INDIANA UNIVERSITY STUDY INFORMATION SHEET FOR RESEARCH
For: Control Group
Study Title: Reliability of spoken discourse in speakers with aphasia
Protocol #1904590484

About this research
You are being asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future. The study is funded by The American Speech-Language-Hearing Foundation. This form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

TAKING PART IN THIS STUDY IS VOLUNTARY
You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with any professional services (e.g. speech-hearing or cognitive), doctors or other medical professionals.

WHY IS THIS STUDY BEING DONE?
Very little is known about how our language and storytelling differ from day to day. Therefore, the current experiment will acquire language and related data from you on two different days. You were selected as a possible participant because you are an adult without aphasia. The study is being conducted by Brielle Stark, PhD, of the Department of Speech and Hearing Sciences.

HOW MANY PEOPLE WILL TAKE PART?
If you agree to participate, you will be one of 42 participants taking part in this study. We anticipate recruiting 21 adults with brain injury as well as 21 older adults to serve as control participants.

WHAT WILL HAPPEN DURING THE STUDY?
Your total commitment to this study will be two sessions. The first session will take approximately one hour. The second session, which will take place 10 +/- 3 days later, will take approximately 30 minutes. The audiovisual data collected during the assessment will be placed in an online (Internet) database called AphasiaBank, which is a large resource for continued research into aphasia. Only members of the AphasiaBank group will be the individuals viewing the videotapes. This website is password protected. Researchers will not be allowed to share the information from the tapes with others. The video will show your face, so it may be possible to identify you from the video on the Internet. However, your name will not be made available; instead, you will be assigned a random study ID.

Please initial one of the following:

__________________     YES, I agree to have my data on AphasiaBank
__________________     NO, I do not wish my data to be on AphasiaBank
WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?
While participating in the study, the risks, side effects, and/or discomforts include:

Behavioral testing is associated with minimal risks, including:
1. Mental discomfort during testing. We expect participants to complete each test to the best of their ability. We are interested in the test results to better understand cognition. All data will remain de-identified when made public and during all analyses. We are happy to discuss the results of these tests in more detail.
2. Fatigue. Testing requires a lot of effort on the part of the participant, and we will offer breaks throughout the testing. We provide snacks and water, and there is a bathroom close by.

Loss of confidentiality. While we do our best to make sure that all records are confidential, there is a risk of the loss of confidentiality. Research information may be given to certain agencies (e.g. governmental agencies) looking into our study. All identifiable information will be kept in locked cabinets or on encrypted servers, only accessibly by appropriate study personnel.

WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THE STUDY?
We will acquire data on language ability and cognition. PI Stark may be able to direct the person to services offered at the Speech and Hearing Clinic of Indiana University, should there be a need.

HOW WILL MY INFORMATION BE PROTECTED?
Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. No information which could identify you will be shared in publications about this study. Data will be collected in the NEURAL Research Lab, which is a 4-room lab that has two testing rooms that are completely sound-proofed for added privacy. We use an online schedule so that study personnel can see when a room is in use. This online calendar is made available so that no other potential or current participants come in contact with the enrolled participant. Study personnel will be the only members aware of sensitive medical information (e.g. who has a brain injury).

Behavioral data with identifiers will be kept in the original form of collection. If forms are collected by paper, in person, these will be kept in the NEURAL Research Lab in a locked cabinet. We will use REDCap, a HIPAA-compliant data management system hosted through Indiana University, whenever possible to directly collect data. REDCap user privileges assure that PHI are kept confidential except to those users assigned as primary investigators on the study. Other study personnel will have access to only de-identified data stored in REDCap. Assessment data will also be kept in Box Health, another HIPAA-compliant system hosted through Indiana University.

WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?
Information collected from you for this study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, we will not ask for your additional consent.

WILL I BE PAID FOR PARTICIPATION?
You will be compensated for participating in this study. You will receive $10/hour. You will be reimbursed in cash immediately following the session or immediately upon withdrawal from a session.

WHAT FINANCIAL INTEREST DOES THE RESEARCHER HAVE?
Investigators have no financial interests in this study.

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, contact the researcher Brielle Stark at bcstark@iu.edu or at (812) 855 7760. After business hours, please call and leave a message or send an email.

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or to offer input, please contact the IU Human Subjects Office at 800-696-2949 or at irb@iu.edu.

WILL I BE CONTACTED ABOUT RESEARCH IN THE FUTURE?
If you agree, we may contact you after your participation is over to request additional information. Please initial one of the following options:

______ Yes, I agree to be contacted for the purpose of collecting additional health and/or biospecimen information.
______ I do NOT agree to be contacted for the purpose of collecting additional health and/or biospecimen information.

CAN I WITHDRAW FROM THE STUDY?
If you decide to participate in this study, you can change your mind and decide to leave the study at any time in the future. The study team will help you withdraw from the study safely. If you decide to withdraw, please make Brielle Stark (bcstark@iu.edu) aware either by writing (a letter or email) or in-person. Information collected prior to withdrawal may be kept and used for analysis, but we will not acquire any information after you withdraw from the study.

PARTICIPANT’S CONSENT
In consideration of all of the above, I give my consent to participate in this research study. I will be given a copy of this informed consent document to keep for my records. I agree to take part in this study.
Participant’s Printed Name: ________________________________

Participant’s Signature: ________________________________ Date:

Printed Name of Person Obtaining Consent: __________________

Signature of Person Obtaining Consent: ____________________ Date: