# RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

**STUDY TITLE:** GABA Abnormalities and Stability in Cervical Dystonia

**VCU INVESTIGATOR:** Brian Berman
*NOTE: In this consent form, "you" always refers to the research participant.*

## ABOUT THIS CONSENT FORM

You are being invited to participate in a research study. **It is important that you carefully think about whether being in this study is right for you and your situation.**

This consent form is meant to assist you in thinking about whether or not you want to be in this study. **Please ask the study doctor or the study staff to explain any information in this consent document that is not clear to you.** You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.
Your participation is voluntary. You may decide not to participate in this study. If you do participate, you may withdraw from the study at any time. Your decision not to take part or to withdraw will involve no penalty or loss of benefits to which you are otherwise entitled.

## AN OVERVIEW OF THE STUDY AND KEY INFORMATION

### Why is this study being done?

The purpose of this research study is to understand the role of the brain chemical GABA in Cervical Dystonia. Dystonia is a neurological disorder characterized by abnormal muscle spasms and posturing of body parts. Cervical dystonia refers to these symptoms occurring primarily in the muscles of the neck. You are being asked to participate in this study because you have been diagnosed with Cervical Dystonia and may meet the study entry requirement, or because you are serving as a healthy control.

### What will happen if I participate?

In this study, you will be asked to do the following things:

1. Visit VCU/VCU Health locations 3 times for study visits
2. Have an MRI
3. Have a neurological exam
4. Take surveys and answer questions about dystonia symptoms, mental health symptoms, cognitive status, and quality of life.

5. Give permission for the researchers to collect information from your medical records about your medical history, diagnosis, and treatment during your participation in the study.

Your participation in this study will last up to 7 weeks. Approximately 45 individuals will participate in this study.

This study will not use any biological samples to sequence all or part of your DNA.

**What alternative treatments or procedures are available?**

You can choose not to participate in this study and you will still receive standard of care for dystonia, including monitoring and treatment of symptoms and referral to appropriate ancillary care providers as needed."

**What are the risks and benefits of participating?**

There are both risks and benefits of participating in research studies. We want you to know about a few key risks right now. We will give you more information in the "WHAT RISKS AND DISCOMFORTS CAN I EXPECT FROM BEING IN THE STUDY?" section.

| Risks and Discomforts | Benefits to You and Others |
|---|---|
| 1. The study questionnaires ask questions that are sensitive in nature and may make you feel uncomfortable.<br>2. The MRI scan may be uncomfortable if you do not like tight spaces. | There is no direct benefit to participants expected in this study. A brain MRI is part of the research protocol, however, and identifying any actionable incidental finding on the brain MRI is a potential benefit to participants. This study may help the study doctors learn things that may help other people with dystonia in the future. |

Now that you have a general overview of the study, we want to provide the details about what your participation involves. Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask the study staff.

**WHY IS THIS STUDY BEING DONE?**

This study plans to assess the levels of a brain chemical known as GABA in individuals with dystonia both before and after the administration of Botulinum Toxin injections. The cause of dystonia is poorly understood, but research suggests that there is a loss of the brain's normal inhibition function. GABA is the primary brain chemical in the brains inhibitory system and is predicted to be involved in this loss of inhibitory function. Botulinum toxin (BoNT) injections are an effective treatment for Cervical Dystonia working by blocking the signals to the muscles that make them contract. BoNT injections can have adverse effects such as pain or weakness, provide only partial relief of symptoms, and be costly to participants. Because of these potential flaws in BoNT injections, it is important for us to understand the physiological impact of both Cervical Dystonia and its treatments to provide patients with more accessible and effective treatments.

An imaging tool called Magnetic Resonance Spectroscopy (MRS), which is obtained using a standard MRI scanner, will measure GABA levels in your brain both before your BoNT injections and 4-6 weeks after. The investigators hope to see if there is a difference in GABA levels in dystonia patients before and after these BoNT injections to understand the role that Botulinum Toxin may have in the signaling of GABA. The data collected from dystonia patients will also be compared to healthy controls.

**WHAT WILL HAPPEN IF I PARTICIPATE IN THE STUDY?**

Visit 1: Screening visit located at VCU Health Neuroscience, Orthopedics, and Wellness (NOW) building

- At your first study visit (Screening visit), we will review information about the study with you and give you the opportunity to read this consent form and to ask questions before agreeing to participate and signing this form. We will review the study in more detail and go over your health history to make sure you are eligible and safe to continue in this study.
- You will have a neurological exam. This includes assessment of your sensory and motor function, reflexes, coordination, and gait. You will be told and referred for appropriate care if the neurologist has any concerns based on your exam.
- If you have dystonia, you will have an assessment of your symptoms.
- We will also measure if you have any depression, anxiety, or thoughts about suicide. If you are found to have severe depression or anxiety, you will be referred to appropriate health care providers.

Visit 2 (~1-2 weeks later) and Visit 3 (~4-6 weeks later): MRI visit located at the Collaborative Advanced Research Imaging (CARI) Center

- You will have GABA MRS scanning in a Magnetic Resonance Image (MRI) scanner. An MRI involves lying down inside a large, tube-like scanner. Using magnet and radio waves, thousands of images are taken of your brain and skull.
    - You will be asked to rest quietly and not think about anything in particular during the MRI scan
    - You will be positioned and supported using belts and pillows to maximize comfort and prevent movement during your scan. These restraints can be removed at any time If you are uncomfortable.
    - If you can have children, you will be given a urine pregnancy test prior to the MRI. A positive pregnancy test means you cannot have an MRI. This study will not use your urine sample to sequence all or part of your DNA.
    - The MRI used in the study is for research purposes only and is not of good enough quality for clinical use. Still, if we find abnormal results on the MRI you may be excluded from the study and will be referred for appropriate care.

We will schedule all of your research visits around the Botulinum Toxin injections that you have already scheduled with your provider. We will not ask you to change your injection schedule or require you to go without your treatment.

**WHAT RISKS AND DISCOMFORTS COULD I EXPERIENCE FROM BEING IN THE STUDY?**

Risks of MRI scan

In this study we will take a Magnetic Resonance Imaging (MRI) scan of your head. The MRI machine uses powerful magnetic waves to take pictures inside the body. The waves themselves are not harmful, but they can cause metal to heat up and electronics to stop working. You should NOT have an MRI if you have metal or electronic devices inside your body. Heart pacemakers and insulin pumps are examples of electronic devices. The MRI machine is a small round tube. It might make you uncomfortable if you do not like tight spaces or loud noises. If you are pregnant, be sure to tell the person giving you the MRI. We do not know if the MRI scan affects pregnancy or fetal development. Therefore, women who are able to become pregnant will have a pregnancy test done before the MRI. You will not be able to participate if the pregnancy test is positive.

Risk of answering Study Questionnaires

Some questionnaires will assess your memory and thinking. You may become fatigued, frustrated, or sad. You may take breaks. If you are found to have more trouble with these

questions than expected, we will work with you to contact your personal physician and may provide you with referrals for further evaluation.

Questionnaires may contain questions that are sensitive or upsetting in nature. You may refuse to answer any question that makes you feel uncomfortable. This study will ask you questions about personal topics that might be embarrassing to talk about and that could affect your family relationships if this information were to become known outside of the study.

There is a risk that we may discover you have severe depression and or thoughts of suicide.

Privacy risks

Participation in research might involve some loss of privacy. There is a small risk that someone outside the research study could see and misuse information about you.

Unknown or Unforeseeable Risks

The researchers will let you know about any significant new findings (such as additional risks or discomforts) that might make you change your mind about participating in the study.

**WHAT ARE THE COSTS?**

You will not be charged for any study visits, tests, or procedures.

Your Botulinum Toxin Injections will be done at your Standard of Care visits, and you or the appropriate third-party insurance will be responsible for paying for those visits and injections.

**WILL I BE PAID TO PARTICIPATE IN THE STUDY?**

You will be paid $25 for each study visit by check for each study visit, and if you complete all scheduled study visits, you will have received a total of $75. If you withdraw before the end of the study, you will be paid $25 per completed study visit.
If you do not have the ability to cash a check, you will be compensated with petty cash. In this case, $25 cash be disbursed at the end of each visit.

Total payments within one calendar year that exceed $600 will require the University to report these payments annually to the IRS and you. This may require you to claim the compensation you receive for participation in this study as taxable income. VCU is required by federal law to collect your social security number. Your social security number will be kept confidential and will only be used to process payment.

There are no plans to share any money or profits with you if the use of your sample(s) results in inventions or discoveries that have commercial value.

**WHAT HAPPENS IF I AM INJURED OR BECOME SICK BECAUSE I TOOK PART IN THE STUDY?**
If you are injured by, or become ill, from participating in this study, please contact your study doctor immediately. Medical treatment is available at the Virginia Commonwealth University Health System (VCU Health System). Your study doctor will arrange for short-term emergency care at the VCU Health System or for a referral if it is needed.

Fees for such treatment may be billed to you or to appropriate third-party insurance. Your health insurance company may or may not pay for treatment of injuries or illness as a result of your participation in this study. To help avoid research-related injury or illness, it is very important to follow all study directions.

**CAN I STOP BEING IN THE STUDY?**
You can stop being in this research study at any time. Leaving the study will not affect your medical care, employment status, or academic standing at VCU or VCU Health. Tell the study staff if you are thinking about stopping or decide to stop.

Your participation in this study may be stopped at any time by the study doctor without your consent. The reasons might include:

- the study doctor thinks it necessary for your health or safety
- you are found to not be eligible for the study
- you have not followed study instructions
- administrative reasons require your withdrawal

**HOW WILL INFORMATION ABOUT ME BE PROTECTED?**
VCU and the VCU Health System have established secure research databases and computer systems to store information and to help with monitoring and oversight of research. Your information may be kept in these databases according to VCU's policies (i.e. for a minimum of 5-6 years). It is only accessible to individuals working on this study or authorized individuals who have access for specific research related tasks.

Identifiable information in these databases are not released outside VCU unless stated in this consent or required by law. Although results of this research may be presented at meetings or in publications, identifiable personal information about participants will not be disclosed.

Personal information about you might be shared with or copied by authorized representatives from the following organizations for the purposes of managing, monitoring and overseeing this study:

- Representatives of VCU and the VCU Health System
- Officials of the Department of Health and Human Services

In general, we will not give you any individual results from the study. If we find something of medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

If you tell us that you may hurt yourself or someone else, the law says that we must let people in authority know. In the future, identifiers might be removed from the information you provide in this study, and after that removal, the information could be used for other research studies by this study team or another researcher without asking you for additional consent.

**HOW WILL MY HEALTH INFORMATION BE USED AND SHARED DURING THIS STUDY?**

As part of this research study, we will ask you to permit us to access existing information from your healthcare records. This type of information is considered "Protected Health Information" that is protected by federal law.

**What type of health information will be used or shared with others during this research?**

The following types of information may be used for the conduct of this research:

- Complete health records
- History and physical exam
- Information about mental health
- Diagnosis and treatment
- Imaging

**Who will use or share protected health information about me?**

VCU and VCU Health VCU are required by law to protect your identifiable health information. By consenting to this study, you authorize VCU/VCU Health to use and/or share your health information for this research. The health information listed above may be used by and/or shared with the following people and groups to conduct, monitor, and oversee the research:

- Principal Investigator and Research Staff
- Health Care Providers at VCU Health
- Institutional Review Boards
- Government/Health Agencies
- Data Coordinators
- Research Collaborators
- Data Safety Monitoring Boards

- Others as Required by Law

Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

**When will this authorization (permission) to use my protected health information expire?**
This authorization will expire when the research study is closed, or there is no need to review, analyze and consider the data generated by the research project, whichever is later.

**Statement of Privacy Rights**
You may change your mind and revoke (take back) the right to use your protected health information at any time. However, even if you revoke this authorization, the researchers may still use or disclose health information they have already collected about you for this study. If you revoke this Authorization, you may no longer be allowed to participate in the research study. To revoke this Authorization, you must write to the Principal Investigator at

Dr. Brian Berman, VCU Neurology 1101 E. Marshall Street, Richmond VA 23298.

**WHOM SHOULD I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY?**

The investigator and study staff named below are the best person(s) to contact if you have any questions, complaints, or concerns about your participation in this research:

**Brian Berman**, Principal Investigator
(804)-628-5276
Brian.Berman@vcuhealth.org

and/or

**Elizabeth Crump**, Study Coordinator
(804)-446-0668
Elizabeth.Crump@vcuhealth.org

If you have general questions about your rights as a participant in this or any other research, or if you wish to discuss problems, concerns or questions, to obtain information, or to offer input about research, you may contact:

Virginia Commonwealth University Office of Research
800 East Leigh Street, Suite 3000, Box 980568, Richmond, VA 23298
Phone: (804) 827-2157
https://research.vcu.edu/human-research/hrppirb/research-participants/

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

**STATEMENT OF CONSENT**

I have been provided with an opportunity to read this consent form carefully. All of the questions that I wish to raise concerning this study have been answered. By signing this consent form, I have not waived any of the legal rights or benefits to which I otherwise would be entitled. My signature indicates that I freely consent to participate in this research study. I will receive a copy of the consent form for my records.

| **Signature Block for Enrolling Adult Participants** | |
|---|---|
| _____<br>Adult Participant Name (Printed) | |
| _____<br>Adult Participant's Signature | _____<br>Date |
| _____<br>Name of Person Conducting Consent Discussion (Printed) | |
| _____<br>Signature of Person Conducting Consent Discussion | _____<br>Date |
| _____<br>Principal Investigator Signature (if different from above) | _____<br>Date |