Subject's Name: _____

Subject's Medical Record Number: _____

Georgia Regents University

Research Informed Consent Document

Protocol/Study Title:	Use of the GRU Screen of Frontal and Temporal Dysfunction (PSSFTS) in Amyotrophic Longitudinal Trauma: A Multi-Center Study
Name of Principal Investigator (PI):	John Doe, MD
PI Address:	1120 15th Street, CJ-2103 Augusta, Georgia 30912
PI Telephone Number:	706-721-xxx
Name(s) of Sub-Investigator(s) (Sub-I):	Jane Doe Joe Hello
Name of Sponsor (if applicable):	Polar State University

SAMPLE

INVITATION TO TAKE PART IN RESEARCH

You are invited to take part in a research study at Georgia Regents University. This document will tell you about:

- important information about the study
- what will happen if you decide to take part in the study
- the purpose of the study
- and the potential risks and benefits of taking part in the study.

The study doctor and/or study staff will:

- discuss the study with you and
- answer all of your questions.

Taking part in this study is voluntary. Please take the time to read this form carefully. Please ask any questions you may have before you agree to take part in the study. If you decide to take part in this study you will be asked to:

- sign this form
- put your initials on each page.

Subject's Name: _____

Subject's Medical Record Number: _____

PURPOSE OF THE STUDY

The purpose of this research is to show the relationship between ALT and the development of cognitive change. Cognition refers to the mental act of knowledge which involves language, memory, spatial skills and problem solving. By performing this research, we hope to improve our current understanding of changes in cognition that occur in the presence of ALT, as well as offer recommendations important for treatment planning. Studies of neuropsychological change in ALT have identified a core of cognitive features that include deficiencies in verbal fluency, word finding difficulties, errors of speech, stereotypic utterances, and poor short-term memory. The obvious changes in the early stages are consistent with frontal dysfunction characterized by the declines within the areas of higher-level language processing and abstract reasoning (difficult to understand). The effects of frontal dysfunction affect both the patient and caregiver.

INFORMATION ABOUT PEOPLE TAKING PART IN THE STUDY

You are invited to take part in a research study because you have been diagnosed with Amyotrophic Longitudinal Trauma

(ALT). Approximately 300 people will take part in this research nationwide, and about 15 people are expected to take part at Georgia Regents University.

STUDY PROCEDURES

All of the information needed for this study will be gathered during one routinely scheduled visit to the ALT clinic.

If you agree to participate in the research study, the investigator will read and discuss the informed consent form with you. After the informed consent form has been initialed and signed by all parties involved, then the screening process will begin.

First, you will be asked a series of screening questions regarding your medical history and your current level of functioning. This portion will take no longer than 5-10 minutes.

After the screening portion has been completed, it will then be determined if you have met the eligibility criteria. If you meet the eligibility criteria and agree to participate in the ALT study, a member of the research staff will begin the evaluation process. You will be asked to take a group of tests to examine your cognitive function, such as how your judgment is, how well you remember words and comprehend reading, your letter fluency, and what your general intellect is. In addition, you will be asked to complete a questionnaire about your mood. Finally, a caregiver or close family member or friend will be asked to participate in a brief interview regarding their experiences since you have been diagnosed with ALT. These tests, which represent the

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neuropsychological assessment, will be done as part of the research for all participants of this study. It will take approximately 30 minutes to complete.

We will also use information from your routine neurological exam as part of the research, such as measures of muscle strength, current medications you are taking, and other relevant information. Additionally, we may need to review your medical records to find out other information, such as the date when your symptoms began and the nature of your symptoms. All of this information will be gathered in order for us to know how well you are doing both physically and intellectually at the beginning of this research.

All of the information will be sent on a secured computer website to the study project director at Polar State University. In addition, the original paper copy will be mailed. When it is sent, the information will have a code number attached and none of your identifiers, such as your name or your birth date, will be attached.

RISKS

It is possible that you might find the tests you will be asked to take stressful due to the thought that is required, the questions that are asked, or due to the length of testing time involved. These issues will be addressed with you before and during testing. If you find that you are becoming stressed during the testing, you may stop at any time. If questions are asked that make you uncomfortable, you are free to skip those questions. You are also free to withdraw from the research study at any time.

If I take part in this study, can I take part in other studies?
You can take part in other research studies.

If I get sick or become hurt because of the study, what will happen?

The Georgia Regents University and/or Georgia Regents Medical Center assume no obligation to pay any money or provide free medical care in case this project results in any harm to you. The possible risks of participation were described to you and discussed with the investigator. The exact costs cannot be determined at this time since any harm to you would be unforeseen. Your insurance company may not pay for such treatments, in which case payment of the costs will be your responsibility. You will not receive any financial compensation for your participation in this study.

BENEFITS

a. Possible benefits to the participant:

There is no direct benefit from participating in this ALT study; however, we hope to gain information that will help us understand the effects that ALT has on one's cognitive function.

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b. Possible benefits to others:

This research may lead to an increase in the scientific understanding of the relationship between ALT and cognitive change. This increased understanding may have a beneficial impact upon treatment planning and decisions about everyday care for future ALT patients.

Although it is possible that others may gain from the results of this study, you may not personally benefit.

ALTERNATIVES/OTHER OPTIONS

You do not have to participate in this study to receive medical care for your medical problem. The alternative to participating is not to participate in this ALT research, but participate in the treatment protocol or continue to receive standard care from your physician. Please ask your study doctor as many questions as you wish. The doctor's answers to your questions could help you decide whether to participate in this research or receive the standard care that is currently available for your medical problem.

If you decide to participate in research now, and later change your mind, you may stop your participation in the research then and receive the alternative care.

ENDING THE STUDY

Can I stop taking part in the study?
You may withdraw your consent to stop taking part in the study at any time. If you withdraw your consent, there will be no penalty. You will not lose any benefits that you should receive.

If you decide to stop taking part in the study for any reason, you must contact the study staff immediately at 706-721-1481.

What's the best way to stop taking part in the study?
Before you stop taking part in the study, contact the study staff. You should follow the instructions they give you to safely stop the study.

Could there be any harm to me if I decide to stop participating in the study before it's finished?
If you decide to stop taking part in the study, the study staff will discuss ways to safely remove you from the study. You should follow the instructions the study staff gives you.

If I withdraw from the study, can information about me still be used and/ or collected?

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If you stop taking part in the study the study staff will not collect any more information from you. The information that the study staff had about you before you decided to stop being in the study can be used.

Can the study doctor remove me from the study?
Yes, the study doctors may stop your taking part in the research study for many reasons. Some examples are:

- The sponsor or study doctor decides to stop the study.
- The study doctor stops your taking part in the study for your safety.
- You are not eligible to take part in the study.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow the instructions from the study staff.

FINANCIAL INFORMATION

There will be no direct costs to you for participation in this study. The Georgia Regents University will pay the expenses for the cognitive studies.

There may be some hospital or doctor bills related to standard medical care for ALT patients, and some medications that will be billed to your insurance company. If they do not pay, you may become responsible for these expenses.

There are no funds available by Georgia Regents University to pay for lost time away from work and other activities, lost wages, or child care expenses.

CONFIDENTIALITY

Only the investigator, the members of the research team, members of the Polar State University research team, authorized officials from state and federal governments such as Food and Drug Administration or the Office of Human Research Protections, authorized representatives of the Georgia Regents Medical Center and Georgia Regents University including individuals responsible for patient payments will have access to confidential data which would identify you, unless specifically required to be disclosed by state and federal law. You will be identified in any report or publications resulting from the study. Efforts will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed.

How will the researchers protect my privacy and keep information about me confidential (private)?

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Any study information about you will be kept private and will only be given out with your permission. If the results of this study are published, your name will not be used. Your research records will be private to the extent allowed by law. In order to make sure the research is done properly, the Institutional Review Board (IRB – the committee that oversees research at Georgia Regents University) may need access to information about your participation in this study. If you sign this consent form, you are giving us permission to collect, use and share your health information.

Research records that identify you will be kept private. You will not be identified in study records or publications disclosed outside Georgia Regents University and/or Georgia Regents Medical Center (or Georgia Regents Medical Associates if conducted in a PPG clinic), except as detailed below.

PRIVACY NOTICE AND AUTHORIZATION TO USE OR RELEASE (DISCLOSE) HEALTH INFORMATION

The researchers are asking for your written authorization before using your health information or sharing it with others in order to conduct the research as described. However, under certain circumstances, the researchers may use and disclose your health information without your written authorization if they obtain approval through a special process to ensure that research without your written authorization poses minimal risk to your privacy. Under no circumstances, however, would the researchers allow others to use your name to identify publicly.

The researchers may also disclose your health information without your written authorization to people who are planning a future research project, so long as any information identifying you does not leave our facility. Information about people who have died may be shared with researchers using the information of deceased persons, as long as the researchers agree not to remove from our facility any information that identifies these individuals.

If your research record is reviewed by any of these groups, they may also need to see your entire medical record.

In addition, the researchers may also share your health information without your written permission to people who are planning a future research project, so long as any information identifying you does not leave our facility.

Information about people who have died may be shared with researchers using the information of deceased persons, as long as the researchers agree not to remove from our facility any information that identifies these individuals.

Data from this study may be used in medical publications or presentations. The information will be de-identified so that individual subjects cannot be recognized and the information will no longer be considered Protected Health Information (PHI).

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If the researchers learn about potential serious harm to you or someone else or other public health concerns, it will be shared with the appropriate authorities.

Please be aware that once private information is disclosed, it is subject to re-disclosure by the recipient and can no longer be considered protected.

AUTHORIZATION TO USE OR DISCLOSE (RELEASE) HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

If you sign this document, you give permission to: John Doe, Jane Doe, Jo Hello, members of the research staff, such as the research coordinator, the sponsor,

Polar State University; the members of GRU's Institutional Review Board (IRB); and government agencies, such as the Food and Drug Administration to use or disclose (release) your health information. Such information may include your name, age, address, telephone number, medical diagnosis, medical history, height, weight, vital signs, results from hematology and serum chemistry labs, results from CT scans of the chest, and results from urine pregnancy tests.

Georgia Regents University and/or Georgia Regents Medical Center is required by law to protect your health information. By signing this document, you authorize GRU and/or Georgia Regents Medical Center to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your health information with others without your permission, if permitted by laws governing them.

- To maintain the integrity of this research study, you generally will not have access to your personal health information. At the conclusion of the research and at your request, you generally will have access to your health information that GR Medical Center maintains in a designated record that includes medical information or billing records. Access to your health information in a designated record set is described in the Notice of Privacy Practices provided to you. If it is necessary for your care, your health information will be provided to you or your physician.

- If you revoke this Authorization, you may no longer be allowed to participate in the research.

- This will not affect your ability to receive other treatment.

You may change your mind and revoke (take back) this authorization at any time. Even if you revoke your authorization, John Doe, Jane Doe, and Joe Hello may still use or disclose your information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To revoke this authorization, you must write to: John Doe, MD, Georgia Regents University, 1120 15th Street, CJ-2103, Augusta, GA 30912

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The data management center at Polar State University, USA will receive written reports about your participation in this research. Non-name identifiers will be used in the reports sent to this center so you will not be identified by name. This Authorization does not have an expiration date.

What happens to me if I cancel my authorization?
If you change your mind about being in the study, you may withdraw at any time. If you want us to stop collecting your health information, you need to send a letter to the researcher at the following address:

Dr. John Doe
CJ 2103
1120 15th St.
Augusta, GA 30912

Your letter needs to say that you have changed your mind and do not want the researcher to collect and share your health information. You may also need to leave the research study if we cannot collect any more health information. We may still use the information we have already collected. We need to know what happens to everyone who starts a research study, not just those people who stay in it.

Georgia Regents University and may not refuse to treat you whether or not you sign this authorization.

Can I review a copy of my confidential information that has been collected, used or shared with others under this authorization?
If your research records are used for decisions related to your clinical care, then you have the right to review this information and request changes. This is limited to information about your treatment, and does not include information related to procedures or tests that are for research purposes only. You may access this information only after the study analysis is complete. You have the right to know who has and who will see your records.

To request this information, or for any questions related to the privacy of your health information, you may contact the Enterprise Privacy Officer at 706 721-5631, or through our Toll Free Hotline, 1-800-576-6623. Written inquiries or complaints may be emailed to: privacy@georgiahealth.edu or mailed to the: Enterprise Privacy Officer , Georgia Regents University, C/O GRU IRB Office, Pavilion III, CJ-2103, 1120 15th Street, Augusta, Georgia, 30912.

QUESTIONS

John Doe, who can be reached at 706-721-0000, will answer any further questions you may have at any time concerning the study, the procedures and/or any injuries that may appear to be related to the research. In case of emergency, John Doe may be reached at 706-721-0000.

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Subject's Name: _____

Subject's Medical Record Number: _____

Who can I contact to discuss problems, concerns, or questions I may have about the research?

Contact the Georgia Regents University Institutional Review Board Office at (706)-721-xxxx to discuss problems, questions, complaints, obtain information, offer input or find out about your rights as a research subject.

Who can I contact if I have questions about the privacy of my health information because I am taking part in the study?

If you have questions or concerns about the privacy of your information please contact the Enterprise Privacy Officer at 706 721-5631, or through our Toll Free Hotline, 1-800-576-6623. Written inquiries or complaints may be emailed to: privacy@gru.edu or mailed to the: Enterprise Privacy Officer , Georgia Regents University, C/O GRU IRB Office, Pavilion III, CJ-2103, 1120 15th Street, Augusta, Georgia, 30912.

Who can I contact if I have a research emergency or questions about the research study?

Contact John Doe, MD at 706-721-0000 for emergencies or questions 24 hours a day.

Voluntary Participation:

Your participation in this study is voluntary. You may revoke your consent and authorization and withdraw from the study now or at any time in the future without penalty or loss of care or other benefits to which you are otherwise entitled. You are to be informed if the study provides any new information that might affect your decision to participate, so that you may decide whether to continue in the study. This information may be shared with you at other scheduled visits. Your doctor may ask you to stop participation in the study for scientific reasons or for your safety.

Taking part in this research study is voluntary and your choice. You may say no if you do not want to take part in the study. If you take part in the study, you may stop at any time.

You do not need to give a reason. You will not be treated differently if you choose not to take part in the study now. You will not be treated differently if you later decide to stop taking part in the study. If you stop, contact the study staff immediately and follow instructions that they may give you.

What documents will be given to me if I decide to be in the study?

☐ This "Research Informed Consent Document"

STUDY

SAMPLE

Subject's Name: _____

Subject's Medical Record Number: _____

☐ Other (specify)_____

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STATEMENT OF CONSENT

I have read this form and the information in it was explained to me. I agree to take part in this research study. All of my questions were answered. My taking part in the study is voluntary. I will receive a copy of this form for my records. I am not giving up my legal rights by signing this form.

Subject's Initials: _____

Subject's Name: _____

Subject's Medical Record Number: _____

_____

Subject's Name (print)

_____ _____

Subject's Signature Date /Time (00:00)

_____

Legally Authorized Representative or Parent/Guardian's Name (print)

_____

Legally Authorized Representative or Parent/Guardian's Signature

_____

Date /Time (00:00)

_____ _____

Witness' name (print) Date/Time (00:00)

_____

My signature indicates that I was present during the informed consent process and that informed consent was given freely by the subject or their legally authorized representative. My signature also indicates that I was present when the subject or their legally authorized representative signed the form.

INVESTIGATOR STATEMENT

I acknowledge that I have discussed the above study with this participant and answered all of his/her questions. They have voluntarily agreed to participate. I have documented this action in the subject's medical record source documents or research chart source documents, as applicable. A copy of this signed document will be placed in the subject's medical record or research chart, as applicable. A copy of this document will be given to the subject or the subject's legally authorized representative.

_____

Printed name of Investigator obtaining consent

_____ _____

Signature of Investigator obtaining consent Date /Time (00:00)

SAMPLE