# CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

**TITLE OF STUDY:** MRI-based Biomarkers for Characterization of Amyotrophic Lateral Sclerosis

**PRINCIPAL INVESTIGATOR:** Bryn Martin, Ph.D., brynm@uidaho.edu, 208-885-1030

**24-HOUR EMERGENCY PHONE NUMBER:** (509)768-1272

## INTRODUCTION

You are being asked to volunteer to take part in this research study because you between 18 and 80 years of age and you have been clinically diagnosed with early stage Amyotrophic Lateral Sclerosis (ALS) or are a healthy control volunteer without ALS. You are being asked to take part in this research study to see if a new way of analyzing information from a magnetic resonance imaging (MRI) study can help identify parameters that can detect ALS. The study is being conducted by the University of Idaho in collaboration with St. Luke's Rehabilitation Institute and Inland Imaging.

Before deciding whether you want to participate in this research study or not, it is important that you read and understand the following explanation of the study procedures. This consent describes the purpose, procedures, benefits, risks, discomforts and precautions of the study. It also describes the alternative procedures, if any, that are available to you and your right to withdraw from the study at any time. No promises can be made about how you will be affected if you consent to be in the study.

This consent may contain words you do not understand. You should ask the study doctor or research staff to explain any words or information you do not clearly understand. Please review this informed consent carefully and, if possible, discuss with your family or friends before agreeing to participate.

For your safety it is important that you be completely honest with your study doctor about your health history in order to provide a complete and accurate understanding of your health condition.

## WHY IS THIS STUDY BEING DONE?

The purpose of this study is to identify possible brain or spinal cord differences in participants with ALS compared to participants without ALS. Research shows that 90 to 95 percent of ALS cases occur at random, with only 5-10 percent of ALS cases being inherited. Current MRI techniques are only partly capable of recognizing the different types of ALS. And, early stages of ALS can be similar to other more treatable disorders. This study hopes to see if there are differences on MRIs that might allow earlier diagnosis and to recognize ALS subtypes.

## HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

A total of about 20 participants will take part in this study that is only being conducted locally. This will include 10 people with ALS and 10 people without ALS.

## WHAT IS INVOLVED IN THE STUDY?

You will have a single MRI scan of your head and spine that will last between 40 and 60 minutes. The MRI procedure will not require you to have an injection of dye that is sometimes used for different types of MRIs. The MRI scan will be performed at 525 S. Cowley St. at Inland Imaging in Spokane, WA. Our Research Staff will schedule a time for your MRI scan. When you arrive, the

MRI technician will ask you to remove all metal objects from your body and change into a hospital gown. We will fill out a form that asks your height, weight, waist circumference, heart rate, and blood pressure. You will fill out a questionnaire that asks about other medical conditions a doctor has told you that you have. You will wear earplugs (provided) and lay still on your back until the MRI is complete.

## HOW LONG WILL YOU BE IN THE STUDY?

Your participation in this study will conclude after you complete the MRI scan procedure.

## WHAT ARE THE RISKS OF THE STUDY?

The MRI technique is painless and does not involve exposure to x-ray radiation. You will have to lie very still for up to 1 hour during the MRI scan. You should breathe normally during the scan.

Because the MRI machine contains a large magnet, it can move objects containing metal (i.e., iron) in the MRI room during your examination, which could possibly harm you. We will take precautions to prevent this from happening. Loose metal objects, like key chains, jewelry, and possibly dentures, are not allowed in the MRI room.

You may be bothered by feelings of claustrophobia (a "closed-in" feeling) and by loud clicking noises coming from the MRI machine during the test. This is why we will ask you to wear earplugs. At times during the test, you may be asked not to move or swallow for a short while, which can be uncomfortable.

***You may stop your participation in this study at any time.***

### Reproductive Risk

**Women-**
If you are of childbearing age, you must not be pregnant at the time you receive the MRI scan. This study could potentially harm your unborn child.

**Men-**
There are no known reproductive risks for men who have an MRI.

**It is possible in any research study that harmful things can happen that are unknown at this time.**

## WHAT ARE THE BENEFITS TO TAKING PART IN THE STUDY?

- This study is not designed to benefit you directly.
- Your MRI scan will not be used, in any way, in your direct medical care.
- Findings from this study may help other patients in the future.


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## WHAT OTHER POSSIBLE OPTIONS ARE THERE?

Being in this study does not replace your regular medical care. Other options include not participating in the study.

## WHAT ARE THE COSTS?

Participation in this study is not a substitute for health insurance. There will be no charge to you or your insurance for your participation in this study. The MRI will be paid for by the funding agency for this study (no cost for you to pay).

You will not be paid for your participation in this study.

## WHO PAYS FOR STUDY–RELATED ILLNESS OR INJURY?

If you have suffered a complication, illness or injury during the course of this study, treatment will be provided to you by Dr. Carter or his associates at St. Luke's or Dr. Petersen or his associates at Inland Imaging. You should contact Dr. Carter at 509-768-1272 or Dr. Petersen at 509-455-4455. No funds have been set aside for payment of expenses for medical treatment, or for lost wages or other non-medical expenses, either as a direct or indirect result of your participation in this study. Such expenses will be billed to you or your insurance company. If you have questions regarding illness or injury related to this study, please discuss this with the study doctor and/or research staff.

## WHAT ABOUT CONFIDENTIALITY?

The following people will have access to review and/or copy your medical records as they relate to your participation in this study:

- Medical personnel associated with the study.
- The Institutional Review Board-Spokane.

We will not share these records with persons not involved in this research study, except as required by law. Although, we cannot guarantee absolute confidentiality, your records relating to this study will be kept confidential and publication of general study results will not personally identify you. You will be required to read and sign an addendum to this consent that explains in detail how your health information will be used and protected.

## WHAT ARE YOUR RIGHTS AS A PARTICIPANT?

Participation in this study is voluntary and refusal to participate will not affect your current or future relationships with St. Luke's or Inland Imaging. There will be no penalty or loss of benefits to which you are otherwise entitled if you decide not to participate. You have the right to know about new information that may affect your health, welfare, or your willingness to continue participating in the study. Your study doctor will give you this information in writing as soon as it becomes available.

The study doctor and St. Luke's Rehabilitation Institute will receive payment from the study sponsor, the National Institutes of Health, for research related expenses. The study doctor and research staff *do not* however hold a direct financial interest in the study sponsor or in this research study. If you have any questions regarding this, any aspect of your illness, your treatment, or your patient rights you may contact Dr. Martin at 208-885-1030 at any time. Should you have further questions

regarding your rights as a research participant or complaints regarding this research study you may contact the Institutional Review Board at (509) 474-3640.

**CAN I STOP PARTICIPATING IN THIS STUDY?**

You may withdraw from this study at any time without prejudice or loss of benefits to which you are entitled.

**WHAT COULD END YOUR PARTICIPATION?**

The study doctor can withdraw you from the study if:

- It is necessary for your safety
- You do not follow instructions
- You do not meet the conditions of the study
- The study is closed for any reason

**PARTICIPANT CONSENT**

**I have read, or have had read to me, the information describing the study and it is written in a language that I understand. All of my questions have been answered to my satisfaction. I am signing this form voluntarily, indicating my willingness to be in this study. I understand that I am not giving up any of my legal rights by signing this form and I will receive a copy of this signed consent form.**

| _____ | _____ | _____ |
|---|---|---|
| Signature of Participant | Printed Name | Date/Time |
| _____ | _____ | _____ |
| Signature of Person Obtaining Consent | Printed Name | Date |

If this consent form is read to the participant because the participant is unable to read the form, an impartial witness not affiliated with the research or investigator must be present for the consent and sign the following statement:

I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood, by the participant. The participant freely consented to participate in the research study.

| _____ | _____ | _____ |
|---|---|---|
| Printed Name of Impartial Witness | Signature | Date |

Note: This signature block cannot be used for translations into another language. A translated consent form is necessary for enrolling subjects who do not speak English.



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**Addendum to Informed Consent Form**: **Authorization to Use, Create, and Share Health Information for Research (Only for participants with ALS)**

This attachment provides additional information about how your medical records and health information (together, your "records") will be used and disclosed for this research study. Your records may include information about your lab tests, physical examinations, x-rays, scans, interviews and medical history. It may also include any other health information created, collected or reviewed during the course of the research study as described in the consent form. In addition, it may include your demographic information, such as your initials and date of birth.

This form allows the study doctor identified in the consent to use your records to carry out the study described in the consent form. If you do not sign this form, you cannot participate in the study. By signing this form, you allow the study doctor to review your records.

All of your records, the signed consent form(s) and this form also might be reviewed or copied by IRB - Spokane, or by other regulatory agencies in this country or in other countries. These agencies might review your records to check the information collected in this study, to check how the study was conducted, or for other uses allowed by law.

Federal and state laws require the study doctor to protect the privacy of your records. However, absolute confidentiality cannot be guaranteed because of the need to disclose information as described above. After the study doctor discloses your records to others, the law may no longer protect the privacy of the information. If you would like to know how the sponsor will protect the privacy of your records, ask your study doctor how to obtain this information.

You have the right to see and copy your records related to the study for as long as the study doctor has this information in his or her possession. However, by signing this form you agree that you might not be able to review some of your records related to the study until after the study has been completed, at which time your right of access will be restored.

**As required by Washington State Law RCW 70.02.030 Patient Authorization of Disclosure must contain an expiration date or event. Your authorization will expire when the goals of the study have been met.**

You can cancel this authorization at any time by giving a written notice to Dr. Bryn Martin at University of Idaho, Department of Biological Engineering, 875 Perimeter Dr. MS 0904, Moscow, ID, 83844-0904. If you cancel this authorization, then you no longer will be able to participate in the study. If you cancel this authorization, any health information collected prior to your cancellation will be retained by the study doctor.

**Authorization**

I authorize the release of my medical records and health information related to this research study, including my signed consent form and this addendum, to the research team, the FDA, IRB - Spokane and other regulatory agencies as described above. I am not giving up any of my legal rights by signing this form. I understand that I will receive a signed copy of this authorization for my records.

_____

Printed Name of Participant

_____ _____

Signature of Participant Date



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