FOX INSIGHT WEARABLES AND FOX INSIGHT MOBILE CONSENT FORM
(Online Research Participants)

Study Title: Fox Insight Wearables and Fox Insight Mobile Scaling Program: A Sub-Study of Fox Insight Web

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Sponsor: The Michael J. Fox Foundation for Parkinson’s Research (MJFF)

INTRODUCTION

You are being asked to participate in a research study. In this consent form, “you” always refers to the person volunteering for the research and whose health information is being collected (i.e., volunteer research subject). A volunteer research subject in this study will include individuals with Parkinson’s disease (PD). In order to decide whether or not you wish to be a part of this research study, you should know enough about its risks and benefits to make an informed decision. This consent form gives you detailed information about the research study, including its purpose, the procedures that will be done, any risk of the procedures, and possible benefits. Once you understand the study, and agree to participate, you will need to sign this consent form. This consent form contains important information and telephone numbers; so you should keep a copy to refer to as the study proceeds.

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 research in PD. If you decide to participate in this research 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 Fox Insight Web Portal.

You may print a copy of this consent form to think about or discuss with family or friends before making your decision on participating.

PURPOSE

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 to use these devices in a home environment using the provided instructions
- Determine if the use of technology can measure day-to-day motor fluctuations and other components of PD (including activity level and medication intake)
ELIGIBILITY CRITERIA FOR PARTICIPATION

A total of approximately 1000 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). You must be 30 years of age or older and diagnosed with PD by a physician. You must be able to walk without any assistance.

PROCEDURES

If the study team determines that you are eligible, you will be contacted by phone or email by one of the research staff. You may be required to participate in the study for up to 6 months.

Creating Your Profile: In order to create your clinical profile, you will be asked to complete information about your symptoms, medical history, family neurological history, and medication history. You may also be prompted to complete other IRB approved assessments in the Fox Insight Web Portal, including patient reported assessments on quality of life.

Receiving the Study Kit and Devices: You will be sent the device 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, however, you will be able to contact technical support staff between 8am and 5 pm E.S.T. if you have any questions on the use of the device. You will then be asked to wear the devices for a period of several weeks to several months. You will also be requested to charge the devices on a daily basis.

Using the Devices: During the study period, the devices will collect information about your movements, how many times you enter information into the smartphone about your PD symptoms and medication intake. Only you should complete these tests and enter this information. You can use the smartphone application anytime throughout the day. Inability to enter information into the smartphone should not discourage your participation in this research study. We are trying to assess real world feasibility. All data collected is valuable.

Technical Support: If the research team determines that your device is not transmitting data at any point during the study period, you will be contacted directly by a member of the research team to fix the problem.

Completing the Study: At the completion of the study data collection period you will be asked to provide written or oral feedback on your experience with the technology. It will be important for you to be completely honest in providing feedback to the research team as to how easy or hard it was to use the device and to follow the instructions in the manual you
were provided. We will also want 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.

You have complete control over the functions of the Fox Insight Mobile Application. You can start and stop data collection at any time at your discretion. You can also uninstall and remove the application for your smartphone at any time for any reason.

**Risks**

Participation in this research carries a small risk of loss of confidentiality. We will code the information we collect from you rather than using your name or other information that can directly identify you. Every effort will be made to maintain your confidential information and protect personal information obtained as a result of this study. However, even with removal of these identifying information points, it is sometimes possible to re-identify individuals uniquely given enough information about the individual. We cannot guarantee that your identity will never become known. This risk should be contemplated prior to consenting to participate.

Personal health information data that is collected on your smartphone (name, phone number, email address, etc. each collected with your express permission) will be saved in a separate database from the database where the other study data is stored. We do this to ensure that data from your phone cannot be used to re-identify you. This type of smartphone data will be saved in a database called the “User Management Engine” which is a secured server. All communication with this server requires a randomly generated password (the authentication process). We will use this information to identify you for technical support and to link your data across Fox Insight Web and the mobile device. We will not record phone calls or store any text messages you send or receive.

Any use by you, or others through you, of the wearable devices that deviates from the study protocol may generate identifiable data that may also be stored in the database or used by third parties. We cannot guarantee the security, privacy or sharing of any data generated through use of the wearable devices outside the scope of the study protocol.

There may be risks or side effects from wearing the devices, which are unknown at this time.

**Benefits**

You are not likely to directly benefit in any way as a result of your participation.
STUDY DURATION

Your participation in the study is expected to be approximately 2 weeks to several months in duration. From the time that you agree to participate to the time that you start wearing the device, may take several weeks depending on how quickly the device kit is delivered to your home.

NEW STUDY FINDINGS

You will be told about any new information that might change your decision to be in this study. This new information will be posted to the study website with confidential email notifications sent to participants.

COSTS

There will be no cost to you to participate in this study.

PAYMENT FOR PARTICIPATION

There is no payment to participate in this study.

CONFIDENTIALITY AND PERMISSION FOR RELEASE OF INFORMATION

There is the risk for loss of confidentiality by participating in this research study. We will code the data we collect from you rather than using your name or other information that can directly identify you. This information will be shared with MJFF and its contractors and collaborators. Every effort will be made to protect the confidentiality of your identifiable information, and your identifiable information will not be stored in a publically accessible database. You are not obligated by the research study to reveal to your insurance or other health provider that you are participating in this research study, and the devices will not affect your health status. Results from this research study will not form a part of your future medical record. De-identified information will be made available to the public, including without limitation through the world wide web, to further research on and about PD and related conditions and for other research purposes.

Any use by you or others through use of the wearable devices that deviates from the study protocol may generate identifiable data that may also be stored in the database or used by third parties. We cannot guarantee the security, privacy or sharing of any data generated through use of the wearable devices outside the scope of the study protocol.

There may be risks or side effects which are unknown at this time.

To meet regulations or for reasons related to this research, the study investigator may share a copy of this consent form and records that identify you with the following people:

- The study staff
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- The data hosting provider
- The Institutional Review Boards at [New England IRB (committees that review research as required by regulations to make certain your rights as a research subject are protected)]
- The Michael J. Fox Foundation for Parkinson’s Research (MJFF), the sponsor of this study
- Clintrex, the company helping to implement this study

If you decide to take part, your Authorization for this study will not expire unless you cancel (revoke) it. The information collected during your participation will be kept indefinitely. You can always cancel this Authorization by writing to wear@foxinsight.org.

As stated in the section on Voluntary Participation below, you can also refuse to sign this consent/Authorization and not be part of the study. You can also tell us you want to leave the study at any time without canceling the Authorization.

VOLUNTARY PARTICIPATION

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your participation in this study may be stopped by the study sponsor or the New England Institutional Review Board at any time and for any reasons, without your consent for any reasons.

SOURCE OF FUNDING

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

QUESTIONS

If you have further questions about this research study, please send your questions via email to Lily Cappelletti at lcappelletti@michaeljfox.org.

If you have any questions about your rights as a research subject, you may contact: New England IRB at 1-800-232-9570.

CONSENT

After you have read and understood this consent document you will be asked to check a box if you agree to participate in this study. By checking the box, you affirm that you have reviewed the consent form and that you understand it and that you consent to participate in the Fox Insight Wearables and Fox Insight Mobile clinical trial.