**STUDY INFORMATION AND CONSENT to RESEARCH**

**TITLE:** Study title

**PROTOCOL NO.:** Number

Protocol #

**SPONSOR:** Sponsor

**INVESTIGATOR:** Name

Address

City, State Zip

Country

**SITE(S):** Name

Address

City, State Zip

Country

**STUDY-RELATED**

**PHONE NUMBER(S):** Name

Phone Numbers

**SUMMARY**

You are invited to participate in a research study to understand variations in symptoms of [insert condition]. This study is designed for persons over 18 years old with or without [insert]. Your participation in this study is entirely voluntary.

To be in a research study you must give your informed consent. The purpose of this form is to help you decide if you want to participate in this study. Please read the information carefully. If you decide to take part in this research study, you will be given a copy of this signed and dated consent form. If you decide to participate, you are free to withdraw your consent, and to discontinue participation at any time.

You should not join the research study until all of your questions are answered.

Participating in a research study is not the same as receiving medical care. The decision to join or not join the research study will not affect your medical benefits.

**PURPOSE OF THE STUDY**

People with [insert condition] can have very different and more or less severe symptoms day to day. This affects quality of life and makes managing treatment difficult. We would like to understand the causes of these symptom variations.

New technologies now allow people to record and track their health and symptoms in real time. This study will monitor individual’s health and symptoms using a mobile phone application.

If you decide to join the study you will need to download the study application on your mobile device. Then periodically we will ask you to answer questions and perform some tasks via your mobile phone. These tasks may include questions about your health, exercise, medicines, and additional surveys, as well as some brief activities that you perform while holding your phone. Your study data will include your responses to surveys and the measurements from the phone itself when you perform a task . Tasks can include [insert tasks].

Your data, without your name, will be added to the data of other study participants and made available to groups of certified researchers for analysis. You also will have a unique account that you can use to review your data on the study website.

**PROCEDURES**

**What will you be asked to do?**

* **Download a mobile app (free) and register an account:** You need to have the study app on your phone in order to participate in this study. Everyone who enrolls will first complete an electronic registration process. The registration process can be done through the study app or the study Web portal. Registration will include entering your name, email address and other general information about yourself. As part of this process you will also confirm your agreement to participate in the study.
* **Health Surveys**: We will ask you to answer questions about yourself, your medical history, and your current health. You may choose to leave any questions that you do not wish to answer blank.
* **Tasks**: We will ask you to perform specific tasks while holding or using your mobile phone. Examples of such tasks are:
  + [insert bulleted list of tasks]

These tasks should take you about [insert number] minutes each week. You have the right to refuse to answer particular questions or participate in particular aspects of the study. We will send notifications on your phone asking you to complete these tasks and surveys. You may choose to act at your convenience, (either then or later) and you may choose to participate in all or only in some parts of the study.

**What we will and will not do with the data?**

* In order to protect your privacy, we will use a random code instead of your name on all your study data. This unique code cannot be used to directly re-identify you.
* Any data that directly identifies you will be removed before the data is transferred for analysis, and data analyzers are required by contract to respect the de-identification.
* However, we cannot guarantee that all data can remain anonymous forever.
* Researchers will have the ability to contact you if you have chosen to allow them to do so.

**RISKS, DISCOMFORTS, AND INCONVENIENCES**

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought.

This is an observation study not a treatment study and we do not expect any medical side effects from participating.

Some survey questions may make you feel uncomfortable. Know that the information you provide is entirely up to you and you are free to skip questions that you do not want to answer.

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. You can avoid that by putting a passcode on your phone to block unauthorized users from accessing your phone content.

Be safe – just as you would not text while driving, do not fulfill study tasks while driving. Wait until you are in a safe place to perform tasks!

You may have concerns about data security, privacy and confidentiality. We take great care to protect your information, however there is a slight risk of loss of confidentiality. This is a low risk because we separate your personal information (information that can directly identify you, such as your name or phone number) from the research data to respect your privacy. However, even with removal of this information, it is sometimes possible to re-identify an individual given enough cross-referenced information about him or her. This risk, while very low, should still be contemplated prior to enrolling.

Data collected in this study will count against your existing mobile data plan. You may configure the application to only use WiFi connections to limit the impact this data collection has on your data plan. You can respond to the surveys via the web portal instead of via your mobile phone but all the tasks must be completed using your mobile phone.

Participation in this study may involve risks that are not known at this time.

You will be told about any new information that might change your decision to be in this study.

**POTENTIAL BENEFITS**

The goal of this study is to create knowledge, which can benefits us as a society. The benefits are primarily the creation of insights to help current and future patients and their families to better detect, understand and manage their health. We will return the insights learned from analysis of the study data to you by sending notifications to the mobile application as those insights are validated. But these insights may not be of direct benefit to you. We cannot, and thus we do not, guarantee or promise that you will personally receive any direct benefits from this study. However you will be able to track your health and export your data at will to share with your medical doctor and anyone you choose.

**COSTS**

There is no cost to you to participate in this study other than to your mobile data plan if applicable.

**ALTERNATIVES**

Since no medical treatments are provided during this study there are no alternative therapies. The only alternative is to not participate.

**AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES**

Because information about you and your health is personal and private, it generally cannot be used in a research study without your written authorization. If you sign this consent form, you will provide that authorization. You do not have to sign this form. But if you do not, you will not be able to participate in this research study.

**What personal information will be used or disclosed?**

Your personal health information that may be used or disclosed in connection with this research study, will include, but is not limited to your body height, weight, gender, age, ethnicity/race, health history, answers to study questions, and health information that may be discernable from your mobile phone’s sensors. Your account information, study data and signed consent form may also be looked at and/or copied by designated personnel for regulatory and quality assurance.

**Who may use and disclose my data?** The study sponsor, investigators, study coordinators and study staff may use and disclose your personal information to do the research described above or as required by law.

**Who May Receive or Use the Information?** The parties listed in the preceding paragraph may disclose your health information as required by law to:

* The US National Institute of Health Office for Human Research Protection, Department of Health and Human Services Office of Civil Rights, and other agencies as required,
* Governmental agencies in other countries,
* [Name of] Institutional Review Board who watch over the safety, effectiveness and conduct of the research,
* Others, if the law requires

We will not disclose your identity in any reports about this study such as scientific publications or presentations.

**When will my authorization expire?** Your authorization for the use and/or disclosure of your health information will expire if you choose to withdraw from the research study.

**CONFIDENTIALITY**

We are committed to protect your privacy. Your identity will be kept as confidential as possible. Except as required by law, you will not be identified by name or by any other direct personal identifier.

To protect your privacy we will use a random code number instead of your name on all your data collected, analyzed, aggregated and released to researchers. Information about the code will be kept in a secure system. Researchers will have access to all the data collected in the study, but will be unable to easily map any particular data to the identities of the participants.

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. However, your identity will not be disclosed. Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

This study anticipates that your de-identified data will be placed in a “repository” - an online database – where qualified researchers can access it. Your data will be included into large, computational studies related to general health and wellness. There is always a risk that the database can be breached by hackers, or that experts in re-identification may attempt to reverse our processes. Total confidentiality cannot be guaranteed.

**COMPENSATION FOR INJURY**

THIS STUDY DOES NOT PROVIDE ANY COMPENSATION, HEALTH OR MEDICAL CARE TO PARTICIPANTS.

If you are injured as a direct result of your participation in this study, the Principal Investigator and the research study staff will assist you in obtaining appropriate medical treatment. Your medical insurance, managed care plan, or other benefits program will be billed for this treatment. You will be responsible for any associated co-payments or deductibles as required by your insurance.

If costs of care related to such an injury are not covered by your medical insurance, managed care plan or other benefits program, you may be responsible for these costs. The sponsor will not routinely pay charges that your insurance does not cover. No payment is routinely available from the study sponsor.

**VOLUNTARY PARTICIPATION AND WITHDRAWAL**

Your participation in this study is voluntary. You do not have to sign this consent form. But if you do not, you will not be able to participate in this research study. You may decide not to participate or you may leave the study at any time. Either of these decisions will not result in any penalty or loss of benefits to which you are entitled.

* You should not feel obligated to participate in this study.
* Your questions should be answered clearly and to your satisfaction.
* You have a right to download or transfer a copy of all of your study data.
* By agreeing to participate you do not waive any of your legal rights.

To withdraw from this study please contact the Study Principal Investigator Dr. [Insert Name] by email [Insert E-mail address] or call [Insert Phone Number].

If you withdraw from the study, we will stop collecting new data and delete your study data from the research servers, but some copies of your data that have already been distributed to qualified researchers will not be able to be destroyed or deleted.

The Study Director or the sponsor may also withdraw you from the study without your consent at any time for any reason, including if it is in your best interest, you do not consent to continue in the study after being told of changes in the research that may affect you, or if the study is cancelled.

**SOURCE OF FUNDING FOR THE STUDY**

The sponsor is [insert Name and weblink]

**QUESTIONS**

Contact Dr. [Insert Name] by email [Insert E-mail address] or call [Insert Phone Number] for any of the following reasons:

* If you have any questions about this study or your part in it, or
* If you have questions, concerns or complaints about the research

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

[Name, address, phone, email of IRB]

[IRB name] is a group of people who independently review research.

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

**USE OF DATA FOR FUTURE RESEARCH**

Before your data is released to the Synapse database, your personal information such as your name, e-mail, etc, will be removed. Your unique code identifier will be used in place of your name when your data is released onto Synapse. This de-identified study data will be made available on Synapse to registered researchers who have agreed to specific terms and conditions including using 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.

Although you can withdraw from the study at any time, you cannot withdraw the de-identified data that have already been distributed through research databases.

The main risk of donating your de-identified data to a centralized database is the potential loss of privacy and confidentiality in case of public disclosure due to unintended data breaches, including hacking or other activities outside of the procedures authorized by the study. In such a case, your data may be misused or used for unauthorized purposes by someone sufficiently skilled in data analysis to try to re-identify you. This risk is low.

**CONTACT INFORMATION**

If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask [Insert E-mail Address].

You should also contact us at any time if you feel you have been hurt by being a part of this study.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Western Institutional Review Board (WIRB) to speak to someone independent of the research team.

**CONSENT**

I have read about this research study (or it has been read to me). All my questions about the study and my part in it have been answered. I freely consent to be in this research study and I authorize the use and disclosure of my unnamed, coded data in electronic database(s) for use in research.

By signing this consent form I have not given up any of my legal rights.

YOUR SIGNATURE INDICATES THAT YOU HAVE READ AND UNDERSTAND THE ABOVE INFORMATION AND THAT YOU HAVE DECIDED TO PARTICIPATE BASED ON THE INFORMATION PROVIDED. A COPY OF THIS FORM WILL BE EMAILED TO YOU.

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Signature of Adult Participant Date