Title of research study: Open-Label Trial of Sulforaphane in Premutation Carriers with Fragile X-Associated Tremor and Ataxia Syndrome (FXTAS)

Investigator: ***Randi Hagerman, MD***

Please note:

- the words "I", "you", "your", "me" and "my" refer to the study participant.

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you have been diagnosed with Fragile X-Associated Tremor and Ataxia Syndrome (FXTAS) and you are within the age range of this recruiting clinical trial (50 to 85).

What are my rights as a research subject?

(Experimental Subject's Bill of Rights)

- Someone will explain this research study to you, including:
  - The nature and purpose of the research study.
  - The procedures to be followed.
  - Any drug or device to be used.
  - Any common or important discomforts and risks.
  - Any benefits you might expect.
  - Other procedures, drugs, or devices that might be helpful, and their risks and benefits compared to this study.
  - Medical treatment, if any, that is available for complications.
- Whether or not you take part is up to you.
- You can choose without force, fraud, deceit, duress, coercion, or undue influence.
- You can choose not to take part.
- You can agree to take part now and later change your mind.
- Whatever you decide it will not be held against you.
- You can ask all the questions you want before you decide.
- If you agree to take part, you will be given a signed and dated copy of this document**.**

How is this research funded?

This research is being funded by private donations to the Innovative Research Fund for FXTAS at the MIND.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team:

- Dr. Randi Hagerman, Principal Investigator (study doctor) at 916-703-0247
- Study Coordinator at 916-703-0200

Do not write below this line. For IRB stamp and version date only.

APPROVED by the Institutional Review Board at the University of California, Davis	
Protocol	APPROVED
1743661	June 25, 2021

For non-emergency issues, you can call the UCDMC Hospital Operator (916-734-2011), tell the Operator you are participating in a research study, and wish to talk to Dr. Hagerman. In the case of an emergency, dial 911 from any phone.

This research has been reviewed by an Institutional Review Board (IRB). Information to help you understand research is on-line at https://research.ucdavis.edu/policiescompliance/irb-admin.You may talk to an IRB staff member at (916) 703-9151, hs-irbadmin@ucdavis.edu, or 2921 Stockton Blvd, Suite 1400, Room 1429, Sacramento, CA 95817 for any of the following:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

Why is this research being done?

This research is being done to answer important questions that might help change or improve the way we do things in the future in managing and/ or treating individuals with Fragile X-associated tremor/ataxia syndrome (FXTAS).

FXTAS is a rare genetic progressive neurodegenerative disorder, linked to a trinucleotide repeat expansion in the *FMR1* gene. FXTAS is characterized by tremor and ataxia in addition to atrophy and white matter disease in the central nervous system (CNS). In addition to the major clinical observations of intention tremor and gait dysfunction, minor symptoms of parkinsonism, neuropathy, and cognitive decline also significantly impact individuals with FXTAS.

The dietary supplement being tested in this study is called Sulforaphane. It is found in broccoli and similar cruciferous vegetables and may cause some gas and discomfort. This is not a study looking at clinical efficacy but instead a study of molecular outcome measures. We want to get more information about how Sulforaphane affects specific biomolecular markers captured in blood.

What is my involvement in the study?

If you decide to participate in this study, you will first be asked to read and sign this consent document before any research related activities are done. In summary, you will be taking an increasing amount of the Sulphoraphane supplement pills (238mg/tablet), starting at 1 and increasing to 6, every morning at breakfast for 6 months. In addition, there will be a total of 3 visits (Initial, 3-month and 6-month) to the MIND Institute where you will be evaluated. At each visit (3 total) you will undergo a battery of medical and neurologic exams which make take 2-3 days to complete each time. You and/or your caregiver will also be asked to fill out questionnaires/surveys. At the initial visit and at 6 months, we will collect blood for analysis; this may cause pain and bruising. You will also undergo two MRI scans, also at the initial visit and at 6 months. A more detailed explanation of participant study involvement can be found in the subsequent sections of this consent form.

How long will the research last?

We expect that you will be in this research study for at least 6 months.

APPROVED by the Institutional Review Board at the University of California, Davis	
Protocol	APPROVED
1743661	June 25, 2021

How many people will be studied?

We expect about 15 people at UC Davis will be in this research study over the next year.

What happens if I say yes, I want to be in this research?

The following are the steps or stages in this study:

Consenting/ Screening Visit (Month 0)

Please take as much time as you need to read this consent document. You may ask questions and discuss this with the research study team (the study doctor and research staff), with family and friends, or with your personal physician or other healthcare professionals. Your questions should be answered to your satisfaction before you make any decision.

If you decide to take part in this study, you will be asked to sign this consent document before any study-related activities are performed. You will receive a copy of this signed and dated consent document for your records.

The following will be included in this first visit:

- Dispense study supplement
- Physical examination
- Neurological examination
- Vital signs measurement (weight, height, heart rate, blood pressure, respiratory rate, oxygen saturation [pulse oximetry], and body temperature)
- Eligibility criteria, other than diagnosis
- Safety laboratory assessment (clinical blood draws for CBC and CHEM 12)
- Concomitant medications
- Adverse Events- Monitoring System of Side Effects
- Blood draw for molecular biomarkers
- MRI Scan
- Motor Exams: Kinesia-One, spirals, GaitRite, Purdue Pegboard, and Grip Strength
- Cognitive exams: Wechsler Adult Intelligence Scale (WAIS) IV, Behavioral-Dyscontrol Scale (BDS-2), Cambridge Neuropsychological Test Automated Battery (CANTAB), Controlled Oral Word Association Test (COWAT), Montreal Cognitive Assessment (MoCA), California Verbal Learning Test (CVLT-2), and Mini-Mental State Exam (MMSE)
- Event-Related Potential (ERP) Measures (Brainwave scan)
- Questionnaires: Neurological Quality of Life Upper and Lower Extremity Function, Instrumental Activities of Daily Living (IADL/ ADLs), SCL-90

Sulforaphane will be taken one tablet in the morning with breakfast and then every other day the dose will be increased by one tablet until a total of 6 tablets are taken in the morning. It is important to try and take the supplement around the same time each day. You should attempt to keep your usual diet.

Follow up Visit -Week 12/ Three Month:

The following assessments will be completed at **Week 12** treatment period:

The following will be included in this visit:

- Dispense study supplement
- Physical examination
- Neurological examination
- Vital signs measurement (weight, height, heart rate, blood pressure, respiratory rate, oxygen saturation [pulse oximetry], and body temperature)
- Safety laboratory assessment (clinical blood draws for CBC and CHEM 12)
- Concomitant medications
- Adverse Events
- Cognitive exams: Behavioral-Dyscontrol Scale (BDS-2), Cambridge Neuropsychological Test Automated Battery (CANTAB), and Controlled Oral Word Association Test (COWAT)
- Questionnaires: Neurological Quality of Life Upper and Lower Extremity Function, SCL-90

End of Treatment (EOT) – at Week 24/ Six Months

A final visit is scheduled at the end of the 24-week period, with assessments collected accordingly.

The following will be included in this visit:

- Physical examination
- Neurological examination
- Vital signs measurement (weight, height, heart rate, blood pressure, respiratory rate, oxygen saturation [pulse oximetry], and body temperature)
- Safety laboratory assessment (clinical blood draws for CBC and CHEM 12)
- Concomitant medications
- Adverse Events- Monitoring System of Side Effects
- Blood draw for molecular biomarkers
- MRI Scan
- Motor Exams: Kinesia-One, GaitRite, Purdue Pegboard, and Force plate postural stability, and Grip Strength
- Cognitive exams: Behavioral-Dyscontrol Scale (BDS-2), Cambridge Neuropsychological Test Automated Battery (CANTAB), Controlled Oral Word Association Test (COWAT), Montreal Cognitive Assessment (MoCA), California Verbal Learning Test (CVLT-2), and Mini-Mental State Exam (MMSE)
- Event-Related Potential (ERP) Measures (Brainwave scan)
- Questionnaires: Neurological Quality of Life Upper and Lower Extremity Function, Instrumental Activities of Daily Living (IADL/ ADLs), SCL-90

Early Discontinuation Visit

If you are withdrawn or you withdrew your consent after the study supplement has already been administered, you shall be asked to take part in the early discontinuation visit, which includes the same assessments as those for the EOT visit (Week 24).

How much blood is collected?

At each study visit approximately 49.5 mL of blood will be taken this is roughly equivalent to 10 teaspoons.

Schedule of Events

Assessment	Baseline	Open label	
	Visit 1	Visit 2	Visit 3
	0 months	3 months	6 months
Informed Consent – 5 min	X		
Inclusion/Exclusion Criteria* - 2 min	X		
Adverse Events Update & Concomitant Medications* - 5 min	X	X	X
Vital Signs & Blood & Safety Draws (CHEM 12, CBC)*- 10 min	X	X	X
Dispense Study Supplement – 5 min	X	X	
Collect Study Supplement – 5 min		X	X
Blood Draw Molecular Biomarkers – 30 mins	X	X	X
Medical History** - 30 mins	X	X	X
Physical and Neurological Exam* - 45 mins	X	X	X
Magnetic Resonance Imaging (MRI) Scan**- 60-90 mins	X		X
Event Related Potential (ERP) Measures** - 30-45 mins	X		X
Cognitive Exams			
BDS-2 (Behavioral-Dyscontrol Scale)** - 10 mins	X	X	X
CANTAB (Cambridge Neuropsychological Test Automated Battery)** - 60-90 mins	X		X
COWAT (Controlled Oral Word Association Test)** - 5-10 mins	X	X	X
WAIS-IV** - 90-120 mins	X		
MoCA (Montreal Cognitive Assessment)** - 10 mins	X	X	X
CVLT2 (California Verbal Learning Test)** - 30 mins	X		X
MMSE (Mini Mental State Exam)** - 10 mins	X		X
Motor Exams			
FXTAS Rating Scale (Video Motor Protocol)** - 45-60 mins	X		X
Grip Strength** - 5 mins	X	X	X
Kinesia One** - 15 mins	X	X	X
Purdue Pegboard** - 15 mins	X	X	X
GaitRite**- 15 mins	X		X
Questionnaires			
Neurological Quality of Life (Neuro-QoL) Upper Extremity Function**	X	X	X
Neurological Quality of Life (Neuro-QoL) Lower Extremity Function**	X	X	X
Instrumental Activities of Daily Living (IADL)**	X		X
Activities of Daily Living (ADLs)**	X		X
Symptom Checklist-90-Revised (SCL-90-R)**	X	X	X

Procedures Involved at Each Visit- Procedures being performed to monitor subjects for safety or minimize risks (*) indicated along with procedures being performed for diagnostic (**) or treatment purposes (***).

Do not write below this line. For IRB stamp and version date only.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for the following:

- Tell the study doctor if you previously took part in this study/other studies, have been in any other study involving an experimental drug in the past year, or are currently involved in any other study.
- Do not take part in any other study without approval from the study doctor. Tell the study doctor immediately if you are taking part, or you want to take part, in other studies while you're in this study. Participating in more than one study at the same time could put your safety at risk.
- Take part in the study only at this location. Participating in this study at more than one study site at the same time could put your safety at risk and is not permitted.
- Follow the instructions you are given by the study doctor and study team.
- When you visit another healthcare facility or other health care providers due to a health concern, tell them about your participation in this study.
- Tell the study doctor or the research staff about all prescription and non-prescription medications, supplements, or vaccines before you take any of them.
- Notify the study team if you move and provide your new contact information.
- You will agree not to post any of the participant's personal data related to the study or any other information related to the trial on any social media site until the study is completed.

What happens if I do not want to be in this research?

You may refuse to participate and still receive the care you would receive if you were not in the study. You can also be withdrawn from the study at the discretion of the investigators. If extended family members do not want to participate or do not give consent, then they will not be included in this study. Significant new findings developed during the research study that may relate to your willingness to continue participation will be provided to you. There may also be other research studies that you may qualify or be eligible for. Ask the study doctor or study staff to discuss these options, and their risks and benefits, with you.

What happens if I say yes, but I change my mind later?

You can leave the research at any time and it will not be held against you.

If you agree to participate and then change your mind for any reason, you are free to stop participating at any time. Your decision will not affect your regular medical care or any benefits to which you are entitled. Tell the study doctor if you are thinking about stopping or if you decide to stop your participation so that you can end participation in the study in the safest way. The study doctor will discuss appropriate other treatment options with you if you decide to end your participation in this study.

Please note that already collected data and any data already generated from your biological samples (such as blood) may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care. If you agree, this data will be handled the same as research data. The study doctor or the sponsor may review study data related to you which were collected prior to your withdrawal from the study and may consult public records, such as those establishing survival status. You may also be asked to continue to participate in the study procedures even though you would no longer take the study supplement.

APPROVED by the Institutional Review Board at the University of California, Davis	
Protocol	APPROVED
1743661	June 25, 2021

In addition, the study team will also tell you in a timely manner if new information is learned that could change your mind or decision about your taking part or continuing in this research study. There will be no penalty, and you won't lose any benefits you receive now or has a right to receive if you do not want to continue with the study.

Is there any way being in this study could be bad for me?

All research has some risk, which may include things that could make you feel unwell or uncomfortable, or that could harm you. You might experience these risks or discomforts while taking part in this study. It is important that you tell the study team if you are feeling or showing any of these things during the study. The study team will monitor you for risks or discomforts during the study. However, the study team does not know all of the effects that the study supplement or your participation in this study may have. These effects might be mild or serious. These may be a minor inconvenience or may be so severe as to cause death. In some cases, these effects might be long-lasting or permanent, and might even be life-threatening.

Based on previous studies, side effects, risks, and/or discomforts from participation in this study may include an increase in gas, constipation, and diarrhea.

Allergic Reaction Risks

All supplements have a potential risk of causing an allergic reaction which (if not treated quickly) could become life-threatening. You should get medical help and contact the study doctor right away if you think you have any of the following symptoms of a serious allergic reaction: trouble breathing or swelling of the face, mouth, lips, gums, tongue or neck. Other allergic reactions may include rash, hives, or blisters. **If you have a known hypersensitivity to cruciform vegetables you will be excluded from the study**.

If you have a very serious allergic

reaction, it could be fatal and life-threatening. Some symptoms of allergic reactions are:

- Rash
- Wheezing (high-pitched whistling sound made while breathing) and difficulty of breathing
- Dizziness and fainting
- Swelling around the mouth, throat or eyes
- Fast pulse
- Sweating

Please seek treatment immediately and tell the study doctor and study staff if you have any of these symptoms.

In addition, other medications may not be compatible with the study supplements, please tell your study doctor/ study coordinator about any new or additional medications, vitamins, supplements and herbs that you are taking.

Pregnancy-Related and Breastfeeding Risks

The research may also hurt a pregnancy or fetus in unknown ways. These may be a minor inconvenience or may be so severe as to cause death.

You should not be or become pregnant while on this research study, or father a child while on this research study, as well. You must use contraception during this study. Effective contraception includes: abstinence, male condom (with spermicide), female condom (with spermicide), contraceptive sponge, contraceptive diaphragm, combined oral contraceptive pill, contraceptive patch, contraceptive vaginal ring, progestin-only pill, injectable, hormonal intrauterine device, non-hormonal intrauterine device, contraceptive implant, male sterilization, female sterilization (including hysterectomy). Once you have completed treatment, you may discontinue birth control three (3) months after completing the study treatment.

For female participants who have the potential to become pregnant:

If you are pregnant or breastfeeding, you cannot be in the study. A pregnancy test is required and will be performed before you start treatment. Pregnancy testing is done by urine. If urine proves to be impossible to collect, then pregnancy testing will be done using blood from already collected samples. No extra blood would need to be collected for this serum pregnancy test. If you become pregnant or suspect being pregnant, you must notify the study doctor immediately.

Risks from Study Procedures

Risks and possible discomforts you might experience from the study procedures include:

- **Blood draws:** This involves taking blood from your arm with the use of a needle. The blood draw may cause temporary stinging, discomfort, or pain when the needle goes into the vein. A bruise may form at the site where the blood was drawn. There is also a slight chance of infection and fainting. This will take approximately 5 minutes.
- **MRI:** The MRI scan (Magnetic resonance imaging) involves lying very still in a long tube with a powerful magnet for approximately 60-90 minutes. The MRI takes a picture of your brain. There are no known risks to the types of magnetic fields and radio waves that are used in these studies, but there is always a possible unknown risk to this or any test. Female subjects must not be pregnant. Subjects who have any metallic materials within the body (metallic chips, surgical clips, artificial joints, metallic bone plates, pacemakers, etc.) must notify one of the researchers, as some people with metal in the body cannot have an MRI scan. Subjects who have pacemakers, bullet fragments, artificial heart valves, metallic ear implants, or metal implants, chips, or clips in or around the eyes cannot be scanned. Rarely (one in thousands of exams), a sunburn-like skin burn may occur over a small area of the body. We take special precautions for this not to occur. In addition, you must lie still in a small space, which may cause a feeling of fear of closed or confined spaces. If any anxiety develops, the exam will be stopped at your request.
- The MRI pictures of the brain are for research and are not meant to evaluate your health as they would be if they were part of a clinical (non-research) visit to the doctor or hospital. The pictures will not receive any routine clinical review by specially trained physicians (neuroradiologists) who interpret MRI scans. This means that all abnormalities may not necessarily be noticed. However, in the event that the research team observes any potential abnormality on your scan, it will be referred for a clinical evaluation by a UCDMC neuroradiologist. In this situation, your identifying information will be revealed to the

neuroradiologist in order to create a medical record which is required for the reading of your brain image. In the event that the neuroradiologist recommends further follow up, you will be contacted by Dr. Randi Hagerman, or Dr. Cameron Carter, who will advise you on how to obtain appropriate medical follow up.

- **EEG/ERP:** For the brainwave scan you will wear an elastic cap (similar to a bathing cap) with sensors on your head that measure the brain activity. The sensors on the cap are filled with anti-allergenic electrolyte paste to increase the connectivity between the sensors and skin. There are no known risks or side effects of a brainwave (EEG/ERP) recording. The only discomfort you might experience is fatigue or boredom during the session. When we apply the elastic cap, you may experience a slight discomfort or feel a slight sensation of touch. Sometimes, taking off the sensor cap may cause some discomfort. On rare occasions, some skin irritation after taking off the cap may occur. This condition is generally mild (redness of the skin) and lasts only some minutes. A possible discomfort after the session is that some paste may remain in the participant's hair until it is washed.

- **Motor Testing:** The exams will include measuring balance and control of the arms and hands. You will be asked to perform some simple motor tasks to assess possible balance and tremor issues. This will include walking across a small padded walkway (GaitRite) and wearing a clip-on sensor as you are guided through various motor movements (Kinesia). A videotaped neurological examination will also be recorded for further evaluation by a movement disorder specialist. Motor testing will require some walking, standing, and sitting for short periods. There is no risk of injury and at most require only 20 feet of walking. You may become tired, frustrated, or anxious, but you will receive frequent breaks between each assessment and when needed.

Other Risks

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your participation in this research. However, it is hoped that knowledge gained through your participation and the data/ information collected from this study may help the fragile X community as a whole and contribute towards future treatments, including developing better prognostic measures.

What happens to the information collected for the research?

Efforts will be made to limit the use or disclosure of your personal information, including research study and medical records, to people who need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the IRB and other University of California representatives responsible for the management or oversight of this study, the sponsor and its representatives, the contract research organization (CRO) and its representatives, and the US Food and Drug Administration. And in situations wherein the research team is likely to uncover any abuse, neglect or reportable diseases, your information may be disclosed to appropriate authorities for safety reasons.

If you agree to participate in this research study, a signed copy of this consent document will be filed in your electronic medical record (EMR) to inform caregivers providing treatment for you while you're on this study.

The sponsor, monitors, auditors, the IRB, the Food and Drug Administration will be granted direct access to your research records to conduct and oversee the study. We may present in meetings and/ or publish the results of this research. However, we will keep your name and other identifying information confidential. The study data collected about you will be identified by a number only assigned to you. This is a unique code that cannot link or directly identify you. The study site will keep the link between the code and your personal information confidential.

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.

We will access protected health information (e.g., your medical record) for this study, and you will be asked to sign a separate form to give your permission (authorization). If you sign the authorization form, you are giving permission for the use and disclosure (share with others) of your health information for purposes of this research study. You do not have to give this permission. However, if you do not, you will not be able to take part in the study. You may also choose to cancel the authorization at any time, but you must notify your study doctor. If you decide to do this, you will no longer be able to take part in the study.

Your medical records may become part of the research record. If that happens, your research records may be looked at by the sponsor of this study and government agencies or other groups associated with the study. They may not copy or take your personal health information from your medical records unless permitted or required by law.

Federal law provides additional protection of your medical records and related health information. These are described in the UC Davis Health System Notice of Privacy Practices (http://www.ucdmc.ucdavis.edu/legal/privacy/) and in an attached document.

Can I be removed from the research without my OK?

The person in charge of the research study (study doctor) or the sponsor can remove you from the research study without your approval. Possible reasons for removal include any of the following:

- You are unable to follow the instructions of the research study team;
- The research study doctor decides that the research study is not in your best interest or that you no longer meet the criteria to be part of it;
- The research study is stopped by the research study sponsor, the institutional review board (IRB) or independent ethics committee (IEC) (a group of people who review the research to protect your rights), or by a regulatory agency.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research. During this study, you will be told about important findings (either good or bad), such as changes in the risks or benefits of participation in the study or new choices to participation that might cause you to change your mind about being in the study. If new information is shared with you, you may be asked to sign a revised consent again continue participating in this study.

Will I receive results from this study?

APPROVED by the Institutional Review Board at the University of California, Davis	
Protocol	APPROVED
1743661	June 25, 2021

We may learn things about you from this study which could be important to your health or treatment. If this happens, you can decide whether you want this information to be shared with you. For example, a blood test may reveal that you are anemic (low blood iron). If you decide that you want this information, you may need to meet with experts to help you learn more about your study results. The study will not cover the costs of any follow-up actions.

If you have not previously had fragile X gene testing, the blood work may show that you carry the fragile X gene mutation or change in the gene. Dr. Hagerman will review these test results with you.

We intend to publish the results of this study in scientific journals, which may take several years and may be reported in stages. You should contact the investigators with questions you have about the study results; however, please keep in mind that the results are often made public for months or years after completion of the study.

Please initial one of the following options:

_____(Initials) Yes, I want my study information shared with me.

_____(Initials) No, I DO NOT want my study information shared with me.

What else do I need to know?

Are there any costs to me if I participate in this study?

The study supplement, study-related procedures, and study visits will be provided at no cost to you. Any other procedures performed for your regular medical care that are required for the study but are not covered by the Sponsor, will be billed to your insurance, or to you if you do not have insurance. These costs may include operating room fees, pharmacy charges, treatments, hospitalization, scans, etc. You will be responsible for any insurance copayments and deductibles that normally apply. Some insurance plans will not pay for these services for people taking part in research studies. Please check with your insurance company to find out what your insurance plan will pay for. No additional funds have been set aside by the Sponsor or the study site to cover regular care services that your insurance plan does not cover, so you may be financially responsible for those costs. Talk to the study team if you have any questions about costs that you may have as a result of taking part in this study.

If you receive a bill related to study activities, please contact the study coordinator who will have these bills adjusted.

For more information about possible costs, please contact the research team. The research team can follow UC Davis Uninsured Non-Emergency Estimate Policy (Policy ID 1883) to work with their department and Decision Support Services to get you a cost estimate.

Will I be paid for my participation in this study?

You will not receive any payment for taking part in this study. It is also important to note you will not be reimbursed for any travel, parking, meals and other expenses associated with this study.

What happens if I get injured during the study?

It is important that you promptly tell the person in charge of the research if you believe that you have been injured because of taking part in this study. Depending on the circumstances, the costs of the

treatment will be billed to your insurance company just like other medical costs. The University does not normally provide any other form of compensation for injury. For more information about compensation, you may call the IRB Administration at (916) 703-9151 or email at HS-IRBAdmin@ucdavis.edu.

To help avoid injury, it is very important to follow all study directions. You are not giving up any of your legal rights by signing this form.

How will the information obtained from specimens collected in this study be used?

During the study, the investigator will remove some blood and/or tissue. Your specimen(s) will be de-identified to protect your privacy, only to be used for research purposes and become the property of the University of California. The specimen(s) (such as blood, tissue, or saliva) collected from you for this study and/or information obtained from your biospecimens may be used in this research or other research and shared with other organizations. The specimen(s) could lead to discoveries that may be of value to the University of California or other organizations. Under state law you will not share in any commercial value or profit derived from the use of your biospecimens and/or information obtained from them.

If you agree to share the biological specimen(s) collected from you or to use them in additional research related to premutation disorders, please initial here: _____

Otherwise, your specimen(s) will be destroyed at the end of this study.

Are there other research opportunities?

If you are interested in being contacted for future research, please provide your phone number and/or email. This is completely optional.

_____(initials) Yes, I am willing to be contacted for future research opportunities. My phone number and/or email is: _____.

CONSENT

My signature below will indicate that I have decided to participate in this study as a research subject. I have read and understand the information above. I understand that I will be given a signed and dated copy of this consent form and the Bill of Rights.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	

Do not write below this line. For IRB stamp and version date only.

APPROVED by the Institutional Review Board at the University of California, Davis	
Protocol	APPROVED
1743661	June 25, 2021

Signature of person obtaining consent | Date

Printed name of person obtaining consent

Do not write below this line. For IRB stamp and version date only.

APPROVED by the Institutional Review Board at the University of California, Davis	
Protocol	APPROVED
1743661	June 25, 2021

Signature Block for Adult Unable to Consent

Your signature documents your permission for the named subject to take part in this research.

Printed name of subject

Signature of legally authorized representative | Date

Printed name of legally authorized representative

Signature of person obtaining consent | Date

Printed name of person obtaining consent

Assent

- ❑ Obtained
- ❑ Not obtained because the capability of the subject is so limited that the subject cannot reasonably be consulted.

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Signature of witness to consent process | Date

Printed name of person witnessing consent process

Do not write below this line. For IRB stamp and version date only.