

**Department of Computer Science and Engineering
University of Notre Dame**

Informed Consent – Study of Impact of Neurological Conditions on Speech

What is the purpose of this project?

You are invited to take part in a research study about the impact of neurological conditions on human speech and cognitive fitness. Such conditions include concussions, Alzheimer's Disease, Parkinson's Disease, Lou Gehrig's Disease, and many others. This study is being conducted by Professors Christian Poellabauer and Sandra Schneider at the University of Notre Dame. The goal of this study is to collect speech samples and various cognitive measures from individuals 18 years and older. Participation in this study is voluntary. Not participating will not affect any benefits, services, etc., received from the University of Notre Dame now or in the future.

If you agree to participate in this study, you will be asked to:

- Answer various health questions about your neurological condition, medications you use, etc. This may also include an evaluation of your speech motor system.
- Perform a sequence of speech tasks using a computer, smartphone, or tablet. These tasks will ask you to read aloud words, phrases, or sentences appearing on the screen of the device. These tasks may also ask you to answer a few generic questions (e.g., "How do you feel today?") or to describe a photo shown on the screen of the device. It takes about ten minutes to complete these tasks.
- Perform a sequence of cognitive tasks using a computer, smartphone, or tablet. These tasks will ask you to trace objects on the screen, play a memory game, name the days of the week, and other similar activities. During some of these tasks, the device may record your face, e.g., to track the movements of your eyes when you look at the device's screen. It takes about ten minutes to complete these tasks.

Note: the voice samples collected will only be used to study certain aspects of speech and cognitive fitness, but will not be used to actually detect or diagnose any medical condition. The collected data (speech recordings and results from the cognitive tasks) will be added to a repository for potential use in various research studies. Scientists at other institutions have to adhere to the same human subject protection requirements as required by the University of Notre Dame to be allowed to access your data and speech recordings. No identifiable information (such as name, address, social security number, etc.) will be associated with your data!

Are there any risks in this research?

We don't believe this study will involve any risks for you. If you find some health questions upsetting, please tell us. You can choose to skip any question. You can stop the evaluation and activities at any time. There may be unknown risks.

What are the benefits of being in this study?

Participating will not lead to any direct benefits. You may learn about the potential long-term effects of neurological conditions and the use of new tools to assess them.

How will we protect your privacy?

The surveys will ask for details of your medical history. We will protect your privacy, as allowed by law, in several ways. First, all collected data will be identified only by a code number. Your name will be stored separately from your data. It will be used only to track potential payments that we may make to you and to ensure that all your data is grouped together. If you decide to participate, you will sign up for an account. Only you will know your account name and password. All data will be saved electronically using the latest security measures. The goal of the study is to make the recordings and data available to medical researchers. They will use it to explore links between neurological conditions and speech. Thus, the collected data will be shared among researchers at different institutions. They will have to comply with our rules about identity and data protection. If you agree to participate in this study, you also agree to this sharing of data collected from you. When such data is shared, and when we report the results of this study, you will never be named or identified in any way.

We are required by law to make reports to prevent serious harm to you or others. If we see evidence of child abuse or neglect, we have to report it.

If you agree to participate, can you change your mind later?

Yes. You are free to join the study or decline. You can begin participating and then cancel your participation at any time, without any penalty, and audio recordings and other data from your participation will be destroyed. Choosing not to participate in the study will not affect any services you may receive from the University of Notre Dame.

If you have any questions about this study, please contact Dr. Christian Poellabauer (574-631-9131, cpoellab@nd.edu). If you have questions about your rights as a research participant, please contact Notre Dame's Office of Research Compliance, (compliance@nd.edu), phone (574-631-1461).

For questions about your rights while taking part in this study, call the Chairperson of the Memorial Hospital Institutional Review Board (a group of people who review the research to protect your rights) at (574) 647-7370.

Participant Certification:

I have read this form (or, it has been read to me), and I have had a chance to ask questions. My questions have been answered. I know that the data relating to my identity will be kept private, and that recordings of my speech may be made available to other research groups under license.

I hereby agree to be part of this study. I know that I can drop out of the study at any time. I also agree to the use and sharing of my information as described above. By signing this, I verify that I am at least 18 years old. I have received a copy of this consent form to keep.

Name

Birth Date

Signature

Date Signed

Current Address _____

Current Phone Number _____

Please check and sign below if you agree to the following:

Permission for future contact

_____ I give permission to be contacted about opportunities to participate in future studies.

Printed Name: _____

Signature: _____ Date: _____