**RHD Bank**

Consent to Participate in a Research Study

Study Title

**Discourse Production Following Right Brain Stroke**

IRB NUMBER: Pro00110635

**CONCISE SUMMARY**

The primary purpose of this research is to determine in what ways the communication of adults who have had a stroke to the right side of the brain use language differently than other adults, such as those with a left brain stroke and healthy volunteers. Another purpose of the study is to contribute to knowledge concerning the communication behaviors of right side stroke survivors.

If you decide to participate, you will be asked to:

- complete hearing tests

- complete vision tests

- complete language tests

These tests will take about one to two hours.

The only risks you may experience are frustration and/or fatigue during the testing and the study tasks. You will not benefit directly from participation, but you will be helping doctors understand stroke effects on communication for future patients.

If you are interested in participating, please read below and speak with a member of the research team.

**INTRODUCTION**

You are being asked to take part in this research study because you have had a right or left brain stroke. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

**WHO WILL BE MY DOCTOR ON THIS STUDY?**

If you decide to participate, Dr. Jamila Minga will be your doctor for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

**WHY IS THIS STUDY BEING DONE?**

The primary purpose of this research is to determine in what ways the communication of adults who have had a stroke to the right side of the brain use language differently than other adults, such as those with a left-brain stroke and healthy volunteers. Another purpose of the study is to contribute to knowledge concerning the communication behaviors of right-brain stroke survivors.

**HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?**

Approximately 90 people will take part in this study at Duke.

**WHAT IS INVOLVED IN THE STUDY?**

If you agree to be in this study, you will be asked to sign and date this consent form. You have provided your email address so that the link to the online document could be sent to you, and so that a copy of it can be emailed to you.

If you decide to participate, you will be asked to:

- Complete hearing tests

- Complete vision tests

- Complete language tests

As part of the language tests, you will be asked questions about pictures, asked to tell a story, describe a procedure, and have a conversation. It will take you about 1-2 hours to complete all study tasks.

All responses to study tasks will be video recorded. Because your voice and face will be potentially identifiable by anyone who views the recording, confidentiality for things you say on the tape cannot be guaranteed although the researcher will try to limit access to the tape

The tests may be done either in person or remotely. If performed remotely, Zoom or Webex will be used and the session will be recorded, stored, and protected in a secure electronic environment at Duke.

**HOW LONG WILL I BE IN THIS STUDY?**

Your participation will only last for the day of your research visit. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

**WHAT ARE THE RISKS OF THE STUDY?**

There are no physical risks associated with this study. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Some of the questions we will ask you or tests you are asked to complete as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study. You may stop your participation in this study at any time.

**ARE THERE BENEFITS TO TAKING PART IN THE STUDY?**

You will not benefit directly from participation, but you will be helping doctors understand stroke effects on communication for future patients. We will be able to give you information regarding your strengths and weaknesses in communication.

**WILL MY INFORMATION BE KEPT CONFIDENTIAL?**

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. By providing your email address for use in the consent process, you are at risk for a loss of confidentiality because email is not a secure means of communication. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

Your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives and affiliates of the National Institutes of Health, the Duke University Health System Institutional Review Board, the Duke Surgery Office of Clinical Research, the duke Office of Audit, Risk, and Compliance, and others as appropriate. If any of these groups review your research record, they may also need to review your entire medical record. Results of tests and studies done solely for this research study and not as part of your regular care will not be included in your medical record.

Data without your name or medical record number will be shared with the RHDBank at Carnegie Mellon. However, video recordings of the study procedures including your date of birth and occupational history will be shared with the RHDBank.

The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

**WHAT ARE THE COSTS TO YOU?**

You or your insurance provider will be responsible and billed for all costs related to your routine medical care, including copayments and deductibles. Routine medical care services are those that you would have received for your condition if you were not participating in this research study. The study will pay for tests and procedures that are done solely for research purposes.

**WHAT ABOUT COMPENSATION?**

You will be compensated up to $25 per hour for your expenses related to your participation (parking, gas, and time). If, on consent, you are found ineligible to participate, you will be compensated $10. The collection of your social security number by the Duke study team is required in order to set up payment.

**WHAT ABOUT RESEARCH RELATED INJURIES?**

Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. Mingaat 919-681-2279 during regular business hours.

**WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?**

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Minga in writing and let her know that you are withdrawing from the study. Her mailing address is DUMC Box 3805, Durham, NC 27710. Your doctor may decide to take you off this study if it is no longer in your best interest to continue.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Your data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your data, we will no longer be able to identify and destroy them.

The use of your data may result in commercial profit. You will not be compensated for the use of your data other than what is described in this consent form.

**WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?**

For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Mingaat 919-681-2279 during regular business hours.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

**STATEMENT OF CONSENT**

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

Subject's Name

(Please sign the consent survey before entering "Submit")

Signature

(click on "Add signature" to sign using a mouse or

touchscreen)

Date and Time

IRB Reference Date:

Email

(Enter email address where you would like copy of signed consent form sent to.)

Print a copy of the signed Consent Form once submitted.