FOX INSIGHT WEARABLES INFORMATION SHEET

**Study Title:** Fox Insight Wearables and Mobile Scaling Program  
**Sponsor:** The Michael J. Fox Foundation for Parkinson’s Research (MJFF)

As an individual with PD, you were contacted about this study via information you provided about yourself in Fox Trial Finder or the Fox Insight Web Portal, including your prior permission to contact you about other research in PD. If you decide to participate in this study, you are agreeing to allow the researchers of this study to access and use the demographic and clinical information about your Parkinson’s disease that you entered into Fox Trial Finder or the Fox Insight Web Portal.

You are being asked to take part in this study because you have Parkinson’s disease (PD) and own a smartphone device. In this research study, we will collect information from people with PD using a smartphone and a smartwatch wearable device. The goals of the study are:

- Determine whether it is feasible for patients with PD to use these devices in a home environment using the provided instructions.

- Determine if the use of this mobile and wearable technology can measure day-to-day motor fluctuations and other symptoms of PD (including activity level and medication intake).

About 1,000 subjects will be included in this study. The study will be conducted virtually/remotely. In order to participate, you must already be registered in Fox Trial Finder or Fox Insight and currently own and use a smartphone device with access to the Internet (either through your cell phone/mobile carrier or through a service provider).

If you decide to take part in this study, you will be asked to do the following activities:

**Creating Your Profile:** You will be asked to register on the Fox Insight web portal, if you have not already done so. You may be asked for information about your symptoms, medical history, family neurological history, and medication history.

**Receiving the Study Kit and Devices:** You will be sent the smart watch kit via delivery service (free of charge), along with an instruction manual describing how to use the device (e.g., how to put the device on, how to turn it on/off, how to charge it, etc.). No in-person instructions will be provided. You will be asked to charge the watch on a daily basis. You are also being asked to wear the watch for up to 1 year.

**Using the Phone and the Watch:** During the study period, the phone and the watch will collect information about your movements and how many times you enter information into the smartphone about your PD symptoms and medication intake. Only you should complete this information. We will also collect data from your smart watch about your activities throughout the day, such as walking or biking. You can use the smartphone application anytime throughout the day. Inability to enter information into the smartphone should not discourage your participation in this study. We are trying
to measure real world usage of this technology. The mobile application will not record information from other activities you do on your phone, such as phone calls, internet searches, or text messaging. The information collected will be stored in a database (data repository) so that other researchers can use the information to develop future research to study PD and other disorders.

**Technical Support:** If the research team determines that your device is not sending data at any point during the study period, you will be contacted directly by a member of the research team to fix the problem. You may also contact technical support staff between 8 am and 5 pm Eastern Time if you have any questions on the use of the watch or phone application.

**Completing the Study:** At the completion of the study data collection period you will be asked to provide feedback on your experience with the mobile technology via an online survey. You will be asked questions about how easy or hard it was to use the watch and to follow the instructions in the manual you were provided. You will also be asked to provide your feedback on the support you received if you called the research team with any technical problems.

**Returning the Devices:** You will not be required to return the smartwatch should you complete the study period.

This study involves collecting personal, identifiable information about you, so there is a potential for invasion of privacy or breach in confidentiality. To minimize this risk, we will not store any directly identifiable information about you with your health information. Your information will also be assigned a unique code number and stored in a secure manner. Information shared with other researchers from the data repository will only include the code number. No personal, identifiable information will be shared outside the study team.

The mobile application is designed to only upload data when you have connected to an available WiFi network. Your confidentiality will be maintained to the degree permitted by the technology used. Specifically, no guarantees can be made regarding the interception of data sent via the internet by any third parties.

There are no expected benefits for you to participate in this study.

In the case your phone is lost, malfunctions, or there is a change in your phone/operating system that no longer supports the current version of the mobile application, you may request a replacement phone or watch in order to continue participation in the study.

There are no costs to you for participating in this study. You will not be paid to participate in this study.

This study is being sponsored and conducted by the Michael J. Fox Foundation for Parkinson’s Research.

The Michael J. Fox Foundation ("Sponsor") makes every effort to keep the information collected from you private. In order to do so, we will keep all information collected from you in a secure online database system, designed for research use, and restrict access with password-protected
computers. Before your health information is given to other researchers the data you provide will be de-identified, which means no personal identifiers are included (for example, your name, date of birth, or address). Also, the data repository will combine all the information provided by everyone in the study before it is made available for research purposes to qualified researchers.

Your permission to use your health information for this study will not expire unless you tell us you want to cancel it. We will keep the information we collect about you indefinitely. If you cancel your permission, you will be removed from the study. You may send email to info@foxinsight.org to cancel your permission.

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time, for whatever reason. You have complete control over the functions of the smart phone application. You can start and stop passive monitoring at any time at your discretion. You can also uninstall and remove the application from your phone at any time for any reason.

For more information or questions about this research, you may email info@foxinsight.org. If you have any questions about your rights as a research subject, you may contact: New England IRB at 800-232-9570.

You may print a copy of this form to think about or discuss with family or friends before making your decision to participate in the Fox Insight Wearables study.

After you have read this form and the Fox Insight website Terms and Conditions, you will be asked to check a box if you agree to participate in this study. By checking the box, you are confirming that you reviewed and you are in agreement with the Fox Insight Wearables Information Sheet and the Fox Insight website Terms and Conditions.