

# Partners HealthCare System Research Consent Form

Subject Identification
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General Template  
Version Date: August 2016

Protocol Title: Development of the smoking cessation app "Smiling instead of Smoking"

Principal Investigator: Bettina B. Hoepfner, Ph.D.

Site Principal Investigator: n/a

Description of Subject Population: non-daily smokers

## About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. 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, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as "Partners."

If you have any questions about the research or about this form, please ask us. Taking part in this research study 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.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, 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 Web site at any time.

## Why is this research study being done?

The purpose of this research study is to develop a smartphone app to support non-daily smokers in quitting smoking. Based on a content analysis of existing apps, and based on the extant literature on smoking cessation, we have developed a smoking cessation app that we think could be helpful to non-daily smokers seeking to quit smoking. We are asking you to participate in this study, because we would like you try out our app and tell us about your experience using this app. This study is our first test of this app, and we hope to work closely with you to shape the next version of this app. In total, we are planning on working with 346 participants in a series of

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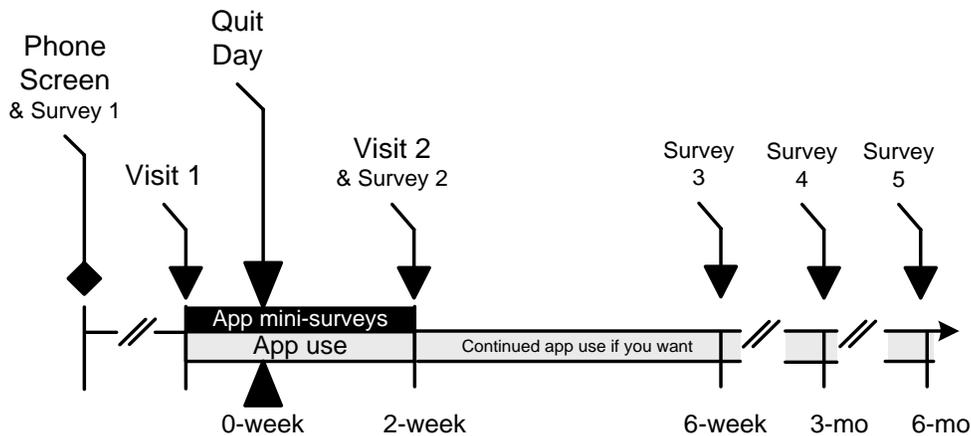
three studies. This is the first study in this series, and will involve 30 participants. The American Cancer Society (ACS) is paying for the study to be done.

## How long will I take part in this research study?

It will take you about 6 months to complete this research study, where most of the study activities will occur within the first three weeks. In total, we will ask you to make 2 study visits to our office here at MGH.

## What will happen in this research study?

Your participation in this study consists of making an attempt to quit smoking while using our smoking cessation app. Our goal is to capture your experience while you do so through four types of interactions: (1) structured feedback sessions with our study staff, (2) surveys, (3) use of our smoking cessation app, and (4) biochemical verification of smoking status.



Timeline of Your Study Participation

Your **office visits** are designed to accomplish the following:

1. Visit 1 – Baseline and set-up (90 min): learn about the study, engage in a structured feedback session with a member of our study staff about smoking cessation apps, download, install and start using our app on your smartphone, including setting your quit day within the app, and talk with study staff about your initial impressions.

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2. Visit 2 – 2 weeks post your quit day (60 min): provide a saliva sample to verify your smoking status, and engage in another structured feedback session with study staff, this time about your experience in using the app during the past 3 weeks.

We will also ask you to complete **online surveys** on five dates:

1. (20-30 minutes) 1 week prior to your smoking quit day – you already completed this survey as part of your screening process
2. (20-30 minutes) 2 weeks post your smoking quit day
3. (15-20 minutes) 6 weeks post your smoking quit day
4. (15-20 minutes) 3 months post your smoking quit day
5. (15-20 minutes) 6 months post your smoking quit day

(If you would like to, you can come to our offices on these dates and complete the surveys using one of our computers.)

Finally, we will ask you to **use our smoking cessation app**:

- For the week prior to your quit day
- For the 2 weeks following your quit day
- As long after that as you want to

Our app is interactive and proactive, and includes both daily and weekly exercises to help you quit smoking. There are also on-demand features, that are designed to give you support in the moment you need it the most. It is possible that you may find some of these features too burdensome, and that is totally ok. The app is designed for you to pick-and-choose what you want to work with. In our structured feedback sessions, we will ask you about what you liked, what you didn't like, and what you wish the app would do. We are very interested in what you think!

Please note that your usage of the app will be recorded. That means that all the responses you provide to questions asked within the app, and your clicking of buttons within the app is recorded and stored in an encrypted database. Only study staff and our hired programmers will have access to these data. Only study staff will be able to link these data to your identifying information. Based on these data, we will generate an app usage report for you for Visit 2 to guide our discussion of what you used, what you didn't use and why.

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

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As part of this study, you will be attempting to quit smoking. Consequently, you may experience nicotine craving and withdrawal symptoms. You may also experience subjective discomfort from answering questions or from providing biological samples (i.e., saliva). Note though that you are free not to answer any question you do not want to.

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

By participating in this research you may benefit from the commitment to quitting smoking that is encouraged by the study, and the smoking cessation support you will receive via our smoking cessation app. Both the provided app and your commitment to quit may help you to quit and to stay quit.

Your participation will also help inform the next version of this app, so that we will hopefully be able to produce a better app to help non-daily smokers like you quit smoking for good.

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

Yes. Your decision won't change the medical care you get within Partners now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. We will tell you if we learn new information that could make you change your mind about taking part in this research study.

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

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

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

To compensate you for the time it takes to complete assessments, we will pay you up to a total of \$434:

	Structured feedback sessions with staff	Surveys (online after Visit 2)	App mini- surveys
Enrollment	\$75	\$40 *	
2-week	\$75	\$40 *	Up to \$84
6-week		\$40 *	
3-month		\$40 *	
6-month		\$40 *	
<b>Total:</b>	<b>up to \$434</b>		

\* minimum of \$10; \$40 if no check items are answered incorrectly

Your payments will depend on your compliance with the study procedures. If you do not participate in the structured feedback session, you will not be paid for it. If you do not complete a survey, you will not be paid for it. As we explained during your phone screen interview, there will also be 3-5 survey questions scattered throughout the survey for which we ask you to respond in a specific fashion (we call these questions “check-items”). For example, a question may read “Please answer “not at all confident”.”). You will need to click the bubble or move the slider to indicate “not at all confident” to answer this question correctly. We are inserting these check-items in the survey to make sure you are reading the survey carefully, and are comfortable with using the buttons and sliders to indicate your responses. If you answer these check items incorrectly, you will receive \$10 less per incorrectly answered check item. At a minimum, you will receive \$10 per survey you completed. The app mini-surveys will occur daily. During your first three weeks of use of the app, we will pay you \$1 for every mini-survey you complete. Each day, there are 3 mini-surveys that occur at random times during the day. Every once in a while, there is a mini-survey in response to you reporting smoking a cigarette. Please note that the app will continue to ask you to complete mini-surveys after the initial three weeks, but you will only be paid for mini-surveys completed during the first three weeks. It is completely up to you if you want to continue completing mini-surveys after payment for them stops. Some smokers find it helpful to keep reporting about their thoughts and feelings in this fashion, and the app does provide feedback based on this information.

Payment will be by check. We will mail you each check to your mailing address after you complete study activities at enrollment, and 2-week, 6-week, 3-month, and 6-month follow-ups of your quit day. Please allow 10 business days for the check to arrive.

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

There are no costs to you to take part in this study.

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

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen 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 research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the next section of this consent form.

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

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

If you have questions about the scheduling of appointments, study visits, troubleshooting the smoking cessation app or other general inquiries, please call the study staff at 617-724-3129, or email us at [SiS@mg.harvard.edu](mailto:SiS@mg.harvard.edu).

If you have questions or concerns that you'd like to discuss with the person in charge of this study, please contact Dr. Bettina Hoepfner, Ph.D. You can call her at 617-643-1988 Monday-Friday, 9am-5pm. Feel free to leave a message at this number 24/7 and Dr. Hoepfner will return your call.

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 857-282-1900.

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You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research

Also, if you feel pressured to take part in this research study, or to continue with it, they want to know and can help.

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

During this research, identifiable information about your health will be collected. In the rest of this section, we refer to this information simply as “health information.” In general, under federal law, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use, and share your health information for research and why they may need to do so.

### **In this study, we may collect health information about you from:**

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

### **Who may see, use, and share your identifiable health information and why they may need to do so:**

- Partners research staff involved in this study
- The sponsor(s) of this study, and the people or groups it hires to help perform this research
- Other researchers and medical centers that are part of this study and their ethics boards
- A group that oversees the data (study information) and safety of this research
- Non-research staff within Partners who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- The Partners ethics board that oversees the research and the Partners research quality improvement programs.
- People from organizations that provide independent accreditation and oversight of hospitals and research
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers

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- Federal and state agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and other US or foreign government bodies that oversee or review research)
- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)
- Other:

Some people or groups who get your health information might not have to follow the same privacy rules that we follow and might use or share your health information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your health information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your health information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. The sponsor has agreed that it will not contact you without your permission and will not use or share your information for any mailing or marketing list. However, once your information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifying information **will not** be used for these purposes without your specific permission.

## Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your health information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others.



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Consent Form Version: 5-18-2017