

## ELECTRONIC CONSENT FORM

**Remote data collection to objectively quantify the severity of Parkinson disease.**

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**Please complete the following to enroll in the study. If you choose not to participate, there will be no penalty to you. A blank copy of this consent form can be downloaded from this attachment for your review prior to providing consent. Please keep this copy for your records.**

- Being in this study is voluntary – it is your choice.
- You can change your mind and stop at any time.
- If you choose not to take part, your [routine medical care, employment status, educational status, etc.] will not be changed in any way.
- There are risks from participating and you should understand what these mean to you.

### **Introduction**

We are inviting you to take part in this study because you have expressed interest in participating in research studies of Parkinson disease (PD). We are interested in enrolling both individuals with Parkinson disease and individuals not diagnosed with Parkinson disease. We would like to study whether the use of web-based technology can measure day-to-day fluctuations in symptoms of Parkinson disease, and distinguish these individuals from individuals who do not have Parkinson disease. This study is being conducted by Dr. Ehsan Hoque and Dr. Ray Dorsey of the University of Rochester's Department of Computer Science and Department of Neurology.

### **Purpose of Study**

The clinical data on Parkinson disease are usually recorded during periodic assessment in the academic research center. These data are low-frequency and are not suitable for computer aided objective analysis. In this study, we want to explore the possibility of a web-based application which is able to capture audio and video data from the research subjects and objectively analyze those generating some feedback (or measure the severity of the disease). The application will give you the instructions to perform the tasks by showing them animation. This collected data and the automatic analysis may uncover key characteristics of the research subjects thus helping the specialist make better recommendations.

The specific objectives of the study are as follows:

Aim 1: To assess the feasibility of research subjects using the web application from their home.

Aim 2: Collect high-quality audio and video data from the research subjects' movement tests.

Aim 3: To objectively measure and quantify five factors of Parkinson disease (voice, postural sway, dexterity, gait, and reaction time) using the application.

### **Description of Study Procedures**

You are being asked to participate in a research study individuals with self-reported Parkinson disease and without Parkinson disease.

You must have a computer/laptop with a working webcam and Internet. Access to Internet connection throughout the duration of this study is necessary. Once you consent to join the study after completing an electronic consent form, you will receive the link to the web-application.

Using the web-application you will perform the twelve tasks once from MDS-UPDRS (Movement Disorder Society - Unified Parkinson's Disease Rating Scale). You need to do the tasks once in one session. However, you can take a break between tasks without closing the application. These tasks are:



1. **Facial Expression Task:** you will sit at rest for 10 seconds. A timer on the web application will allow you to see how much time left. After 10 seconds, you need to recite the following sentences: "The quick brown fox jumps over the lazy dog. The dog wakes up and chases the fox into the forest."
2. **Finger Tapping:** you need to tap the index finger on the thumb 10 times as quickly and as big as possible. First, you need to do this on right hand and then left hand.
3. **Hand Movements:** you will make a tight fist with the arm bent at the elbow so that the palm faces the web interface. You will do this for 10 times as fully and as quickly as possible.
4. **Pronation-supination Movements of Hands:** you have to extend the arm out in front of your body with the palms down; then to turn the palm up and down alternately 10 times as fast and as fully as possible.
5. **Postural Tremor of Hands:** you have to stretch the arms out in front of the body with palms down. The wrist should be straight and the fingers comfortably separated so that they do not touch each other.
6. **Eye gaze tracking:** you will be asked to follow a moving ball across the screen with their eyes.
7. **Vocalization test:** you will be asked to vocalize the sound "ahhh..." for as long as they can.
8. **Scripted Speech:** you will be asked to read aloud a short paragraph of text.
9. **Spontaneous Speech:** you are asked to answer a simple question such as "what did you have for breakfast".
10. **Facial expression mimicry:** you will be asked to mirror an expression shown on the computer display. For example, mirroring a smile.
11. **Head pose Task:** you will be asked to tilt their head up and down and or left and right (i.e., nodding yes or no).
12. **Limb movement task:** while seated, you will be asked to move their limbs as shown in a video (e.g., please touch your nose with your index finger).

Each task should not take more than one minute. You will be able to close the web-application anytime they want. You will be able to redo a test. Also, the web application allows you to take rest in between the tasks if you want to. During the tests, the web-application will collect the audio and video data using the microphone of the computer

and the webcam. After the completion of the tests, the web-application will upload the data to our secure web server. This web server is password protected and only the study personnel will have access to this data. After the recording, you will fill out an online survey. This survey will include questions regarding your experience with the web application, your feedback, and demographic information.

### **Number of Subjects**

We aim to enroll approximately 2000 research subjects in this study, 1500 with self-reported PD and 500 with no PD.

### **Duration of the Study**

The total time involved for the study visit is at most 20 minutes, including both the tasks and the online survey.

### **Risks of Participation**

There is minimal risk to you from this research, as no human tissue will be collected, and no procedures or human testing (beyond surveys and standard clinical assessments) will occur. Participant risks from participation in this research study are considered minimal and include breach of confidentiality and privacy of information transmitted using technology.

However, protection against these risks is a priority. The research subjects with PD may feel stress. To minimize this the web application will allow you to stop the application anytime they want. There is risk involved with your privacy. All data will be securely transmitted from the web application and de-identified before data analysis. Data collected from surveys will be transmitted in encrypted form and stored in a secure database housed at the University of Rochester. All web-based assessments will be conducted using secure, HIPAA-compliant videoconferencing software to protect your confidentiality.

### **Benefits of Participation**

There are no direct benefits; however, the data collected may inform future research and increase understanding of Parkinson disease (PD).

### **Costs**

There will be no cost to you to participate in this study. You can withdraw anytime. Withdrawal will have no effect on your current or future treatment or other benefits.

### **Payments**

After completing the program (recording and survey) we will ask you whether you want to receive an Amazon gift card (\$50) or not. If you want to have it then we will ask for

your email address where we will send the gift card. We will not pay for the cost associated with the internet connection.

### **Confidentiality of Records**

The University of Rochester makes every effort to keep the information collected from you. In order to do so, we will store the data in password protected lab machines. All the data will be de-identified by replacing the names with an ID number. The videos will be transferred from the web application to the server using a secure web transfer protocol. The server is password protected and only the research staff has access to it. We will not keep the videos which include your face or any object that can identify you. Your information will not be included in any Electronic Medical Report (EMR). Sometimes, however, researchers need to share information that may identify you with people that work for the University, regulators or the study sponsor. If this does happen we will take precautions to protect the information you have provided. Results of the research may be presented at meetings or in publications, but your name will not be used.

### **Contact Persons**

For more information concerning this research or if you feel that your participation has resulted in any research-related injury, emotional or physical discomfort please contact: Mohammad Rafayet Ali (research coordinator) at 585-520-8113 (Email: [mali7@cs.rochester.edu](mailto:mali7@cs.rochester.edu))

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420628, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;
- To voice concerns about the research;
- To provide input concerning the research process;
- In the event, the study staff could not be reached.

### **Voluntary Participation**

Taking part in this study is voluntary. You are free not to take part or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you are entitled. In the event that you withdraw yourself from this study, the information you have already provided will be kept in a confidential manner.

### **Permission**