CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

TITLE OF STUDY: Non-invasive MRI-based Biomarkers for Neurological Diseases

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Call 410-955-6070 and ask for the doctor on call for Neurosurgery to speak with a physician available 24 hours a day.

This consent form contains important information to help you decide whether to participate in a research study.

KEY INFORMATION

You are being asked to take part in a research study. Research Studies include only people who choose to take part. The study team members will explain the study to you and will answer any questions you might have. You should take your time to make your decision.

- This research aims to develop MRI protocols that help diagnose neurological diseases
- Both healthy people and people with neurological diseases may participate in the study
- Your involvement would require two MRI scans separated by 6-months
- The MRI scans in this study are non-invasive and last approximately 1 hour
- You may feel uncomfortable and/or claustrophobic during the MRI scans
- Upon study completion, you will be compensated $250

There are no known risks or side effects related to MRI performed in this study.

There will be no direct benefit to you from participation in the study. However, this study will help doctors learn more about neurological diseases and it is hoped that this information will help in the treatment of future patients.

You may withdraw from the research study at any time. If you are a patient, you will still receive treatment for your neurological disorder if you decide to stop being in the study.

INTRODUCTION

You are being asked to volunteer to take part in this research study because you between 18 and 55 years of age and you have been clinically diagnosed with a neurological disease, are a healthy control volunteer, or are asymptomatic or minimally symptomatic for a neurological disease.

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 neurological diseases. The study is being conducted by the University of Idaho in collaboration with Johns Hopkins Medical Center.

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 your 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 the study personnel 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 neurological diseases compared to participants without neurological diseases. Research shows that there is currently a lack in understanding of what MRI-based indicators can best identify many neurological diseases and predict the disease course. Current MRI techniques are only partly capable of recognizing the different types of neurological diseases. And, early stages of many neurological diseases have overlapping clinical signs and symptoms. This study hopes to see if there are differences on MRIs that might allow earlier diagnosis, to recognize neurological disease subtypes, and/or understand how surgical treatment can impact the neurological disease.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

A total of about 200 participants will take part in this study. This will include people with Type 1 Chiari malformation, Amyotropic Lateral Sclerosis, Parkinson's disease, Alzheimer's disease, Multiple sclerosis, Hydrocephalus, Normal Pressure Hydrocephalus and other neurological disorders. It will also include healthy people and people that are asymptomatic or minimally symptomatic with the above disorders.

WHAT IS INVOLVED IN THE STUDY?

As a participant in this study, you will fill out questionnaires and then have a total of two MRI scans that are separated by approximately 6-months.

Questionnaires: After consenting to participate in the research study, the study team will measure your height, weight, waist circumference, heart rate, and blood pressure. You will also fill out

questionnaires that ask about other medical conditions a doctor has told you that you have and your symptoms. The approximate time needed to complete these forms is 1-hour.

1st MRI scan: After filling out the questionnaires, you will have an MRI scan of your head and/or spine that will last approximately 1-hour. The MRI procedure is non-invasive and 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 Johns Hopkins Medical Center (location to be communicated to you by study coordinator).

Our Research Staff will schedule your MRI scan date and time. When you arrive at the MRI facility, the MRI technician will ask you to remove all metal objects from your body and change into a hospital gown. During the MRI scan, you will wear earplugs (provided) and lay still on your back until the MRI is complete.

If you are a patient scheduled to receive surgical treatment for your neurological condition, you will receive surgical treatment as normally planned within 30-days of your 1st MRI scan (above). Your surgery will be scheduled with your doctor.

2nd MRI scan: You will have a 2nd MRI scan approximately 6-months after your 1st MRI scan. Our Research Staff will schedule you for the second MRI scan. If you had a surgical treatment, you will fill out a second questionnaire before your 2nd MRI scan.

IMPORTANT: **If you have significant tremor when lying on your back you may not participate in this study.** Unfortunately, significant tremor while lying down on your back will make MR imaging result in poor quality images.

HOW LONG WILL YOU BE IN THE STUDY?
Your participation in this study will conclude after you complete the 1st and 2nd MRI scan and questionnaires. The time between each MRI scan will be approximately 6-months.

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.

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?

You will receive a separate Insurance and Research Participant Financial Responsibility Information Sheet (Sheet). This Sheet will give you the following information:

- The procedures, tests, drugs or devices that are part of this research and that will be paid for by the study (no cost to you).
- The procedures, tests, drugs or devices that will be billed to you and/or your health insurer. If you have health insurance, you will be responsible for any co-pays or deductibles not covered by your insurance.

You will receive a $250 compensation for participating in this study. You will not be compensated for participation if you do not complete the entire study (2 MRI scans and questionnaire). You may be required to provide your social security number to be paid for taking part in this study. Federal tax law requires that you report your research payments when you file your taxes. If your total payments from Johns Hopkins exceed $600 per year, Johns Hopkins will report these payments to the Internal Revenue Service and you will receive a 1099-MISC form from us.

WHO PAYS FOR STUDY–RELATED ILLNESS OR INJURY?

Johns Hopkins, University of Idaho, and the federal government do not have programs to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people. The costs for any treatment or hospital care you receive as the result of a study-related injury that are not covered by a health insurer will be billed to you. By signing this form, you will not give up any rights you have to seek compensation for injury.

WHAT ABOUT DATA CONFIDENTIALITY AND FUTURE USE?

Sharing data is part of research and may increase what we can learn from this study. Often, data sharing is required as a condition of funding or for publishing study results. It also is needed to allow other researchers to validate study findings and to come up with new ideas.

Your data may be shared:

- directly with research collaborators, other researchers, sponsors, government agencies, publishers of papers and other research partners
- through government or other databases/repositories

Data/biospecimen sharing could change over time and may continue after the study ends.

Although, we cannot guarantee absolute confidentiality, your records relating to this study will be kept confidential and publication of general study results cannot be linked back to you. We will do our best to protect and maintain your data in a safe way. Generally, if we share your data without identifiers (such as your name, address, date of birth) further review and approval by an IRB is not needed. However, when we share data, we limit the uses of the information and whether these data can be shared with another research team. If data are shared with identifiers, further IRB review and approval may be needed and the IRB will determine whether additional consent is required.

Johns Hopkins researchers may also use the data collected in this study for future research purposes. Possible future research may include, for example: studying the causes and progression of different diseases and conditions, and developing and testing methods to diagnose and treat different diseases and conditions. This future research may be unrelated to the current study and may include outside collaborators. Because science constantly advances, we do not yet know what future testing may include. If biospecimens are tested/used in ways not described above, further IRB review and approval may be needed and the IRB will determine whether additional consent is required.

Your data collected in this study may be de-identified and used for secondary academic or commercial research purposes without your additional permission. You will not share in this commercial profit. Your de-identified data may be shared with other research, academic, and medical institutions, other researchers, drug and device companies, biotechnology companies, and others. If you are not comfortable with the use of your data/biospecimens in future research, you may not want to participate in this study.

NATIONAL INSTITUTES OF HEALTH CERTIFICATE OF CONFIDENTIALITY

Your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not 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 any of the participating medical providers. 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. The study personnel will give you this information in writing as soon as it becomes available. You may also request to receive a copy of your MRI data for your personal records.

A referring doctor and/or clinical center may receive payment from the study sponsor, for research related expenses. The doctors and research staff *do not* however hold a direct financial interest in the study sponsor or in this research study.

WHAT IF MY IMAGING STUDY SHOWS AN INCIDENTAL FINDING?
As part of this research study, you will undergo an imaging procedure. A qualified professional will review your research imaging. This research imaging will not include the full diagnostic information that you would get if your primary doctor referred you for imaging.

There is a possibility that while reviewing your imaging we may see an unexpected abnormality. This is called an "incidental finding."
We will let you know if we see such an incidental finding. Depending on the type of incidental finding, we may contact you by mail, email, or phone. In the case of a potential serious emergency, someone may go to your home.

A qualified person (usually a member of the research team) will talk to you if there is an incidental finding. <u>You do not have an option to decline information about an incidental finding from an imaging procedure.</u>

If you want, we will give information about this incidental finding to your primary doctor or we will refer you to an appropriate doctor for further evaluation.

What could happen if there is an incidental finding?

- An incidental finding may cause you to feel anxious.
- Since a report of the incidental finding may be part of your medical record, it may be available to those accessing your medical record for your clinical care and may affect your current or future life or health insurance coverage. This risk will vary depending on the type of insurance plan involved.

The costs for any care that may come from the incidental finding, such as the need to see a doctor to diagnose or treat an incidental finding, will not be paid for by this research study. These costs would be your or your insurance company's responsibility.

WHO DO I CONTACT ABOUT MY RIGHTS AS A RESEARCH PARTICIPANT?
This study has been reviewed by an Institutional Review Board (IRB), a group of people that reviews human research studies. The IRB can help you if you have questions about your rights as a research participant or if you have other questions, concerns or complaints about this research

study. You may contact the Johns Hopkins IRB at (410)502-2092 or jhmeirb@jhmi.edu. You may contact the University of Idaho Institutional Review Board at (208)885-6340 or irb@uidaho.edu.

If you have an urgent medical problem related to your taking part in this study, call 410-955-6070 and ask for the doctor on call for Neurosurgery to speak with a physician after hours and on weekends.

If you are having a medical emergency, call 911.

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. However, you will only receive the $250 reimbursement for participation if you complete the entire study. If you are a patient, you will still receive treatment for your neurological disorder if you decide to stop being in the study.

If more medical information becomes available about the treatments used in this study or new treatments for your disease, you will be informed of these results as soon as possible so that you can decide if you wish to continue participating in this project.

If your doctor feels that your continued participation in the study is not in your best interest, or if you have a bad reaction to the treatment, you may be taken off the study without your consent. Your doctor will let you know if it is necessary to take you off the study.

If you withdraw from the study, it still might be necessary for the investigators to look at your medical records to follow your medical progress. If you do not want the investigators to look at your records after you've left the study, you will need to let the investigators know.

WHAT COULD END YOUR PARTICIPATION?
You may be withdrawn 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

What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Johns Hopkins Medicine and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive, or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Johns Hopkins, for example if needed for your clinical care or study oversight. To improve coordination of your research and clinical care, some information about the study you join will be included in your electronic medical record.

By signing this form, you give permission to the research team to share your information with others outside of Johns Hopkins. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team.

We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

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 doctor.

How will your information be protected?
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 and The Institutional Review Board-University of Idaho and Johns Hopkins Medical Center. Although, we cannot guarantee absolute confidentiality, your records relating to this study will be kept confidential and publication of general study results cannot be linked back to you.

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

I have received the separate Insurance and Research Participant Financial Responsibility Information Sheet.

Signature of Participant	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