COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH STUDY

YALE UNIVERSITY SCHOOL OF MEDICINE

Study Title: Smartband mindfulness study

Principal Investigator (the person who is responsible for this research): Kathleen A Garrison, 1 Church Street #730, New Haven CT 06510
Phone Number: (203) 737-6232

Research Study Summary:

- We are asking you to join a research study.
- The purpose of this research study is to test the feasibility of using a smartband to automatically monitor and detect smoking and deliver real time mindfulness interventions by smartphone app to help reduce smoking.
- Participating in this study will take 60 days total.
- Study procedures will include:
    1) Setting a quit date for 30 days from when you start the study.
    2) Zoom/Online Training– We will take you through step-by-step instructions (provided on a zoom call/online) to set up and use your smartband.
    3) Wearing a smartband – We will ask that you wear a smartband on the hand you use to smoke, daily during waking hours for 60 days.
    4) Using a smartphone app – The smartband will work together with a smartphone app to deliver the intervention as described below.
    5) Tracking smoking – For the first 21 days, you will be asked to wear a smartband that will monitor and detect smoking and notify you in real time each time you smoke.
    6) Online mindfulness training – Next, we will ask you to take part in a short online mindfulness training to introduce you to how mindfulness may help you quit smoking.
    7) Mindful smoking – For the next 7 days, each time smoking is detected by your smartband it will trigger a short (2 min) “mindful smoking” exercise to bring awareness to how smoking makes you feel. We will ask you to continue to wear the smartband during this time.
    8) “RAIN” – For 30 days after your quit date, at the times you typically smoke, we will automatically send you another short (2 min) mindfulness exercise (“RAIN”) to help you cope with cravings rather than smoke. We will ask you to continue to wear the smartband during this time.
    9) Ratings – When you complete each mindful smoking and RAIN exercise, the smartphone app will ask a few questions about whether or not you found the exercises helpful and timely, and about how you are feeling.
    10) Surveys – At four time points across the 60 days, we will ask you to take an online study survey. As part of the final study survey, you may be asked to provide a biochemical measure of your cigarette smoking, either from your breath or saliva. This is described in more detail below.

11) Optional debriefing – At the end of the study, we may ask you to take part in an optional zoom/phone call, during which we will ask you about your experiences during the study.

- No in-person visits are required. All study procedures will take place online and by smartphone/smartband.
- There are some risks from participating in this study. These include risks to privacy and risks and inconveniences to wearing a smartband and completing study exercises and surveys. These are described in more detail below.
- The study may help you quit smoking. We expect that the results of the study will benefit science and others by increasing our knowledge about technology-based treatments for smoking.
- There are other choices available to you outside of this research. You can use quit smoking medications, therapy, another smartphone app, or take part in another study.
- Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You can also change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.
- If you are interested in learning more about the study, please continue reading, or have someone read to you, the rest of this document. Take as much time as you need before you make your decision. Ask the study staff questions about anything you do not understand. Once you understand the study, we will ask you if you wish to participate; if so, you will have to click "I accept" at the end of this form.

Why is this study being offered to me?

We are asking you to take part in a research study because **you are at least 18 years old and smoke cigarettes daily but do not use e-cigarettes**. We are looking for **110** participants to be part of this research study.

Who is paying for the study?

Funding is provided by the National Institutes of Health, National Center for Complementary and Integrative Health.

What is the study about?

The purpose of this study is to test the feasibility of a smartband/smartphone based mindfulness intervention to help people quit smoking. This means testing whether the intervention is delivered to you correctly, whether you are able to follow the study instructions, and whether you find the intervention acceptable and helpful.

What are you asking me to do and how long will it take?

If you agree to take part in this study, this is what will happen:

1. **Shipping the smartband:** After you click the box indicating you consent to the study, we will ask for your shipping information to ship you a smartband.
2. **Zoom/Online Training:** When you receive your smartband, we will provide you with step-by-step instructions on how to set up and get started using your smartband, via zoom/online.
3. **Baseline survey:** When you receive your smartband, you will also be directed to the online baseline study survey. This survey will ask about: your demographics (age, race/ethnicity, sex/gender, etc.), smoking (how much you smoke per day, whether you are taking any quit smoking medications, whether or not you are feeling withdrawal),

how you are relating to your everyday experiences, and some questions about the technology used in this study (smartband, smartphone app).

4. **Wear a smartband:** We will ask you to wear a smartband on the hand you use for smoking for 60 days. We will ask you to wear the smartband from the time you wake up until the time you go to sleep each day, for a minimum of 12 waking hours per day. Throughout the study, we will automatically monitor whether or not you are wearing the smartband, and will send you a text reminder if you forget to wear the smartband. The smartband will automatically monitor and detect when you smoke. This is described in more detail below. The smartband will be provided to you for free, and will be sent to you in the mail. Due to limited equipment, we are not able to provide replacement smartbands in the event that your device is lost, broken, or stolen.
5. **Set a quit date:** We will ask you to set a quit date 30 days from when you start the study (i.e., 30 days from when you start wearing your smartband).
6. **Tracking smoking:** For the first 21 days, you will be asked to wear a smartband that will automatically monitor and detect when you smoke, and notify you in real time each time you smoke. You will be asked to smoke as much or as little as you like during this time. When the smartband detects that you have smoked, the smartphone app will ask you to confirm or deny smoking. If you smoke and the smartband does not detect it, you can also report this on your app.
7. **Online mindfulness training:** Next, we will provide you with brief mindfulness training (less than 15 min) that will introduce you to how mindfulness can help you quit smoking, and will review the study procedures, including introducing you to the mindfulness exercises described next.
8. **Mindful smoking:** For the next 7 days, each time smoking is detected by your smartband it will trigger a short “mindful smoking” exercise to bring awareness to how smoking makes you feel in the present moment. This is a short 2-minute audio exercise that will also have subtitles. After each mindful smoking exercise, the app may ask you a few questions about whether or not the exercise was helpful and timely, and about how you are feeling. We’ll monitor whether or not you are completing the mindful smoking exercise, and will send you a reminder to encourage you to complete them.
9. **“RAIN:”** For 30 days after your quit date, at the times you typically smoke, we will automatically send you a mindfulness exercise called “RAIN” that will help you cope with cravings rather than smoke. The app will first ask you a few questions about how you are feeling. Next it will trigger the RAIN exercise, a short 2-minute audio exercise that will also have subtitles. After each exercise, the app may ask you a few more questions about whether or not the exercise was helpful and timely, and about how you are feeling. You will be asked to continue to wear the smartband for this 30 day period. If you do relapse (smoke), the smartband will automatically send you the mindful smoking exercise described above. We’ll monitor whether or not you are completing the RAIN exercise, and will send you reminder to encourage you to complete them.
10. **Surveys:** We will ask you to complete four online study surveys at the following times: **(1)** baseline survey (described above), **(2)** after you have completed 21 days of tracking smoking, **(3)** after you have completed 7 days of mindful smoking (i.e., on your quit date), and **(4)** after you have completed 30 days of RAIN (i.e., at the end of the study). These surveys will ask about your smoking, withdrawal, daily experiences and your experiences using the technology (smartband, smartphone app). These surveys will also provide you with more detailed information and instructions about each next step of the study**.**

11. **Measure of smoking:** As part of the end of study survey, you may be asked to provide a measure of how much you are smoking, measured either from your breath or saliva. A measurement kit will be shipped to you by mail with instructions. You will follow the instructions to provide this measure (breath/saliva) and email or text a video of you completing this process to a researcher. You can take and send this video using your smartphone. You may be required to return the measurement kit by mail using pre-paid postage. You may be randomly asked to provide this measurement.
12. **Optional debriefing**: At the end of the study, we may ask you to take part in an optional zoom/phone call, during which we will ask you about your experiences during the study.

What are the risks and discomforts of participating?

Common

1. **Smartband, Rating Scales and Surveys:** Wearing the smartband and answering rating scales and surveys are noninvasive and should add no risk. The major disadvantages are the possible minor discomfort of wearing the smartband, the time taken to complete the exercises, ratings and surveys, and possible breach of confidentiality. Careful efforts to maintain your confidentiality will be made.
2. **Nicotine withdrawal:** You may experience nicotine withdrawal such as craving cigarettes, mild anxiety, restlessness, irritability, difficulty concentrating, loss of energy and excessive hunger. These are normal symptoms that people get when they do not smoke, and they can be uncomfortable but are not life threatening. They are minimal compared to the health risks of continued smoking.

How will I know about new risks or important information about the study?

We will tell you if we learn any new information that could change your mind about taking part in this study.

How can the study possibly benefit me?

You will receive a free smartband (for the duration of the study) and smartphone application and exercises which may help you quit smoking.

How can the study possibly benefit other people?

The benefits to science and other people may include a better understanding of technology-based mindfulness interventions for smoking.

Are there any costs to participation?

You will not have to pay for taking part in this study. If you use the app while outside of wifi you may incur charges related to data use from your cell phone provider.

Will I be paid for participation?

You will be paid for taking part in this study. You will be paid $10 upon completion of the zoom/online training, $20 upon completion of the second study survey, and $10 upon completion of the third study survey. At the end of the study, you will be paid $1 per day for each day of the 60-day study that you have worn your smartband for 12 waking hours (up to $60). At the end of the study, you will also be paid $10 for the end of study survey, and a $50 bonus payment if you have completed all parts of the study. **Total study payment will be up to $160** (up to $40 paid upon each survey completion, up to $120 paid at the end of the study). Please note that all study equipment (smartband, smoking measurement kit, if applicable) must

be returned before the final study payment. Finally, you may be invited to take part in an optional debriefing at the end of the study, for which you will be paid an additional $10. Study payments will be by amazon.com gift card. We will have to share your email address with Amazon in order to send you the electronic gift card. You are responsible for paying state, federal, or other taxes for the payments you receive for being in this study. Taxes are not withheld from your payments.

What are my choices if I decide not to take part in this study?

Instead of participating in this study, you have some other choices.
You could:

- Get treatment without being in a study. The following treatments are available over the counter at your local pharmacy: nicotine replacement therapy including the nicotine lozenges, nicotine chewing gum or the nicotine patch. Nicotine nasal spray, the nicotine inhaler, bupropion, and varenicline are available by prescription to aid in stopping smoking. There are also group counseling treatments available for stopping smoking. If you would like to pursue an alternative treatment rather than participate in this study, please let us know and we will help you arrange these services.
- Take part in another study.

How will you keep my data safe and private?

We will keep information we collect about you confidential. We will share it with others if you agree to it or when we have to do it because U.S. or State law requires it. For example, we will tell somebody if you we learn that you are hurting a child or an older person.

Your name or other personal information that identifies you will not appear on the study materials. Instead, you will be assigned a study number that will be used for all data. The document linking your name and study number will be kept on a password protected secure computer that is only accessible to approved members of the study team.

When we publish the results of the research or talk about it in conferences, we will not use your name. If we want to use your name, we would ask you for your permission.

We will also share information about you with other researchers for future research but we will not use your name or other identifiers. We will not ask you for any additional permission.

All identifiers might be removed from the identifiable private information and, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your parent.

What Information Will You Collect About Me in this Study?

The information we are asking to use and share is called “Protected Health Information.” It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission. If you want, we can give you more information about the Privacy Rule. Also, if you have any questions about the Privacy Rule and your rights, you can speak to Yale Privacy Officer at 203-432-5919.

The specific information about you and your health that we will collect, use, and share includes:

- Research study records
- Records about phone calls made as part of this research
- Information obtained during this research regarding
    - Smoking
    - Ratings
    - Questionnaires
    - Records about the smartband and smartphone app

How will you use and share my information?

We will use your information to conduct the study described in this consent form.
We may share your information with:

- The U.S. Department of Health and Human Services (DHHS) agencies
- The funding agency: National Institutes of Health, National Center for Complementary and Integrative Health
- Representatives from Yale University, the Yale Human Research Protection Program and the Institutional Review Board (the committee that reviews, approves, and monitors research on human participants), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.
- The manufacturer of the smartband and smartphone app, Somatix, Inc.
- Laboratories and other individuals and organizations that analyze your health information in connection with this study, according to the study plan.
- Those individuals at Yale who are responsible for the financial oversight of research including billings and payments
- Co-Investigators and other investigators
- Study Coordinator and Members of the Research Team
- Data and Safety Monitoring Boards and others authorized to monitor the conduct of the Study

We will do our best to make sure your information stays private. But, if we share information with people who do not have to follow the Privacy Rule, your information will no longer be protected by the Privacy Rule. Let us know if you have questions about this. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

Why must I click the check box to indicate my consent?

By checking that you agree to participate, you will allow researchers to use and disclose your information described above for this research study. This is to ensure that the information related to this research is available to all parties who may need it for research purposes.

What if I change my mind?

The authorization to use and disclose your health information collected during your participation in this study will never expire. However, you may withdraw or take away your permission at any time. You may withdraw your permission by telling the study staff or by writing to **Dr. Kathleen Garrison, 1 Church Street #730 at Yale University, New Haven, CT 06510**.

If you withdraw your permission, you will not be able to stay in this study but the care you get from your doctor outside this study will not change. No new health information identifying you will be gathered after the date you withdraw. Information that has already been collected may

still be used and given to others until the end of the research study to insure the integrity of the study and/or study oversight.

What if I want to refuse or end participation before the study is over?

Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

We would still treat you with standard therapy or, at your request, refer you to a clinic or doctor who can offer this treatment. Not participating or withdrawing later will not harm your relationship with your own doctors or with this institution.

To withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want to take part.

The researchers may withdraw you from participating in the research if necessary. **For example, if you do not wear your smartband as instructed.**

If you leave the study for any reason, the study team may ask if you wish to take part in the follow up portion of the study. If you agree to continue with the follow up portion of the study, information about your health will continue to be collected as described above. The study team will discuss with you the different withdrawal options.

What will happen with my data if I stop participating?

If you withdraw from the study, deidentified data obtained as part of the research will be unable to be withdrawn.

Who should I contact if I have questions?

Please feel free to ask about anything you don't understand.

If you have questions later or if you have a research-related problem, you can call the Principal Investigator, **Dr. Kathleen Garrison, at 203-737-6232**.

If you have questions about your rights as a research participant, or you have complaints about this research, you call the Yale Institutional Review Boards at (203) 785-4688 or email hrpp@yale.edu.

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.

Authorization and Permission

I have read (or someone has read to me) this form and have decided to participate in the project described above. Its general purposes, the particulars of my involvement and possible hazards and inconveniences have been explained to my satisfaction. Clicking the check box also indicates that I have received a copy of this permission form.

By signing this form, I give permission to the researchers to use [and give out] information about me for the purposes described in this form. By refusing to give permission, I understand that I will not be able to be in this research.

We will give you a copy of this form.

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator, Dr. Kathleen A. Garrison at (203) 737-6232.

If after you have clicked the check box to indicate your consent you have any questions about your privacy rights, please contact the Yale Privacy Officer at (203) 432-5919.

If you would like to talk with someone other than the researchers to discuss problems, concerns, and questions you may have concerning this research, or to discuss your rights as a research subject, you may contact the Yale Human Investigation Committee at (203) 785-4688.