HOUSTON Methodist LEADING MEDICINE

**INFORMED CONSENT FOR PARTICIPATION IN RESEARCH AND AUTHORIZATION TO DISCLOSE HEALTH INFORMATION**

**Sponsor / Study Title: NINDS/NIH, "Clinical Trial Readiness for SCA1 and SCA3"**

**Principal Investigator:**
**(Study Doctor)**

**Telephone:**

**Address:**

**Participant's Name: _____Participant ID Number: _____**

This form is for use in a research study that may involve participants who may or may not have the capacity to consent to take part in the study. Accordingly, when the participant cannot legally consent to take part, pronouns "you" and "your" should be read as referring to the participant rather than the person (legally authorized representative) who is signing this form for the participant. In cases where the participant's representative gives consent, the participant should be informed about the study to the extent possible given his/her understanding. During the course of the study, if the participant regains the capacity to consent, informed consent should be completed and the participant offered the ability to leave the study if desired.

**Before consenting to participate in this research study, you should have enough time to read the information in this form, or have it read to you. A member of the research team will discuss it with you. Be sure to ask questions about anything that is not clear before giving consent.**

**Your participation in this study is voluntary. You can choose not to participate at any time, even after starting the study, without any penalty or loss of benefits to which you are entitled.**

**Why me:** You are being asked to participate in a research study, because **of one of the following:**

- You tested positive for the Spinocerebellar ataxia type 1 (SCA1) or type 3 (SCA3) gene mutation. You may or may not show signs of ataxia.
- Your affected family member(s) tested positive for the SCA1 or SCA3 gene mutation, therefore you are at risk for developing SCA1 or SCA3.
- You are an individual without any neurological conditions.

Approximately 200 subjects will participate in the study.

**Study Purpose:**

Spinocerebellar ataxias (SCAs) are a group of rare diseases involving progressive cerebellar degeneration, leading to loss of control of bodily movements. SCA1 is the fastest progressing SCA among those that have been investigated, whereas SCA3 is the most common SCA in the US and Europe. SCA1 and SCA3 are such rare diseases that not enough is known about how these diseases progress and what biomarkers can be used to predict the rate of progression, especially in the early stages of disease. A biomarker is a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, disease causing processes, or drug treatment related responses to therapy for a disease or illness. Therapies targeting early stages of disease are more likely to be effective than those started at later stages of disease. At the present time, there are only therapies to treat the symptoms of the diseases and not the diseases themselves. Therefore, it is essential to acquire enough data to understand SCA1 and SCA3 disease progression, in particular before disease symptoms start to show or during early stages of disease. A better understanding of SCA1 and SCA3 disease progression is necessary to conduct future clinical trials that will test therapies, which may actually prevent disease progression.

This study is to establish the world's largest group of participants who carry the genetic mutation but have no ataxia symptoms or who have early-stage SCA1 or SCA3 and to obtain clinical, imaging, and biochemical data, which are necessary for planning future clinical trials and for determining whether a treatment is effective. To accomplish this, we will obtain clinical data from participants with early-stage SCA1 and SCA3, participants who are at risk for developing SCA1 and SCA3, and participants who were previously diagnosed as early stage when evaluated in the 2009-2012 Natural History Study by the United States Clinical Research Consortium for Spinocerebellar Ataxias (CRC-SCA), as well as healthy control participants in the US and Europe. A subcategory of these participants will be recruited, under a separate informed consent form, for imaging studies, using magnetic resonance imaging (MRI) equipment. Imaging biomarkers are especially promising for determining SCA1 and SCA3 disease progression and effectiveness of early interventions. Please indicate your interest in discussing participation in this sub-study at the end of this form.

## What is the usual medical approach to SCA1 and SCA3?

You are being asked to take part in this study to help gather research data about SCA1 and SCA3. There are no approved treatments for SCA1 or SCA3 other than supportive therapy. Although intense coordinative physical therapy and vibration therapy have shown beneficial effects in groups of patients with mixed types of ataxia, efficacy has not been adequately evaluated in patients with SCA1 or SCA3.

Preliminary data suggest that some medications are effective in treating different types of ataxia; however, most of these medications were not specific in treating SCA1 or SCA3, except varenicline (also known as Chantix®), which has been effective in some SCA3 patients. Unfortunately, the use of varenicline for SCA3 is severely limited by side effects and has not been approved by the United States Food and Drug Administration (FDA). Therefore, there is no single FDA-approved treatment for SCA1 or SCA3.

## What will happen if you join this study?

*Screening visit*

At the screening visit, the study doctor and study coordinator will ask you to bring your medical records and DNA test results, if available. If you agree to participate, you will be asked to sign and date the Institutional Review Board (IRB)-approved informed consent form. You will be screened for COVID-19 symptoms and possible exposure prior to the visit and a COVID-19 survey will be completed during the visit. Subsequently, you will undergo a general physical assessment, medical history review and your scale for the assessment and rating of ataxia (SARA) score will be determined by an additional 10-minute examination. This examination and all subsequent SARA assessments will be videotaped. Approximately 30 ml (2 tablespoons) of blood samples may be collected by blood draw during this visit. The study doctor or study coordinator will then assess your status with the inclusion and exclusion criteria to determine your eligibility for participating in this study.

*Baseline visit*

If you are qualified to participate in this study, you will have the baseline visit, which will follow the screening visit. At the baseline visit, additional clinical tests will be performed on you by the study doctor and his/her study staff. These clinical tests include clinical measures of ataxia by examinations, including Cerebellar Cognitive Affective Scale (CCAS), which tests your mental capacity, and questionnaires about your health, quality of life, and activities of daily living. If not collected during your screening visit, approximately 30 ml (2 tablespoons) of blood samples will be collected by blood draw.

Some of the exams, tests, and procedures will be the usual medical approach for assessing and treating SCA1 or SCA3. However, there are extra tests that you will need to have if you participate in this portion of the study, and the total time to complete these tests will typically be about 2 hours. Including the screening and routine medical care, the baseline visit will take about half a day.

You will also be asked to undergo a spinal tap to provide approximately 20 ml (4 teaspoons) of spinal fluid. However, declining to provide a sample of spinal fluid will not disqualify you for this study. If you agree to undergo a spinal tap, an additional 10ml (less than one tablespoon) of blood sample will be collected at the time of blood draw during the study visit. The spinal fluid collection is not standard of care for SCA. If you were not in this research study, this would not be done.

If you have a spinal tap, you will be asked to lie on a bed in a fetal position or will sit up and bend forward, whichever is easier for you. Antiseptic will be applied to the lower part of your back. To prevent pain, a local anesthetic, lidocaine, will be injected into the skin of your lower back. A needle will be inserted into the lower part of your spine so the cerebrospinal fluid (the fluid that bathes your brain and spinal cord) can be withdrawn. Normally about 3-5 teaspoons of spinal fluid are required for routine laboratory analysis. Approximately 3 teaspoons of spinal fluid will be needed for this study. After the fluid is withdrawn, the needle will be removed. Your body replaces this spinal fluid within 1–2 hours. You will then be asked to lie on the bed for 30 minutes or more following the procedure to decrease the risk of developing a headache following the procedure.

If you agree to participate in the optional lumbar puncture, the procedure may be performed by a radiologist (doctor) under X-ray imaging. This is called image-guided lumbar puncture or fluoroscopy. This (fluoroscopy) allows the doctor to view the movement of the lumbar puncture needle through your body in detail. The procedure is performed while you are awake.

You should avoid strenuous physical activity (lifting, bending, housework, gardening, or exercise) for 24 hours. Our study staff will call you the next day to see how you are.

You may be asked to participate in our magnetic resonance (MR) biomarker study using the MRI equipment at the baseline visit. The MR study is a sub-study and requires signing and dating a separate informed consent form to participate.

*Follow-up visits*

Follow-up visits will occur annually during the 5-year funding period. SARA scoring and other clinical testing performed at the baseline visit will be repeated at each annual visit. Potential COVID-19 exposure will also be assessed at each visit using a questionnaire. Approximately 20ml (less than 2 tablespoons) of blood samples will be collected by blood draw at each follow-up visit. If you are at risk for developing SCA1 or SCA3 an additional blood sample may be required to confirm the results of your genetic testing. If spinal tap is performed at a follow-up visit, then an additional 10ml of blood will be collected. If you declined the spinal tap, you may be asked again about volunteering for the procedure. You can continue in the study even if you decline the spinal tap. The duration of each follow-up visit will be about 2 hours.

*Results of Genetic Testing*

If you have no symptoms and are at risk of SCA because a first-degree relative has genetically confirmed SCA and you want to know the DNA tests results of the blood, we will release the results to your designated physician or genetic counselor after you sign a release form, which will be available in the clinic. All laboratories that perform health-related testing, including genetic testing, are subject to federal regulatory standards called Clinical Laboratory Improvement Amendments (CLIA) or even stricter requirements. Note that your DNA testing will be performed in a research laboratory that is **not** CLIA-certified, which means the result may not be accepted as legal or medical evidence of your genetic mutation. Our research lab will not be able to release genetic results directly to you. We strongly recommend genetic counseling for the disclosure of DNA results. Arranging genetic counseling will be the responsibility of you and your physician.

**What risks will I face by taking part in the study and how will researchers protect me from these risks?**

Potential risks for this project include the following:

- Risk of falls and resultant injuries during neurological evaluations. If you have ataxia, the fall risk is higher than unaffected individuals. Even if you do not have walking difficulty, subtle unnoticed imbalance may exist. Study staff will take special precautions to prevent falls.
- Risk of loss of confidentiality: You will be asked to provide medical information documenting your condition. This information will be stored in a secured access database. Only personnel working on this project will have access to the data.

  The de-identified data (data that do not contain your protected health information) will be sent to a central database where investigators and staff of the research team will analyze your data. With the exception of the study doctor and research team where you are examined, the de-identification prevents researchers from linking your data to your personal identity. If results of the study are published, the identity of participants will not be disclosed.
- Risk of bruises and infection from blood drawing: Blood will be drawn from your vein. Local bruises or rare infection may occur. We will use sterile techniques and hemostatic precautions (applying pressure) to minimize such risks. You may also faint when blood is drawn due to a condition known as vagal syncope (fainting). If this occurs, you will lie down and your vital signs will be monitored to ensure the expected recovery.

- Risk of complications of spinal tap (if you choose to have it): The risks associated with spinal tap include temporary pain or discomfort at the site of the needle insertion, occasional bruising, sweating, or lightheadedness, and in rare cases, faintness or infection. You may experience pain or tingling when the anesthetic is injected. There is the possibility of an allergic reaction to the anesthetic. Headache, which may be severe, occurs in approximately 10-30 persons in 100 who have spinal tap, and may last several days. The risk of headache is less if you are well hydrated (drink an adequate amount of fluids). If you feel unwell or have any unusual discomfort (for example, headache) during or after the spinal tap, it is important that you tell the study doctor as soon as possible. In rare cases, spinal fluid sometimes can leak, decreasing the pressure of the spinal fluid. This low pressure can cause a persistent headache. A headache after a spinal tap can cause severe pain with standing or sitting, and no pain with lying flat. If you have a low-pressure headache, your study doctor may first instruct you to rest, lie flat, and drink plenty of fluids. If this does not help, the study doctor may refer you for a "blood patch." During the blood patch procedure, some of your own blood is injected in the spinal canal close to the area where the spinal tap was performed. This seals the leak of spinal fluid and relieves the headache. In order to reduce any potential side effects from the spinal tap, we will ask you not to do any strenuous activity for 24 hours after the spinal tap. This includes lifting, bending, doing housework, gardening, or doing exercise such as jogging or bike riding. Less than 1 individual out of 100 may develop infection as a result of the procedure, bleeding into the spinal canal which could cause paralysis of the legs. To minimize the risk of bleeding into the spinal canal the study doctor will review your medical history and perform blood clotting tests if there is a concern for blood clotting issues. In addition, there is an extremely rare risk of death. However, these serious complications are preventable by taking precautions and using simple proper techniques. All of the spinal taps will be performed using sterile technique by experienced physicians to lessen the risks.
- Risk of fluoroscopy: This is a minimal risk procedure. The average radiation exposure of image guided lumbar puncture is similar to having two x-rays of your back or one year of exposure to natural background radiation. This is an optional procedure and the alternative is not to participate.
- Privacy Risks of genetic testing: If your genetic research data are shared with unauthorized users, you may be at risk of loss of the privacy of your health data. This risk is minimized by protections described in the section' What information about me could be seen by the researchers or by other people?' below.

**The alternative to participating in this project is to decline.**

You will be at no risk if you decline to participate.

As with any research study, there may be additional risks that are unknown or unexpected. If these become known, the study team will notify you in a timely manner of any changes that may change your willingness to participate. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new informed consent form that includes the new information.

As standard practice for clinical studies in our centers, a detailed data and safety monitoring plan will be implemented. Study doctors or study coordinators will report all adverse events (side effects) associated with clinical evaluations, blood draws and spinal tap to the Houston Methodist Research Institute Coordination Center (HMRICC) (Dr. Ashizawa, Director). Serious adverse events such as inpatient hospitalizations, death or life threatening medical events or permanent disability will be reported to the HMRICC and Institutional Review Board (IRB), which protects human subjects during clinical studies, within 24 hours, and the HMRICC will immediately notify officials at the National Institute of Neurological Disorders and Stroke, members of the Steering Committee, and members of the Data and Safety Monitoring Committee, an independent group of experts selected to ensure that necessary measures are taken to address medical needs resulting from the adverse event and concerns regarding patient safety. The Steering Committee is a group of principal investigators who decide the priorities and manages the general course of operations of the Clinical Trial Readiness for SCA1 and SCA3 study.

The researchers have taken steps to minimize any risks to participants in this study. Please tell the study staff about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

**How could I and others benefit if I take part in this study?**

You will not personally benefit from participating in this study. However, information obtained from this study is expected to make clinical trials of disease-modifying drugs possible and to improve the quality of therapeutic trials of symptomatic therapies in SCA1 and SCA3. This study is unlikely to help you, but may help us learn things that may help people in the future.

**Are there any costs or payments?**

You and/or your insurance company will be responsible for payment of items and services that you would receive even if you were not participating in the research study. You will be responsible for your normal co-payments and co-insurance/deductibles. Tests and procedures that are done only for the study will not be billed to you or your insurance company.

If you have any questions as to what your obligations are for payment for items or services under this study, or would like to see a list of procedures or items for which you are responsible financially, please talk with the study team and/or your insurance company.

You will not be paid for taking part in the study other than the $100 compensation for having a spinal tap to provide your spinal fluid if you decide to participate in that part of the study.

**Who could profit or financially benefit from the study results?**

Payments are made to the institution where you are participating in this study and the funds are used to cover the expenses of the study and the related academic and research activities of the institution.

The study doctor and the institution where the study is performed do not have any financial interest in the outcome of the study.

**If I take part in this study, can I also participate in other studies?**

Being in more than one research study at the same time, or even at different times, may increase risks to your health. It may also affect the results of the studies, depending on the other study's protocol. You should not take part in more than one study without approval from the researchers involved in each study.

**If I want to stop participating in the study, what should I do?**

If you wish to stop your participation in this research study for any reason, you should let the study doctor/study coordinator know as soon as possible so that you can stop safely. You may be asked why you are leaving the study and your reasons for leaving may be kept as part of the study record.

**Could I be taken out of the study even if I want to continue to participate?**

You could be removed from the study if:

- The study doctor believes that it is not in your best interest to stay in the study.
- You become ineligible to participate (your disease progressing to a more advanced stage will not disqualify you).
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the study staff.
- The study is suspended or canceled.

If you are taken out of active participation, ongoing follow-up may continue.

**What happens if I get hurt, my condition worsens, or I have other problems as a result of this research?**

If you are injured as a direct result of this study, medical care is available. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the study institution. You do not waive (give up) any legal rights by signing this informed consent form.

**What information about me could be seen by the researchers or by other people? Why? Who might see it? How will it be protected?**

Release of Health Information – If you decide to participate in this study, information about your health may be used or disclosed (shared outside of the Hospital) for the purposes of conducting this study. This information may include information from your medical record that is relevant to this study, such as your medical history, medications, test results, diagnoses, treatments, operative reports (reports from operations that you have undergone), and discharge summaries. It may also include information relating to: Human Immunodeficiency Virus ("HIV") infection or Acquired Immunodeficiency Syndrome ("AIDS"); treatment for or history of drug or alcohol abuse; or mental or behavioral health or psychiatric care. Information collected by the study doctor and/or study staff, specifically for this study, such as test results, blood samples, physical examinations, information about possible side effects, and surveys could also be used or disclosed.

Individuals that may use or release this information include: physicians, physicians' office staff, hospital staff, the study doctor, and authorized members of the study staff. These individuals may release this information to the study investigator, authorized members of the study investigator's staff, the funding agency of the study as well as its agents or contractors, other researchers, the IRB, the FDA and its representatives, and other government agencies.

In most cases, the information released to the above listed individuals or entities will not contain your name, social security number, or any other personal information. However, authorized representatives of your study investigator, IRB, FDA, or other government agencies may review records containing personal information to make sure that the study information is correct. Because of the need to provide information to these parties, absolute confidentiality cannot be guaranteed.

Use of Information – This information may be used to determine whether you meet all requirements for participation in the study, to monitor your healthcare during the study, to enable the sponsor to answer the scientific questions for which the study was designed, and to ensure that the study has been done properly. Examples of the use of this information are as follows: the sponsor may use the information in submissions to government agencies throughout the world, to request approval of the study drug or device; the sponsor may use the information for reporting adverse events to government agencies, such as the FDA; the sponsor may also transfer the information to business partners or companies it hires to provide study-related services; the sponsor may also provide overall study results, including your information, to other study investigators; and the sponsor may reanalyze the data from this study in the future or combine it with data from other studies for analysis. In addition, both the sponsor and the study doctor may use the information to prepare reports or publications of the study results.

However, when results of the research study are reported in medical journals or at scientific meetings, the people who were in the study are not named and identified. Therefore, your names would not be disclosed in any presentation or publication.

You need to understand that once your information has been released, it may no longer be protected by United States federal regulations relating to data privacy and could be used or re-disclosed in ways other than those listed in this section of the informed consent form.

You have the right to see and copy your medical records, but information relating to this study may be withheld until the end of this study.

**Will my genetic information be protected?**

A Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Since its implementation on May 21, 2010, all health insurance companies and group health plans must follow this law. All employers with 15 or more employees must follow this law as of November 21, 2009.

Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

**What happens to information about me after the study is over or if I cancel my permission?**

If you stop participating in this study, you also have the right to revoke (withdraw) your authorization to disclose and use your information. Revoking your authorization means taking back the permission you gave the study investigator to send information about you to the sponsor or other people and entities. If you revoke your authorization, your study doctor/investigator will not use or release any more information about you after receiving your request, except to tell the sponsor that you have stopped early and have revoked your authorization. However, the sponsor and the study investigator can still keep and use any information that it has already received to the extent necessary to preserve the integrity of the research study. To revoke this authorization, contact the research team. The research team will accept either a written or verbal request. Their contact information is listed on the first page of this form.

**When does my permission expire?**

Because this information is being disclosed for research use, there is no expiration date for the authorization to disclose and use this information. The sponsor may keep and continue to use your study information for many years. Your study doctor/investigator may need to add to or correct information about you even after your study participation is over, including providing updates of your health status if that is important for the purpose of the study. Review of your medical records may also take place after the study is over. This authorization will remain in effect unless you revoke it or if required by state law. If state law applies, your permission to use and share health data about you will end on December 31, 2068.

Authorization – By signing this informed consent form, you authorize the use and disclosure of personal information to, and review of your medical records by, the people and entities described above. You do not have to authorize this disclosure of information. However, if you do not, you will not be able to participate in this study.

**What are my rights in this study?**

Taking part in this study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights to which you are otherwise entitled.

**Whom to contact about this study**

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact**:**

- By mail:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Drive
  Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00022607.

An IRB is a group of people who review research studies to protect the rights and welfare of research subjects.

A description of this clinical trial will be available on http://www.clinicaltrials.gov/, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

## Optional Participation

### Spinal Tap to Obtain Spinal Fluid

Spinal fluid is an important resource for future development of biomarkers. Spinal tap is routinely done with a small amount of local anesthesia in the skin on the lower back. There may be some discomfort associated with the procedure. Your participation is optional.

**Please initial one:**

_____ Yes, I agree to participate in the spinal fluid collection.

_____ No, I do not agree to participate in the spinal fluid collection.

### Use of Data and/or Samples

The researchers would like to use your excess tissue/blood/body fluid/cell samples and data for future research. Your samples may be kept by an external third party, Houston Methodist Research Institute, or a collaborative organization designated by Houston Methodist Research Institute (such as another research organization, university, or a private company). Once you contribute data and samples, they may no longer be in an identified form that would allow them to be located and destroyed, or there may be other reasons why the samples need to be retained for further study and validation of results. Therefore, when you contribute data or samples, you should assume that it will not be possible for you ever to get them back.

**Please initial one:**

_____ Yes, I agree to allow the use of excess tissue/blood/body fluid/cell samples and data for future research and I understand that I may not be able to stop their use after signing this consent.

_____ No, I do not agree to allow the use of excess tissue/blood/body fluid/cell samples and data for future research.

### MR Study

Please indicate whether you would be willing to be contacted about participating in an MR sub-study at one of four MR centers: the University of Minnesota in Minneapolis, MN; Johns Hopkins University in Baltimore, MD; Massachusetts General Hospital in Boston, MA; or the University of Florida in Gainesville, FL. If you need to travel to one of these sites to participate in the imaging study, your travel expenses will be covered. To communicate about the MR sub-study we may contact you via phone or email. We will limit the use of email to such things as arranging phone calls, travel dates, flights, hotel, sending samples of consent forms for prior review, and other practical information. We encourage you to limit your emails to us to similar topics, and avoid sending any information about your current medical status or medical history because we may use an unencrypted email system.

_____ Yes, I agree to be contacted about participating in an MR study.

_____ Yes, I agree to be contacted about participating in an MR study, but only via phone call.

_____ No, I do not agree to be contacted about participating in an MR study.

**Video Recording and Storage on Box.com**

This study involves the video recording of your SARA examination with the study doctor. Neither your name nor any other identifying information other than your face will be associated with the recording. Only the local research team, the HMRICC, and a selected group of SARA examination experts will be able to view the recordings. During year 5 of the study period, video recordings will be centrally rated by the experts to ensure the accuracy of scores across institutions.

**Please initial all that apply:**

_____ Yes, I agree to have my SARA examination recorded and stored for the duration of this study and post-study analysis by SARA examination experts. My recordings can be archived for future research in the field of ataxia, including any future use of archived video that involves either research beyond the scope of the current project or sharing with an external party.

_____ No, I do not agree to have my SARA examination videotaped.

**Future Contact**

Please indicate whether you would or would not be willing to let our researchers get in touch with you in the future, to ask whether you would be willing to contribute more tissue samples or data or participate in another study at that time:

**Please initial one:**

_____ Yes, the researchers may contact me in the future.

_____ No, the researchers may not contact me in the future.

**Notice to Participants**

**Not Recontacting Participants**

It is possible that, in studying biological samples and data from you and others, researchers may discover information that would be potentially relevant to your future health. In the event that this occurs, there are no plans to make this information available to you. This is because the biosamples may have been coded or de-identified in a way that makes it difficult to trace the result back to a specific person, and because the results of research often are too uncertain to be used as specific medical information. By signing this form, you are agreeing that you will not be contacted with information learned about your samples.

**For Profit vs. Not for Profit Research Sharing**

It is possible that de-identified data and biological samples from you and others may be provided to researchers at academic institutions, hospitals, and biotechnology/pharmaceutical companies.

Successful research using your data and/or samples could result in a commercial or therapeutic project with significant value. You will not share in any financial benefits of these uses. By signing this form, you are agreeing that you understand this to be true.

**Notice of New European Regulations**

A new set of European regulations known as the General Data Protection Regulation (GDPR) has gone into effect as of May 25, 2018. The GDPR requires specific consent by the research subject for sharing his/her data and samples in a research study with European entities and/or subjects. This research study will involve such sharing, and therefore must comply with the GDPR rule. We therefore ask you to sign an additional consent form supplementary to this consent form for such sharing. By signing the supplementary consent form, you agree with such sharing as specified in that form. However, it is your right to opt out from sharing your own data and samples at any time. Please refer to the form entitled "Data Collection for Prospective Participants - Information Sheet and Informed Consent Form" provided as an attachment to this form.

**Notice of Certificate of Confidentiality**

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);
2) you have consented to the disclosure, including for your medical treatment; or
3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

**Signatures**

**Study Participant or Legally Authorized Representative (LAR)**

I have read this informed consent form or had it read to me. I have discussed it with the study team and my questions have been answered. I will be given a signed and dated copy of this form. I agree to take part in this study including any options where I checked 'yes'.

**Name of Participant (Print Legal Name): _____**

**Signature: _____ Date: _____ Time: _____**
(Participant or LAR)

**Name of LAR (Print Legal Name): _____**

Legally Authorized Representative Information (if applicable): Phone: _____

Relationship to participant: □ Parent □ Spouse □ Child □ Sibling □ LAR Other:
_____

Reason participant is unable to sign for self:
_____

**Person Obtaining Informed Consent:**

**I have given this research participant (or his/her LAR) information about this study that I believe is accurate and complete. The participant has indicated that he or she understands the nature of the study and the risks and benefits of participating.**

Name: _____ Title: _____

Signature: _____ Date: _____Time:_____

**Witness** ***(when participant is physically unable to read, write, talk or see):*** **I was present as an impartial witness (not a member of the research team or family) for the informed consent process. I observed the above participant (or his/her legally authorized representative, if applicable) indicate consent.**

**If the applicable participant was unable to sign, how did he or she indicate consent?**
_____

Name: _____

Signature: _____ Date: _____Time:_____