Neurolex Laboratories
Information Sheet for Adults
Screening and diagnosis of medical and behavioral health conditions through use of extracted speech features from a voice sample

TITLE:	Screening and diagnosis of medical and behavioral health conditions through use of extracted speech features from a voice sample
PROTOCOL NO.:	None WIRB® Protocol #20170781
SPONSOR:	Neurolex Laboratories, Inc.
INVESTIGATOR:	James William Schwoebel, BS 95 Inland Circle Newnan, Georgia 30263 United States
STUDY-RELATED PHONE NUMBER(S):	James William Schwoebel, BS 412-206-9085 (Office) 412-613-0772 (24 Hours)

Researchers' statement

We are asking you to be in a research study. The purpose of this information sheet is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. Our goal is for you to understand the purpose of the research, what we would ask you to do, the possible risks and benefits, and your rights as a volunteer. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent." We will give you a copy of this form for your records.

PURPOSE OF THE STUDY

Our research group is interested in identifying medical and behavioral health conditions (such as Alzheimer's, depression, schizophrenia, Parkinson's, or suicidality, to name a few) earlier and more accurately than what currently happens. We aim to explore if there are voice features that reliably predict disease signs and symptoms using a simple and brief speech sample. We are hoping that if this is possible, we can treat these illnesses earlier and more effectively and then help patients feel better in all areas of their life sooner.

STUDY PROCEDURES

The study would happen at set intervals when you have a moment using your mobile device or computer. It would involve recording about 30 seconds of your speech in response to a question such as "How has your week been?" or "name as many animals as you can in 1 minute." We will also record your answers to a screening questionnaire related to the illness. Additionally, you may be asked to answer questions regarding your hope, secrets, anger, fear and emotional pain for 5-6 minutes. The intervals to collect this data will be either weekly or monthly for up to 6-months. We will use a website or a mobile app to capture this information. You may participate anonymously, in which case you will create a login ID to the mobile app or website so that we can link all of your data across the intervals but we will not know your identity. You may also choose to provide an email address or phone number as an ID, and this will allow us to reach you directly in the future to submit more information as part of the study or to notify you of a prize drawing or other compensation.

This procedure should take less than 10 minutes to complete each time and will be completely anonymous. We want to be able to collect voice samples from random, everyday speech. We ask that you do not include any personal or identifiable information during your voice recordings.

We will obtain some basic demographic information such as age, race, gender and confirm current and past diagnoses, if any. We may also obtain current medication treatment because this may have an impact on your current symptoms and your voice. We may ask a few questions about things that would affect your voice, such as if you smoke.

Your participation in this research is voluntary, and you can refuse to participate or withdraw from this study at any time and there will be absolutely no repercussions.

RISKS, STRESS, OR DISCOMFORT

As with any study, there is always the potential for some stress and discomfort. Although this study appears benign in that it does not involve taking a medication or any physical contact, but only gathers speech samples and some basic data, such as your symptom score could trigger some anxiety or discomfort. However, the risks you face while participating in this research are no greater than what you experience in your daily life. There is a slight risk of loss of confidentiality if a researcher could identify your voice. However, this risk is highly unlikely to occur.

If at any time, you change your mind or feel uncomfortable with continuing in the study, you may stop at any time.

BENEFITS OF THE STUDY

Your participation is strictly voluntary. There is no anticipated benefit to you for participating. However, the information collected from this research may help others in the future through development of technology used to diagnosis conditions faster than is available at present. Since this is not a treatment study, your alternative to participating in this research is simply not to participate.

PAYMENT FOR PARTICIPATION

You may be offered compensation or entry in a prize drawing for participation in this study depending on the funds available to the researchers. James William Schwoebel, BS has a financial interest in the sponsor. Please feel free to ask any further questions you might have about this matter.

CONFIDENTIALITY OF RESEARCH INFORMATION

We are taking every measure to abide by strict federal requirements to protect your information and confidentiality. We are storing your speech samples on secure, password protected, HIPAA compliant servers. If you provide direct identifiers such as your name, phone number, address, etc. we will store this securely and will never sell or transfer this information to another party. It will only be used for research related activities including reminders for follow up submissions or sending compensation.

We may share your anonymous speech samples and survey responses with other researchers. Your data is anonymous because there are no means to connect your identity to your speech sample or survey responses.

All the information you provide will be confidential. If you should reveal you intend to harm yourself or others based on one of your survey answers, we will remind you that we are not monitoring your answers in real time and cannot respond. You will be provided some general information and resources for you to use such as calling 911.

Government Agencies such as the FDA, monitors, auditors, IRB/Ethics Review Boards sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, all study records may be examined. Your privacy will be protected because we will not have your identity.

QUESTIONS

Contact James William Schwoebel, BS, at 412-206-9085(Office) or 412-613-0772 (24 Hours) for any of the following reasons:

- if at any time, you feel you have had a research-related issue, or
- if you have questions, concerns, or complaints about the research.

If you have questions about your rights as a research subject, or if you have questions, concerns, or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com

WIRB is a group of people who perform independent review of research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Subject's statement

This study has been explained to me and all my questions, if any, have been answered. I volunteer to take part in this research. I give permission to the researchers to use my voice sample and survey responses as described in this information sheet. I have received a copy of this information sheet by printing a copy of this page for my records.

Please indicate your agreement and consent to participate in this research by checking the "I agree" box in the application used to collect your speech sample.