CONSENT FORM

Study title:
Tele-health outcomes as digital biomarkers of Parkinson's disease progression during extended follow-up of STEADY-PD III and SURE-PD3 trial participants

Abbreviated title:
AT-HOME PD: **A**ssessing **T**ele-**H**ealth **O**utcomes in **M**ultiyear **E**xtensions of **PD** trials

Principal Investigators:
Ray Dorsey, MD, MBA - of the University of Rochester
Lara Mangravite, PhD - of Sage Bionetworks
Michael Schwarzschild, MD, PhD - of Harvard Medical School
Tanya Simuni, MD - of Northwestern University

This consent form describes a research study, what you may expect if you decide to take part and important information to help you make your decision. Please read this form carefully and ask questions about anything that is not clear before you agree to participate. You may print this consent form to review and discuss with family or friends.

Key Information

- Being in this research study is voluntary – it is your choice.
- You are being asked to participate in this study because you have participated in either the STEADY-PD III or the SURE-PD3 trial.
- The purpose of this study is to provide remote (at home) follow-up to participants in the STEADY-PD III and SURE-PD3 trials and see how well different tests measure Parkinson's disease (PD) and disability changes.
- Your participation in this study is expected to last about 24 months.
- Activities will include annual tele-visits (video-based research visits you can do from your home or another private location), quarterly smartphone application (app) activities, and quarterly online surveys. The tele-visits will not be recorded.
- The risks of participating in this study are very low:
    - The most common risk is discomfort with some of the questions or assessments.
    - Another risk is breach of confidentiality if someone were to access your study information without authorization. See the "Risks of Participation" section in this consent form for more information. You should discuss these risks in detail with the study team.
- You will not directly benefit from participating in this study.

Purpose of Study

The purpose of this study is to follow people with Parkinson's disease (PD) through tele-visits, smartphone-based activities, and online surveys and see how well these different

activities measure changes in health in people who previously participated in the STEADY-PD III and SURE-PD3 trials.

Description of Study Procedures

1) If you decide to take part in this study, you will be asked to complete three tele-visits and related surveys over a 2-year period. The tele-visits will be done using a secure video-conferencing system on a smartphone, tablet, or computer. If needed, we will mail you a webcam and help with installation. The surveys will be completed online.

2) You will also be asked to enroll in a separate, online research study (Fox Insight) and complete online questionnaires every 3 months.

3) If you own a smartphone and agree to participate in smartphone assessments, you will be asked to download a free mPower app and to complete some simple activities on your smartphone on at least 10 days of a 2-week period every 3 months. You can choose whether to complete your study activities in the morning or in the afternoon. You will be asked to always complete your study activities either in the morning or in the afternoon (depending on which one you chose).

Tele-visits

If you are interested in participating in the study and you provide eConsent, you will be asked to complete a technology survey within REDCap.

Screening Visit (video conference)

At the screening visit you will be asked to verify your identity by showing the study team member your photo ID. The identity verification will be done by only viewing the ID during the tele-visit and this information will not be collected. If you do not have a photo ID a study team member will verify your identify by asking the questions below:

i. You will be asked to repeat your name
ii. You will be asked to state your year of birth
iii. You will be asked to provide your address of record

After providing your electronic consent on this informed consent document, we will ask you a few questions about your use of technology. You will then complete an about 30-minute screening visit, conducted remotely using a web-based video platform, with a coordinator from the University of Rochester. During this visit, the study coordinator will:

- Review your understanding of the study
- Confirm that you meet the study criteria to participate
- Collect some basic information about you
- Set up and walk you through a tele-visit
- Create your global unique identifier – GUID (a code we use to identify you in the study) if you do not already have one
- Create a Fox Insight account with you

- Show you how to use the scheduling software (SimplyBook.me) and schedule your baseline tele-visit

Baseline Tele-visit
This tele-visit will take about 60-90 minutes to complete and will be done with a coordinator and investigator from the University of Rochester.

Pre-tele-visit – Up to one week prior to each visit, you will be emailed the direct links to the REDCap surveys, for you to complete before the tele-visit, that will:
- Ask you about your experience with PD
- Ask you about any falls
- Ask you about your level of illness

During the visit, we will:
- Review your current medications
- Ask you questions and perform a PD examination
- Ask you about any mobility symptoms or falls
- Test your memory and thinking
- Ask questions to determine the severity of your symptoms
- Review whether you have completed certain study activities

If you are participating in the smartphone piece of the study, we will also:
- Help you install the smartphone mPower app and show you how to use it
- Ask you to complete a full set of smartphone activities

Post-tele-visit – After the visit we will send you an email with a link to complete a survey that:
- Asks about your experience in the study and thoughts about research

Month 12 and Month 24 Tele-visits
These tele-visits will take about 60 minutes and will be done with a coordinator and investigator from the University of Rochester. Activities will be the same as the baseline tele-visit, except the surveys sent prior to the visit will also ask about change in your level of illness.

The investigator from the University of Rochester will not change any of your medications. If you have any questions regarding your medications or health, you should discuss these with your primary care doctor or neurologist.

Premature Withdrawal Tele-visit
If you decide to stop participating in the study or are withdrawn from the study, we will ask you to complete one more tele-visit. This tele-visit will take about 60 minutes to complete and will be done with a University of Rochester coordinator and investigator. The visit will be the same as the month 12 and month 24 tele-visits, except you will also be asked to complete a survey asking why you decided to stop participating.

Smartphone Assessments:
If you have a personal smartphone, you are encouraged to participate in the smartphone assessment part (mPower app) of the study to add to the value of the study. During the baseline tele-visit the coordinator will help you install a free app created by Sage Bionetworks and show you how to use it.

The smartphone assessment includes questionnaires and activities that you can conduct using a smartphone/mobile application (mPower app). You will be asked to provide some basic information about yourself, your symptoms and to record when you take your medications. You will receive reminders on your smartphone to do the following motor tasks and games.

You will be asked to do the following motor tasks daily on at least 10 days over a 2-week period every 3 months:

- Walking – Walk with your smartphone in your pocket for 30 seconds.
- Finger Tapping – Quickly tap your fingers on your smartphone for 30 seconds.
- Tremor – Hold your smartphone in your lap for 30 seconds with each hand.
- Balance – Stand still while holding your smartphone for 30 seconds.

You will be asked to complete the following games daily on at least 3 days over the same 2-week period every 3 months:

- Number span – Report back numbers shown on your smartphone.
- Matching – Match the right symbol with the right number on your smartphone.
- Memory – Test your memory on your smartphone.

There are a few more things to note about the smartphone app:

- We prefer that you complete all smartphone activities at about the same time each day.
- You can use the app as often as you want.
- Occasionally, we may re-contact you to ask for your feedback about using the app and about the kind of questions included in the study.

Passive Monitoring
Within the smartphone-mPower app, you will be asked for permission to collect data about your daily movement and activity. For instance, we would like to know how far you travel, how much time you spend sitting or typing on your phone, walking, or exercising, and how you walk. This is to see if the sensor measurements are the same when you are doing the mPower app activities or when you are doing normal daily activities. During passive data collection, the sensors will only be collecting data on your movements. We will not collect data on your exact location or what you are typing on your phone (for example text messages, emails, etc.). You can enable or disable this passive data collection function in the mPower app at any time. You can participate in the smartphone part of the study even if you choose not to share this kind of data with the study investigators.

The data collected through the mPower app is managed by Sage Bionetworks, a non-profit research organization and research partner in this study. Sage Bionetworks may use the data collected through the app for this and future studies. For example, Sage Bionetworks may use these data to design and develop other mobile apps or sensor technologies without obtaining additional consent from you. In addition, Sage Bionetworks may use or share with other researchers the information collected through this app to perform additional research on PD or other conditions. To protect your privacy and the confidentiality of your data, your name and contact information will not be used. All the data from AT-HOME PD will be stored at Sage in a database called Synapse (an open source collaborative databank).

Fox Insight:

You will be asked to complete questionnaires through Fox Insight (https://foxinsight.michaeljfox.org), an online research study that collects patient-reported data. The Fox Insight study is sponsored by The Michael J. Fox Foundation for Parkinson's Research, which is a research partner in this study. During the screening tele-visit, a coordinator will create a Fox Insight account for you using some of your personal information. You will then receive an email with instructions as to how to complete the registration and consent process for Fox Insight.

- You will be asked to complete some questionnaires every 90 days. They may be completed in a single sitting or over multiple sittings. The baseline (initial) questionnaires will take approximately one hour to complete. Subsequent questionnaires will take approximately 10-15 minutes to complete.
- Additional questionnaires and study opportunities outside of the Fox Insight standard questionnaires, such as genetic testing and more, are optional for study participants.

Data associated with all AT-HOME PD (AHPD) participants enrolled in Fox Insight will be stored in the MJFF-sponsored data repository developed by the Laboratory of Neuroimaging (LONI) at the University of Southern California. LONI will develop software to compile, update and export all Fox Insight questionnaire data for AHPD subjects to Synapse.

The Fox Insight data set will be made available through LONI to qualified researchers who agree to and sign a Fox Insight Data Use Agreement. All data collected through Fox Insight will be placed in an online research portal (http://www.loni.usc.edu/) for use by the research community. The visit time and dates will be a part of the LONI dataset. The data set will notate a subject, by their GUID.

Data Sharing

Your data will be shared between the research partners conducting this study, the University of Rochester, Massachusetts General Hospital, Northwestern University, Sage Bionetworks, and The Michael J. Fox Foundation for Parkinson's Research. All tele-visit, smartphone and FI survey data will be combined within Synapse using the GUID, and the dates and the times associated with your visits. After combining the data from the tele-visit, smartphone, and FI in Synapse, the event dates and times will be converted to a time window and the only identifier that will remain will be the GUID number.

Combined tele-visit, smartphone and FI survey data will eventually be transferred to the National Institute of Neurological Disorders and Stroke (NINDS) Parkinson's Disease Biomarkers Program Data Management Resource (PDBP DMR). Your study data may be sent to one or more other databanks, where it will be stored with data from other studies. The databanks may be kept at universities, government agencies or private companies. The data may include health information. Importantly, your name will never be included in information that is sent to PDBP DMR. This means that your data will only be identified by your unique GUID, which links to information gathered from other studies you may have participated in prior to this study. Researchers will always have a duty to keep your information confidential to the best of their ability.

Often it is helpful for scientists to share data they get from studies to learn more about health and disease. Combining information from different studies in one place may help them learn even more. This collection of information is called a databank. In the future we will combine your information from STEADY-PD III and SURE-PD3 with your information from AHPD study for the purpose of evaluating long-term follow up.

Number of Subjects

We estimate that approximately 420 subjects will take part in this study.

Risks of Participation

Some of the questions in the questionnaires may be upsetting or make you feel uncomfortable. You are free to stop a test at any time. You may feel frustrated while taking a test used to evaluate your memory or thinking: it is meant to be challenging. You can take breaks as needed.

During the tele-visits we will watch you walk, and there is a possibility that you could fall. If you typically walk with an assistive device (such as a cane or walker) or with the help of a caregiver, you will only be asked to walk under your usual conditions. You will not be asked to try to walk if you typically use a wheelchair or if you or the investigator has concerns about your risk of falling. If you do fall, or have another medical event during the tele-visit that requires emergent evaluation, we will assist in contacting emergency services if needed.

Because this study involves collecting personal, identifiable information about you, there is a potential for invasion of privacy or breach in confidentiality. Accidental release of information to the public may occur due to unintended data breaches. In such an event, your data may be misused or used for unauthorized purposes. Every effort will be made to maintain confidentiality and protect personal information obtained as a result of this study.

- We will assign you a GUID number instead of labeling the information we collect from you with your name (or medical record number). We will use GUID instead of your name on all your study data. Information about the GUID code will be kept in a secure system. Only the study investigators and some technical staff for AHPD,

STEADY-PD III or SURE-PD3 studies and some FI clinical operations staff will have the key to link your coded study data to your name and account information.
- We will use a HIPAA compliant, secure video-conferencing system for the tele-visits.
- The software that we will use for the surveys and to store your information from the tele-visits has been specifically designed to protect the privacy of research subjects and access to the database is restricted.
- Data obtained through Fox Insight questionnaires are stored in a secure databank. Only the Fox Insight study team will have access to this information before any parts that could identify you are removed.
- Your combined data will be stored securely in Sage Bionetworks' databank Synapse (synapse.org), using Amazon-Web Cloud Services.

Smartphone Application

There are a few additional risks to participating in the smartphone assessments:
- Other people may glimpse the study notifications and/or reminders on your phone and realize you are enrolled in this study. This can make some people feel self-conscious.
- Be safe – just as you would not text while driving, do not attempt to complete study activities while driving. Wait until you are in a safe place to perform study-related activities!
- There is a potential for invasion of privacy or breach of confidentiality. The data collected through the mPower app will be encrypted on the smartphone, transferred electronically and stored securely in Synapse. We will separate your account information (name, email, contact information, etc.) from your study data (your responses to surveys and the measurements from the phone itself when you perform activities).
- We will NOT access your personal contacts, other apps, text or email message content, or websites visited. We will never sell, rent, or lease your contact information.
-

A description of this clinical study is available on http://www.ClinicalTrials.gov where it is registered under NCT03538262, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this website at any time.

Benefits of Participation

You will not directly benefit from being in this research study.

Costs

There is no direct cost to you to participate in this study. If you participate in the smartphone component of this study, data collected through the app may count against your existing mobile data plan. You may configure the app to only use Wi-Fi connections to limit the impact running this app has on your data costs.

Payments

You will be compensated $[*X*] for each of the three tele-visits via a check (baseline, month 12 and month 24) for a total of up to $[*X*] for expenses you incur to participate. You will not be paid for tele-visits that you do not complete. If a web camera is provided to you, you will be allowed to keep it after completion of the study for your own use.

If you are a participant belonging to a minority group and do not have the required adequate technical resources - the costs of standard internet access and/or a smartphone/data plan (above the reimbursement payment) will be reimbursed.

Confidentiality of Records and Authorization to Use and Disclose Information for Research Purposes

The University of Rochester makes every effort to keep the information collected from you private. In order to do so, we will conduct all assessments using secure platforms and store your information in secure databases with restricted access. Sometimes, however, researchers need to share information that may identify you with people that work for the University, regulators or the study sponsor.

What information may be used and given to others?

The study doctor will get your personal and medical information. For example:

- Research records
- Records about phone calls made as part of this research
- Records about your study visits

Who may use and give out information about you?

- The study doctor and the study staff
- URMC and Affiliates

Your information may be given to:

- The Department of Health and Human Services
- The University of Rochester
- Your data with your GUID (without your name, contact information will also be shared broadly across the research community with qualified researchers to benefit future research. The shared study dataset, including tele-visit, smartphone and FI survey data, will be made available to qualified researchers who have agreed to use the data in an ethical manner, to do no harm and not attempt to re-identify or re-contact you unless you have chosen to allow them to do so. Researchers will have access to the shared study data but will be unable to easily map any particular data to the identities of the participants. The Principal Investigators and Sponsor will have a committee that will have oversight on the future use of the shared study data by other researchers.

Why will this information be used and/or given to others?

- To do the research

- To study the results
- To see if the research was done correctly

If the results of this study are made public, your name and contact information will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

How long will this permission be valid?
This permission will last indefinitely.

May I cancel my permission to use and disclose information?
Yes. You may cancel your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. Upon receiving the written notice, the study team will no longer use or disclose your health information and you will not be able to stay in this study. Information that has already been gathered may need to be used and given to others for the validity of the study.

May I withdraw from the study?
Yes. If you withdraw your permission to be in the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
No. There is a risk that your information will be given to others without your permission.

Circumstances for Dismissal
You may be withdrawn from this study if you cannot complete the study activities or do not complete the study tele-visits.

New Study Information
If we discover anything that might make you change your mind about continuing in the study, we will let you know.

Sponsor Support
The University of Rochester is receiving payment from the Massachusetts General Hospital (MGH) from a grant through the National Institutes of Health for conducting this research study.

Commercial Profit
We will use your information for research only. However, the results of this research might someday lead to the development of products (such as a new smartphone app or

medication) that could be sold by a company. You will not receive money from the sale of any such product.

Return of Research Results

In general, we will not give you any individual results from your participation in the study. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

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: E. Ray Dorsey, MD, MBA at phone number [redacted]
Please contact the University of Rochester Research Subjects Review Board at [redacted] 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 do withdraw from this study, the information you have already provided will be kept in a confidential manner.

Use of E-mail for Communication in Research

When using e-mail to communicate with you in this study, the researcher cannot guarantee, but will use reasonable means to maintain security and confidentiality of e-mail information sent and received. You and the researcher should understand the following conditions, instructions and risks of e-mail use:

Conditions for e-mail use:

a) E-mail is not appropriate for urgent or emergency situations. The researcher cannot guarantee that any particular e-mail will be read and responded to.
b) E-mail must be concise. You should schedule an appointment if the issue is too complex or sensitive to discuss via e-mail.
c) Essential E-mail communications between you and the researcher will be filed in your research record.
d) Your messages may also be delegated to any member of the study team for response.
e) The researcher will not forward subject-identifiable e-mails outside of URMC and Affiliates without your prior written consent, except as authorized or required by law.
f) You should not use e-mail for communication regarding sensitive medical information.

g) It is your responsibility to follow up and/or schedule an appointment if warranted.

Instructions for e-mail use:

a) Avoid use of your employer's computer.
b) Put your name in the body of the e-mail.
c) Put the topic (e.g., study question) in the subject line.
d) Inform the researcher of changes in your e-mail address.
e) Take precautions to preserve the confidentiality of e-mail.
f) Contact the researcher's office via conventional communication methods (phone, fax, etc.) if you do not receive a reply within a reasonable period of time.

Risks of e-mail use:

Sending your information by e-mail has a number of risks that you should consider. These include, but are not limited to, the following:

a) E-mail can be circulated, forwarded, stored electronically and on paper, and broadcast to unintended recipients.
b) E-mail senders can easily misaddress an e-mail.
c) Backup copies of e-mail may exist even after the sender or the recipient has deleted his or her copy.
d) Employers and on-line services have a right to inspect e-mail transmitted through their systems.
e) E-mail can be intercepted, altered, forwarded, or used without authorization or detection.
f) E-mail can be used to introduce viruses into computer systems.

****

Signatures/Dates

After reading and discussing the information in this consent form you should understand:

- Why this study is being done
- What will happen during the study
- Any possible risks and benefits to you
- Other options you may have instead of being in the study
- How your personal information will be protected
- What to do if you have problems or questions about this study
- How your information from STEADY-PD III or SURE PD-3 will be linked to your data in AT-HOME PD

Subject Consent

I have read (or have had read to me) the contents of this consent form and have been provided the opportunity to ask questions. I have received answers to my questions. I agree to participate in this study. I may download or print a copy of this form for my records and future reference.

_____ _____

Subject Name Date

If you have a personal smartphone and wish to participate in the smartphone piece of the study, please provide your consent below.

Subject Consent: Smartphone Component

I have a personal smartphone and agree to participate in the smartphone piece of this study.

□ Yes

□ No

_____ _____

Subject Name Date