

Partners HealthCare System Research Consent Form

Subject Identification

General Template

Version Date: February 2010

Protocol Title: Smartphone app for management of type 2 diabetes

Principal Investigator: Stanley Shaw, MD PhD

Site Principal Investigator: Stanley Shaw, MD PhD

Description of Subject Population: Individuals 18 or over with type 2 diabetes or pre-diabetes who live in the United States

About this consent form

The following pages explain important information about the Glucosuccess app, and how the app is part of a research study.

Please read this form carefully.

Taking part in this research study is voluntary and is up to you. If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep. If you have any questions about the research or about this form, please ask us.

People who agree to take part in research studies are called “subjects”. This term will be used throughout this consent form. Partners HealthCare System is made up of Partners hospitals (including Massachusetts General Hospital, where this study originates), health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as “Partners”.

This study is sponsored by the Center for Assessment Technology and Continuous Health (CATCH) at Massachusetts General Hospital in Boston, MA.

Why is this research study being done?

Type 2 diabetes is the most common form of diabetes, affecting 25.8 million children and adults in the United States (8.3% of the population). Diet and exercise play an important role in type 2 diabetes, and also to decrease the rate of progression of pre-diabetes to type 2 diabetes. However, it is extremely difficult to start and maintain healthy changes in health behaviors such as a health diet, regular exercise, and taking all medications regularly.

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Today's mobile phones (especially smartphones) are becoming powerful platforms for communicating, computing and sensing. We are investigating ways to help people make use of the capabilities of their smart phones to improve their health, and more successfully manage their type 2 diabetes or pre-diabetes.

This study will make available to the public a free app (Glucosuccess) that users can install on their smartphones. The app will provide a variety of services to help users track their daily behaviors (such as activity/exercise, eating, logging blood glucose checks, and taking medications). Moreover, it will help them gain insight into their behavior patterns while attempting to encourage healthy activities. For instance, by analyzing the glucose, diet and exercise data, the app can give users personal insights into what food items and exercise patterns are most commonly associated with optimal levels of blood glucose.

At the same time, app data from user's smartphones will be stripped of any features that might be personally identifiable (such as name or email address), and each user's app data will be associated with only a randomized number. By analyzing this coded data across all app users, researchers can better understand the relationships between food, exercise, medications and blood glucose levels in large numbers of people with type 2 diabetes.

The goals of this research study are:

- Examine the feasibility of enrolling a large cohort of users who download and install the app, complete informed consent, and use the app. The app will be made available to the public via the Apple iTunes Store at no cost.
- Study whether displaying tracked health behaviors to users on their smartphones can help users improve their health behaviors, engage with the app over a sustained period of time, and keep their blood glucoses in the optimal range.
- Better understand the relationships between food, exercise, medications and blood glucose levels in large numbers of people with type 2 diabetes.

How long will I take part in this research study?

If you choose to participate, this study lasts for one year. After one year, your app data will no longer be analyzed as part of the study; however, you are free to continue using the app for the personal insights if you wish.

Entering information and responding to surveys should take on average a few minutes each day. Occasionally, tasks may take a little longer (e.g., a longer questionnaire).

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What will happen in this research study?

This study will ask you to perform tasks and respond to surveys.

When users first launch the app, they will be asked to review a series of phone screens that describe the study and the relevant risks and benefits (“informed consent” process) so they they can decide whether or not they wish to participate in the research study (participation in the research study is required in order to use the app); if they wish to participate, users will certify their agreement with the informed consent by entering their name and an email address (the email address is *only* used to enable users to receive a copy of the completed informed consent document – this document – in their email. Name and email will *not* be associated with any app data).

GlucoSuccess will ask you to:

- Answer survey questions about your health and health behaviors
- Log your finger-stick glucose values
- Log what you eat, as best as you can. We will ask you to log your meals using the free app “Lose It!”, which will provide nutritional information to GlucoSuccess.

The app sends occasional reminders to complete study activities.

GlucoSuccess uses the iPhone’s built-in accelerometer to passively keep track of physical activity (“passive” because this happens automatically and you do not need to enter any information). The app interprets accelerometer data as steps taken, or as different intensity levels of activity.

For these activity measures to be accurate, you should carry the iPhone on your person as much as possible (e.g., in your pocket, or clipped to your waist). For instance, if the iPhone is resting on a table when you go for a walk, it will not be able to detect this activity.

GlucoSuccess will collect some of its data on your health behaviors through short survey questions, such as:

- Over the past week, did you take some or all of your diabetes medications?
- What was your blood glucose this morning?
- Did you inspect your feet today?

Occasionally, there will also be longer surveys that evaluate aspects such as your quality of life, or your sleep duration and quality.

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For dietary information, GlucoSuccess will ask you to use the free “Lose It!” app to log what you eat for meals.

GlucoSuccess will also ask about some information that requires a brief task away from the iPhone, such as:

- Checking and entering your finger-stick blood glucose values
- Your weight
- Your waist circumference (occasionally)

GlucoSuccess provides personalized feedback in the form of graphs and text on the smartphone to display your progress, and provide insights into your health behaviors. The app summarizes data about how food or exercise patterns are associated with your glucose values. These insights may help you understand your health behaviors better, and help you manage your type 2 diabetes. Viewing the graphs and text is optional but may be useful or interesting to you.

In your Profile within GlucoSuccess, you can set reminders for yourself to complete app activities. In general, more data entered in the app results in more accurate and informative insights.

What are the risks and possible discomforts from being in this research study?

There are possible risks, discomforts and inconveniences associated with any research study. This study does not involve testing any new drugs or therapies, so we do not expect any medical side effects from participating.

The app is not designed to give medical advice, nor make suggestions related to diabetes treatment or medications.

The primary concern associated with this study is privacy risk. For instance, if someone sees the app on your phone screen, they may guess that you have diabetes.

You may feel inconvenienced by having to enter information into the app, or seeing the reminders or messages that are sent by the app.

Any information you provide is completely up to you. You can decline to answer survey questions or participate in the app’s tasks. If a survey question makes you feel uncomfortable, you are free to leave questions blank.

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As with any smartphone app, use your common sense and follow prevailing laws about when and where you use your iPhone. Just as you would not text while driving, do not interact with the app while driving or doing any other activities which could result in injury. You can always wait until you are in a safe place to perform any app-related tasks.

Please see the sections on “Protecting Your Privacy” to learn more. Study participation may involve risks that are not known at this time.

What are the possible benefits from being in this research study?

One of the biggest challenges for people with type 2 diabetes is the difficulty of tracking their finger-stick blood glucose values, diet, exercise and other health behaviors. GlucoSuccess may help by streamlining these daily tracking tasks.

GlucoSuccess analyzes your data to provide personalized insights and feedback to help you understand how your health behaviors (e.g., diet, physical activity) can influence your glucose values. This may help you manage your type 2 diabetes.

More generally, patients with type 2 diabetes may ultimately benefit from this research, because GlucoSuccess and its research study will create an unprecedented crowd-sourced database of health behaviors and glucose values from people like you. Studying all this real-world data will help researchers better understand the relationships between diet, exercise, and glucose control in real-world people with type 2 diabetes. (Traditionally, these studies are done by asking people to fill out very long questionnaires on paper every few years.) It will also help explore how the iPhone or smartphones can enable new kinds of clinical research.

By combining a personal app and a research study, GlucoSuccess will help explore how the iPhone can enable new kinds of clinical research.

This study may also help researchers better understand what strategies in smartphone apps are well received among users, encourage more durable use of the app, and are most effective in reinforcing healthy behaviors.

Can I still get medical care with Partners if I don't take part in this research study, or if I stop taking part?

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Yes. Regardless of where you get your medical care, your decision to participate or not will not change the medical care you get at a Partners hospital or anywhere else. Taking part in this research study is up to you.

What should I do if I want to stop taking part in the study?

If you start the research study but later wish to drop out, simply use the “Leave Study” link in the Profile (this action cannot be undone), or contact the study investigators through the app. You may choose to leave the study at any time. Your decision will not result in any penalty or affect your medical care through your usual physicians or providers. Afterwards, you are free to delete the app from your smartphone.

The study investigators may also withdraw you from the study without your consent at any time for any reason, including if the study is cancelled.

Will I be paid to take part in this research study?

There is no compensation or payment for taking part in this study.

What will I have to pay for if I take part in this research study?

Participation in this study does not require you to change anything related to your iPhone account or data plan. The app can use either an existing mobile data plan or WiFi connections; you may configure the app to use only WiFi connections if you wish to limit impact on your data usage.

What happens if I am injured as a result of taking part in this research study?

This study does not provide any health or medical care to participants, or compensation. Because this is a nationwide study that does not provide any health care to users, in the unlikely event that you are injured as a direct result of your participation in this study, users are advised to first seek medical treatment locally. The study investigators can also be contacted through the app or through the information below to assist in obtaining appropriate medical treatment. Your medical insurance, managed care plan, other benefits program, or other third parties, if appropriate, 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

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covered by your medical insurance or benefits program, you may be responsible for these costs. The study sponsors will not pay charges that your insurance does not cover. Neither the offer to provide medical assistance or any actual provision of medical services shall be construed as an admission of negligence or acceptance of liability.

Unanticipated injuries sometime occur in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this study, contact study investigators through the app or through the information below as soon as possible.

If I have questions or concerns about this research study, whom can I call?

If you have any questions about the study, your participation in the study, or concerns or complaints about the research, a member of our research team is available to communicate with you. You can contact the study investigator team through the app, or at the following email:

Email: GlucoSuccess.help@partners.org

You can also contact the principal investigator as below:

Dr. Stanley Shaw

Massachusetts General Hospital

Phone: 617-643-6124

If you'd like to speak to someone not involved in this research about your rights as a research subject, or any concerns or complaints you may have about the research, contact the Partners Human Research Committee at:

Partners Human Research Committee Office

Phone: 617-424-4100

The Partners Human Research Committee Office are independent of the study investigators and are not directly involved in this research study.

If I take part in this research study, how will you protect my privacy?

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We are committed to protecting your privacy. We take several steps to protect your privacy and the privacy of your app data.

For security, GlucoSuccess requires that your iPhone be protected either by a passcode or the Apple Touch ID fingerprint sensor. This ensures that only you can enter and use the app. One potential loss of privacy would be if someone sees GlucoSuccess on your iPhone and then suspects that you have diabetes.

To certify that you consent to participate in the study, the app asks you to enter your name and an email address. This allows study investigators to have a record of who participates in the study, and to email a copy of the signed consent form to you.

Your name and email are *only* used for the consent process, and are not associated with data collected from the app. Your identity (name, email) will be separated from your app data and kept as confidential as possible. Your app data will be associated only with a randomized study code that bears no relation to any identifiable information. This random code is stored completely separately from any personally identifying information. Only select individuals that are part of the research study will know the identities of people who participate in the study. These steps ensure that researchers analyzing the coded study data will not be able to connect it to any individual user.

Whenever app data is transferred to a research study computer, it will be encrypted so that others cannot interpret the data or associate it back to you.

Encrypted app data (stripped of personal identifiers, and associated only with a random code) will be sent to secure data servers used for the GlucoSuccess research study that are maintained by Sage Bionetworks (<http://sagebase.org>). Sage is a non-profit organization dedicated to the advancement of science by making available to the scientific community secure computing and database architectures. Sage uses Amazon Web Services (AWS) Cloud enhanced computational capacity to securely store GlucoSuccess data. AWS poses no additional security concerns over existing traditional local computer cluster environments. All communications are encrypted when transmitting data or commands to and from the AWS. (Further information about data security within AWS can be found at <https://aws.amazon.com/security/#features>)

Study investigators chose Sage Bionetworks for this important responsibility because they are a world leader in the secure storage and protection of sensitive research data. They have a proven track record of safeguarding and managing potentially sensitive biomedical data in accordance with regulations that govern human research and medical information (e.g., regulations mandated by Institutional Review Boards [IRB] and the Health Information Portability and Accountability Act [HIPAA]).

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Study investigators will analyze coded app data from everyone who agrees to participate in the GlucoSuccess study, but they will be unable to connect it back to any individual user.

The results of this research may be published in a scientific or medical research journal, or presented at a medical research conference, so that others can learn from this study. Results will never be publicly presented in a way that would allow data to be associated with individual users.

After this study is completed, other researchers who are not part of the original study may request access to the coded study data (already stripped of personal identifiers such as your name or email), so that it can be analyzed in a new way to benefit medical research, or help guide development of future apps. Those requesting data must agree to use the data for research purposes responsibly and ethically, and in accordance with applicable regulations. Qualified researchers must agree to not attempt to re-identify any individuals. Criteria for qualified researchers will be set by the GlucoSuccess investigators and representatives of Sage Bionetworks. Such criteria may include, but are not restricted to, being associated with an accredited research institution or not-for profit research institution, or submitting proof of IRB approval for their intended data use. Data sharing requests will be reviewed by a group of GlucoSuccess study investigators and representatives of Sage Bionetworks. Sage Bionetworks will have no oversight over future research conducted with coded study data.

During the consent process, you will have the option to choose whether you agree to:

- (i) share your coded study data with qualified researchers (as described in the above paragraph), or
- (ii) share your coded study data only with the GlucoSuccess team and its research partners; if you choose this option, your coded study data will be accessible only to the GlucoSuccess team and its research partners, and will not be made available to other outside researchers.

Your choice will not affect your ability to participate in the GlucoSuccess study.

Study data will never be sold to any third party.

If required by law, your data (study data and account information), and the signed consent form may be disclosed to:

- The US National Institute of Health, Department of Health and Human Services agencies, Office for Human Research Protection, and other agencies as required,
- the Institutional Review Board at Massachusetts General Hospital that monitors the safety, and conduct of human research,
- Others, if the law requires

We are required by the Health Insurance Portability and Accountability Act (HIPAA) to protect the privacy of health information obtained for research. This is an abbreviated notice, and does

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not describe all details of this requirement (see Partners Privacy Notice*). During this study, identifiable information about you or your health will be collected and shared with the researchers conducting the research. In general, under federal law, identifiable health information is private. However, there are exceptions to this rule. In some cases, others may see your identifiable health information for purposes of research oversight, quality control, public health and safety, or law enforcement. We share your health information only when we must, and we ask anyone who receives it from us to protect your privacy. *Partners HealthCare Notice for Use and Sharing of Protected Health Information

http://www.partners.org/Assets/Documents/Notices/Partners_Privacy_Policy_English.pdf

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read about this research study and this consent form, including potential risks and benefits (if any).
- I have had the opportunity to ask questions about the study and my part in it
- I understand the information presented to me
- Data sharing choice: You selected:
 - ☐ **Share broadly with qualified researchers**
 - ☐ **Share with the GlucoSuccess team and its partners only**

Signature of Subject:

I give my consent to take part in this research study and agree to allow my unnamed, coded data to be used and shared as described above for use in the research.

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.

Subject

Date/Time

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