiable information removed and then be sent to the NIH data bank. Your de-identified data that is sent will be given a unique ID number, but only those at UF or your affiliated institution will be able to match this unique ID number to identify you.

Who Can Use Your Stored Data:

At the NIH, de-identified genetic data that has been collected from you and other participants may be given to researcher from around the country who apply to the NIH to receive de-identified data to use in their research projects. This request will first have to be approved by an NIH committee that oversees the release of the data. Once the NIH committee approves the release of the de-identified data, the researcher will have to get local 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) approval before they can start their study and use this de-identified genetic data.

At the NIH, since your data is de-identified in the data bank, neither you nor UF nor your affiliated institution will receive any information when data is used in future research or receive any results from that future research.

Benefits to You in Storing Your Data:

There is no direct benefit to you for participating in this data bank.

Risks to You in Storing Your Data:

At NIH:

- Risk of Identification: The genetic data being sent to the NIH Data Bank is de-identified, however there is a slight chance that identifiable information may be mistakenly sent.
- Risk Associated with the Freedom of Information Act: Your information that is sent to the NIH will be kept in an NIH data bank and will, thereby, become U.S. government records that are subject to the Federal Freedom of Information Act (FOIA). As an agency of the Federal government, the NIH is required to release government records in response to requests under the federal Freedom of Information Act (FOIA), unless the records are exempt from release under one of the FOIA exemptions. The NIH believes that the only release of your data under such a request would be your data with the unique ID number removed.
- Risks Associated with Law Enforcement Access: It is possible that law enforcement agencies could request access to the de-identified genetic data within the NIH data bank and, for example, search for matches to DNA data collected as part of some criminal activity. While this is expected to be rare, such requests may be granted by the NIH. Law enforcement officials might then try to identify you by requiring your study doctor to release the key to the unique ID number which could identify you. However, the release of identifiable information by your study doctor may be protected by the Certificate of Confidentiality.

In order to better protect access to your genetic information, both UF and the NIH have obtained a Certificate of Confidentiality. Certificates of Confidentiality are issued by the National Institutes of Health (NIH) to protect researchers from being forced to release research records, which in this case is your genetic information. These Certificates allow the researchers and others who have access to research information to refuse to release information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.

- Risks to Specific Populations, Groups, and Communities: Medical research has already shown that some populations demonstrate a higher likelihood to develop certain medical diseases than others. It is possible that if you have some rare condition or rare physical characteristics, that someone could identify you based on the de-identified data in the NIH data bank.

Can You Withdraw Your Consent to Store Your Data?

If you decide that your genetic data can be kept for research but you later change your mind, tell the study staff listed in question #1 of the “Consent Addendum” who will inform the Federal Data bank to remove your de-identified data from the data bank. There will be no cost to you for this storage of your de-identified genetic data.

Do You Agree to Participate?

Please review the statement below and initial by your choice:

I agree to have my de-identified genetic data shared with the NIH databank (dbGaP) to be used for future unknown research.

Initials _____ YES

Initials _____ NO