Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

TITLE OF RESEARCH: **Development and Testing of a Depression-Specific Behavioral Activation Mobile App Paired with Nicotine Replacement Therapy Sampling for Smoking Cessation Treatment Via Primary Care (RCT)**

Concise Summary

You are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to take part. The purpose of this study is to evaluate the benefits of different resources that may help cigarette smokers quit smoking.

If you agree to participate, you will be randomly assigned into one of two groups. If you are assigned to group A you will receive educational material on quitting smoking. If you are assigned to Group B, you will be asked to utilize Goal2Quit mobile application regularly, at least once per day; you will also receive a sample of Nicotine Replacement Therapy (NRT). Approximately 100 participants will be invited to use the Goal2Quit app and receive the two-week NRT sampling and the remaining 50 participants will not.

Participants in both groups will be asked to complete questionnaire measures weekly, including today, for a total of 8 weeks. You will be asked to complete a final set of questionnaires 12 weeks following your study enrollment. Participation in this study will last about 12 weeks, beginning today. Questionnaires will assess cigarette smoking, mood, and other related constructs.

Participation in this study may help you to quit smoking, but that cannot be guaranteed. The greatest risks of this study include frustration, side effects that you may experience if you are provided the Nicotine Replacement Therapy (e.g., nicotine patch and lozenge) and decide to use it, and potential loss of confidentiality.

If you are interested in learning more about this study, please continue to read below.

A. PURPOSE OF THE RESEARCH

You are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to take part. Please read this consent document carefully and take your time deciding whether you would like to participate. The purpose of this study is to evaluate the benefits of different resources that may help cigarette smokers quit smoking. This information

will help us to improve treatment resources, including Goal2Quit, a mobile application for cigarette smokers. You are being asked to participate in this study because you were identified as being a current smoker and having symptoms of low mood during your initial screening. The investigator in charge of this study is Dr. Jennifer Dahne. The study is sponsored by a grant from the National Institutes of Health (NIH). Portions of Dr. Dahne's and her research team's salaries will be paid by this grant. The study is being done at one site. Approximately 150 people will take part in this phase of the study, all at the Medical University of South Carolina (MUSC).

B. PROCEDURES

Study participation is voluntary. You will note whether you agree to be in this study at the end of this form, which will occur prior to any study procedures. You have already completed preliminary screening for eligibility. Agreeing to be in this study will allow the research team to access and utilize for research purposes the information you provided during your screening.

If you agree to participate in this project, the following will happen:

1. You will be randomly assigned into one of two conditions. You will not have the opportunity to choose which condition you receive.
2. Approximately 50 participants will be assigned to Group A (the *control condition*). If you are randomly assigned to Group A, you will receive:
   A. Educational material on quitting smoking
   B. A handout detailing subsequent assessments and payment schedule for assessments
3. Approximately 100 participants will be assigned to Group B (the *experimental condition*). If you are randomly assigned to Group B, you will receive:
   A. A code to download a mobile app called Goal2Quit and assistance from a member of the research team to download Goal2Quit
   B. A two-week "starter kit" sample of nicotine replacement therapy (NRT; 14mg patch and 4mg lozenge)
   C. Educational material suggesting you utilize Goal2Quit regularly, at least daily, and the provided NRT in an attempt to quit smoking
   D. A handout detailing subsequent assessments and payment schedule for assessments
   E. Educational material on quitting smoking

   If you are assigned to Group B, you will be asked to utilize Goal2Quit regularly, at least once per day, as well as the NRT sample to attempt to quit smoking.
4. You will be asked to complete questionnaire measures weekly, including today, for a total of 8 weeks. You will be asked to complete a final set of questionnaires 12 weeks following your study enrollment. You will be emailed and/or texted a link to complete these questionnaires via MUSC's REDCap (MUSC secure server where research information is stored) system and we request that you complete the questionnaires within 24 hours of receiving the link. You will be compensated for completion of the questionnaires if they are completed within 72 hours of receiving the link. Questionnaires

will assess cigarette smoking, mood, and other related constructs. If you agree to participate in this study, you will complete your first set of questionnaire measures immediately after reviewing this form.

It is very important that all research assessments are completed honestly and you should take sufficient time to read each assessment and respond accurately.

C. DURATION

Participation in this study will take about 12 weeks, beginning today. Participation includes completion of weekly online assessments, which each should take between 15 and 20 minutes to complete.

D. RISKS AND DISCOMFORTS

1. **Frustration:** You will complete questionnaires throughout the duration of this study. The questions that will be asked may be sensitive in nature and make you feel uncomfortable. You may be asked personal questions that you find distressing. You may refuse to answer any question(s) that you do not wish to answer. Similarly, if randomized to Group B, you may become frustrated while using the Goal2Quit app. To reduce this risk, we invite you to contact us via phone or e-mail to troubleshoot difficulties with the app.

2. **Clinical deterioration:** Your symptoms of low mood may become worse throughout the course of this study. These symptoms will be monitored weekly by the Principal Investigator. Should your symptoms of low mood worsen, or should you have thoughts of harming yourself throughout the study, the Principal Investigator will contact you via phone and will provide referrals for local mental health resources. In the event that you report suicidal ideation either during study assessments, the Principal Investigator will complete a risk assessment with you over the phone. The Principal Investigator will ask you questions about your thoughts of harming yourself, including a likelihood of harming oneself imminently and a plan for committing suicide. If you report an imminent likelihood of harming yourself or a plan for committing suicide, the Principal Investigator will call emergency services and will remain on the phone with you until emergency services arrives. If you report an imminent likelihood of harming yourself and the connection between you and the Principal Investigator is lost, the Principal Investigator will contact emergency services and will provide them with your contact information, including your address. If you do not respond to the Principal Investigator's attempt to reach you via phone within 48 hours, the Principal Investigator will contact you via e-mail and will e-mail you a list of local mental health treatment options with a suggestion that you engage in additional treatment. The Principal Investigator will also ask that you respond to this e-mail within 24 hours to confirm receipt. If you report an imminent

likelihood of killing yourself on study assessments and do not respond to the Principal Investigator's attempt to contact you via phone or e-mail, the Principal Investigator will contact emergency services and will provide emergency services with your contact information, including your home address. In the event that your depressive symptoms worsen, you will be allowed to continue in the trial. However, you will be e-mailed a list of local mental health treatment providers and will be encouraged to seek additional mental health treatment.

3. **Data breach:** Health information will be collected within Goal2Quit (e.g., daily mood ratings, number of cigarettes smoked, activities), if you are randomized to Group B. However, personally identifiable information will not be collected within the app (e.g., name, phone number, email address, etc.), and thus we will not collect nor will we retain protected health information (PHI) within Goal2Quit. In the event of a data breach, it is important to note that health information will not be able to be tracked back to specific individual users. By refraining from collection of PHI within Goal2Quit, we protect the identities of our users. In the event of a data breach, all app users will be notified via email.

4. **Nicotine Replacement Therapy:** You may experience side effects if you use the nicotine patch and lozenge. The most common side effects for the patch include redness or irritation (itching) on skin; it is also possible to feel mild nausea, or headache, or trouble sleeping. The most common side effect of the lozenge is nausea, headache, and heartburn. Most of these are mild and go away over time. Few smokers (<5%) have to stop using these products because of the side effects. Serious side effects from these products are very rare (less than 1%). Using nicotine replacement therapy (of which nicotine lozenge and patch is one type) and smoking at the same time might be harmful but most studies suggest this is not true. You will be screened for all precautions with regard to using these products. Also, some smokers are concerned about getting addicted to nicotine products. Since we are only giving you small samples, this is unlikely (less than 5% of smokers have difficulty when stopping the lozenge and patch.

   If you are provided with the patch and lozenge, you have the option to use either one, both, or none. If you use both, this is generally okay. A number of studies have shown that combined use of patch and lozenge is safe and effective. If you do use both together, the most common side effect would be nausea or headache. If you experience either, you can cut down, or use only one product (or neither).

   Smoking can harm the unborn. Whether the nicotine from the patch or lozenge also harms the unborn is unclear. Because you might be asked to use nicotine patch or lozenge as part of this study, if you are pregnant (or planning to become pregnant) or breastfeeding, you should not be in this study.

Use of the patch or lozenge for any reason other than complete quitting is experimental. The current recommendations in the U.S. are to use these products only for quitting for good. Several countries other than the U.S. currently allow use of nicotine replacement products to relieve withdrawal symptoms and craving for temporary abstinence periods of a few hours to a few days.

To decrease these risks, you will be provided with educational information about NRT products. In addition, our research team is available to you by telephone and/or e-mail. Using the patch and/or lozenge is your option and you can stop using it if you wish.

5. **Confidentiality:** There is a risk of a loss of confidentiality of your personal information as a result of participation in this study. Efforts will be taken to ensure that all information you provide throughout the course of this study is kept confidential. In order to ensure confidentiality, all participant information will be identified with a number and kept under lock and key or on a secure MUSC server accessible only to our study team. Your information may be shared with representatives of the Medical University of South Carolina or governmental authorities if you or someone else is in danger or if we are required to do so by law.

E. MEDICAL RECORDS

Information about your study participation will not be in your medical record. This means that neither your research participation nor any of your research results will be included in any MUSC medical record.

F. BENEFITS

There will be no guaranteed direct benefit to you from participating in this study. The potential benefit to you is that the treatment you receive may prove to be more effective than other available treatments for smoking cessation, although this cannot be guaranteed. It is hoped that the information gained from the study will help in the treatment of future smokers.

G. COSTS

You will not be charged for participation in the study. If you use your mobile phone for study participation, normal data rates and usage will apply.

H. PAYMENT TO PARTICIPANTS

In return for your time and effort, you will be compensated via electronic gift cards (e.g., Amazon), which will be emailed to you for your participation in this study. You will receive a $10 electronic gift card for completion of the baseline assessment questionnaire, which you will be taken to after reviewing this form. After completing each follow-up questionnaire within 72 hours of being emailed the link, you will be compensated $10. You will be compensated $20 for completion of at least 6 out of the 9 follow-up assessments and an additional $20 for completing all follow up surveys. **Total compensation is $140 for completion of all aspects of the study.**

Payments that you receive from MUSC for participating in a research study are considered taxable income per IRS regulations. Payment types may include, but are not limited to: checks, cash, gift certificates/cards, personal property, and other items of value. If the total amount of payment you receive from MUSC reaches or exceeds $600.00 in a calendar year, you will be issued a Form 1099.

I. ALTERNATIVES

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes. Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled and will not affect your access to health care at MUSC. If you decide to withdraw, we ask that you contact Dr. Dahne to let her know that you are withdrawing from the study.

You may be withdrawn from the study without your consent if the researchers believe it is in your best interest or if there is evidence of fraud within completed surveys.

J. DATA SHARING

Information about you (including your identifiable private information) may have all of your identifiers removed and used for future research studies or distributed to other researchers for future research without additional informed consent from you or your legally authorized representative.

K. STUDENT PARTICIPATION

Your participation or discontinuance will not constitute an element of your academic performance, nor will it be a part of your academic record at this Institution.

L. EMPLOYEE PARTICIPATION

Your participation or discontinuance will not constitute an element of your job performance or evaluation, nor will it be a part of your personnel record at this Institution.

M. CLINICAL TRIAL REGISTRY DATABANK

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website 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.

N. FUTURE CONTACT

The researcher in charge of this study might like to contact you in the future about other research opportunities. Please initial by your choice below for paper consents, or scroll down and select your choice electronically:

____Yes, I agree to be contacted

____No, I do not agree to be contacted

O. CONFIDENTIALITY

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The investigators associated with this study, the sponsor, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event that you are injured as a result of participation in this study, you should immediately go to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital, and tell the physician on call that you are in a research study. They will call your study doctor who will make arrangements for your treatment. If the study sponsor does not pay for your treatment, the Medical University Hospital and the physicians who render treatment to you will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact the Principal Investigator, Dr. Jennifer Dahne (843-876-2280, dahne@musc.edu). I may contact the Medical University of SC Patient and Family Care Liaison (843) 792-5555 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights as a research subject in this study.

I agree to participate in this study. I have been given a copy of this form for my own records.

If you agree to participate, please sign below for paper consents or scroll to the bottom of the screen to provide an electronic signature.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

_____ _____
Signature of Person Obtaining Consent Date

MUSC
MEDICAL UNIVERSITY of SOUTH CAROLINA

NOTICE OF PRIVACY PRACTICES

MUSC Organized Health Care Arrangement (OHCA)

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESSS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

The Medical University of South Carolina and its affiliates (including but not limited to the Medical University Hospital Authority, MUSC Physicians, and MUSC Physicians Primary Care) participate in a clinically integrated health care setting. As a result of this clinical integration, these organizations function as an Organized Health Care Arrangement (OHCA) as defined by the Health Insurance Portability and Accountability Act (HIPAA). For purposes of this notice, the members of the MUSC OHCA are collectively referred to in this document as "MUSC." W**e collect or receive this information about your past, present or future health condition to provide health care to you, to receive payment for this health care, or to operate the hospital and/or clinics.**

HOW WE MAY USE AND RELEASE YOUR PROTECTED HEALTH INFORMATION (PHI)

A. The following uses do NOT require your authorization, except where required by SC law:

1. For treatment. Your PHI may be discussed by caregivers to determine your plan of care. For example, the physicians, nurses, medical students and other health care personnel may share PHI in order to coordinate the services you may need.

2. To obtain payment. We may use and disclose PHI to obtain payment for our services from you, an insurance company or a third party. For example, we may use the information to send a claim to your insurance company.

3. For health care operations. We may use and disclose PHI for hospital and/or clinic operations. For example, we may use the information to review our treatment and services and to evaluate the performance of our staff in caring for you.

4. For public health activities. We report to public health authorities, as required by law, information regarding births, deaths, various diseases, reactions to medications and medical products.

5. Victims of abuse, neglect, domestic violence. Your PHI may be released, as required by law, to the South Carolina Department of Social Services when cases of abuse and neglect are suspected.

6. Health oversight activities. We will release information for federal or state audits, civil, administrative or criminal investigations, inspections, licensure or disciplinary actions, as required by law.

7. Judicial and administrative proceedings. Your PHI may be released in response to a subpoena or court order.

8. Law enforcement or national security purposes. Your PHI may be released as part of an investigation by law enforcement.

9. Uses and disclosures about patients who have died. We provide coroners, medical examiners and funeral directors necessary information related to an individual's death.

10. For purposes of organ donation. As required by law, we will notify organ procurement organizations to assist them in organ, eye or tissue donation and transplants.

11. Research. We may use your PHI if the Institutional Review Board (IRB) for research reviews, approves and establishes safeguards to ensure privacy.

12. To avoid harm. In order to avoid a serious threat to the health or safety of a person or the public, we may release limited information to law enforcement personnel or persons able to prevent or lessen such harm.

13. For workers compensation purposes. We may release your PHI to comply with workers compensation laws.

14. Marketing. We may send you information on the latest treatment, support groups and other resources affecting your health.

15. Fundraising activities. We may use your PHI to communicate with you to raise funds to support health care services and educational programs we provide to the community. You have the right to opt out of receiving fundraising communications with each solicitation.

16. Appointment reminders and health-related benefits and services. We may contact you with a reminder that you have an appointment.

B. You may object to the following uses of PHI:

1. Hospital directories. Unless you object, we may include your name, location, general condition and religious affiliation in our patient directory for use by clergy and visitors who ask for you by name.

2. Information shared with family, friends or others. Unless you object, we may release your PHI to a family member, friend, or other person involved with your care or the payment for your care.

3. **Health plan.** You have the right to request that we not disclose certain PHI to your health plan for health services or items when you pay for those services or items in full.

C. Your prior written authorization is required (to release your PHI) in the following situations:

You may revoke your authorization by submitting a written notice to the privacy contact identified below. If we have a written authorization to release your PHI, it may occur before we receive your revocation

1. Any uses or disclosures beyond treatment, payment or healthcare operations and not specified in parts A & B above.

2. Psychotherapy notes.

3. Any circumstance where we seek to sell your information.

WHAT RIGHTS YOU HAVE REGARDING YOUR PHI

Although your health record is the physical property of MUSC, the information belongs to you, and you have the following rights with respect to your PHI:

A. The Right to Request Limits on How We Use and Release Your PHI. You have the right to ask that we limit how we use and release your PHI. We will consider your request, but we are not always legally required to accept it. If we accept your request, we will put any limits in writing and abide by them except in emergency situations. Your request must be in writing and state (1) the information you want to limit; (2) whether you want to limit our use, disclosure or both; (3) to whom you want the limits to apply, for example, disclosures to your spouse; and (4) an expiration date**.**

B. The Right to Choose How We Communicate PHI with You. You have the right to request that we communicate with you about PHI in a certain way or at a certain location (for example, sending information to your work address rather than your home address). You must make your request in writing and specify how and where you wish to be contacted. We will accommodate reasonable requests.

C. The Right to See and Get Copies of Your PHI. You have the right to inspect and receive a copy of your PHI (including an electronic copy), which is contained in a designated record set that may be used to make decisions about your care. You must submit your request in writing. If you request a copy of this information, we may charge a fee for copying, mailing or other costs associated with your request. We may deny your request to inspect and receive a copy in certain very limited circumstances. If you are denied access to PHI, you may request that the denial be reviewed.

D. The Right to Get a List of Instances of When and to Whom We Have Disclosed Your PHI. This list may not include uses such as those made for treatment, payment, or health care operations, directly to you, to your family, or in our facility directory as described above in this Notice of Privacy Practices. This list also may not include uses for which a signed authorization has been received or disclosures made more than six years prior to the date of your request.

E. The Right to Amend Your PHI. If you believe there is a mistake in your PHI or that a piece of important information is missing, you have the right to request that we amend the existing information or add the missing information. You must provide the request and your reason for the request in writing. We may deny your request in writing if the PHI is correct and complete or if it originated in another facility's record.

F. The Right to Receive a Paper or Electronic Copy of This Notice: You may ask us to give you a copy of this Notice at any time. For the above requests (and to receive forms) please contact: Health Information Services (Medical Records), Attention: Release of Information / 169 Ashley Avenue / MSC 369 / Charleston, SC 29425. The phone number is (843) 792-3881.

G. The Right to Revoke an Authorization. If you choose to sign an authorization to release your PHI, you can later revoke that authorization in writing. This revocation will stop any future release of your health information except as allowed or required by law.

H. The Right to be Notified of a Breach. If there is a breach of your unsecured PHI, we will notify you of the breach in writing.

HEALTH INFORMATION EXCHANGES

MUSC, along with other health care providers belongs to health information exchanges. These information exchanges are used in the diagnosis and treatment of patients. As a member of these exchanges, MUSC shares certain patient health information with other health care providers. Should you require treatment at another location that is a part of one of these exchanges, that provider may gather historical health information to assist with your treatment. You have the option of saying that this cannot be done. If you choose not to take part in these alliances, please contact the MUSC Privacy Office at 792-4037.

HOW TO COMPLAIN ABOUT OUR PRIVACY PRACTICES

If you think your privacy rights may have been violated, or you disagree with a decision we made about access to your PHI, you may file a complaint with the office listed in the next section of this Notice. **Please be assured that you will not be penalized and there will be no retaliation for voicing a concern or filing a complaint. We are committed to the delivery of quality health care in a confidential and private environment.**

PERSON TO CONTACT FOR INFORMATION ABOUT THIS NOTICE OR TO COMPLAIN ABOUT OUR PRIVACY PRACTICES

If you have any questions about this Notice or any complaints about our privacy practices please call the Privacy Officer (843) 792-4037, the Privacy Hotline (800) 296-0269, or contact in writing: HIPAA Privacy Officer / 169 Ashley Avenue / MSC 332 / Charleston SC 29425. You also may send a written complaint to the Office of Civil Rights. The address will be provided at your request.

CHANGES TO THIS NOTCE

We reserve the right to change the terms of this Notice at any time. We also reserve the right to make the revised or changed Notice effective for existing as well as future PHI. This Notice will always contain the effective date. You may view this notice and any revisions to it at: http://www.musc.edu/privacy.

EFFECTIVE DATE OF THIS NOTICE

This Notice went into effect on April 14, 2003.
Revised September 2013.