SOCIAL, BEHAVIORAL, and NON-CLINICAL RESEARCH PLAN

CPHS template v. 04172017

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Important Note: The CPHS Department (Chair & Scientific) Review Form is required with this application. Find the form in the RAPPORT Library or on the CPHS Website.

- **Respond to each item, even if to indicate N/A or not applicable**
- **Attach and/or upload this form as your 'Investigator Protocol' in Rapport**
- **If you are completing this form on a Mac, indicate your answer to any checkboxes by bolding or highlighting, or by deleting any incorrect options.**

1. Introduction and Background

Cigarette smoking accounts for nearly 1 in 5 preventable deaths in the United States, and approximately 16 million American live with a smoking-related disease. Fortunately, smoking cessation is associated with health improvements, including reduced cardiovascular disease, lower cancer risk, and improved life expectancy. Reducing cigarette smoking has been advocated for those not yet ready to quit, and cigarette reduction has been shown to longitudinally predict eventual cessation. Evidence suggests that smoking is highly sensitive to environmental stimuli (e.g., triggers).

One potential approach to reduce smoking is implementation intentions (II), which has shown promise in reducing cigarette use. These II interventions help individuals identify critical situations where smoking is likely to occur and then develop appropriate alternative responses to avoid cigarette use. When II is delivered as a brief, single session intervention, II increases cessation rates relative to control conditions.

Although II is well-suited for EMI because the brief messages are designed to be contextually relevant, to our knowledge, no research has evaluated whether repeated administration of II delivered by EMI reduces cigarette use, though EMIs featuring remotely and repeatedly delivered II messages increase physical activity and decrease alcohol consumption. EMI-II may be beneficial with greater exposure and when delivered in the contexts where a behavior, such as smoking, is likely to occur. This study aims to test an ecological momentary intervention of implementation intentions (EMI-II) to reduce cigarette smoking. This evaluation will combine EMI-II with daily ecological momentary assessments (EMAs), which are brief surveys in which participants report their current context and recent behavior and events.

2. Objectives and Hypotheses

Aim 1: Test the feasibility and acceptability of a customized micro-randomized trial using EMI-II for smoking reduction.
We will contract with Chorus, an online platform that allows for customizing content and automating delivery of text messages, to conduct EMAs and deliver micro-randomized EMI-IIs. Prior to the EMI-II period, adult smoker participants will develop personalized II content during an online session. These EMI-IIs will then be micro-randomized such that each participant will receive an EMI-II after approximately 40% of EMAs on average. Participants will also rate the acceptability of the EMI-II weekly.
Hypothesis (1): At least 75% of participants who start the EMA + EMI-II component will complete the two-week active study period.

Hypothesis (2): Participants will rate the acceptability of the EMI-II at least a 3.5 out of 5 on average.

Aim 2: Test the initial effectiveness of EMI-II for reducing cigarette smoking.
Participants will be recruited online using Facebook advertising. Eligible individuals will be randomized to either a two-week micro-randomized EMI-II condition with a two-week follow-up period or a wait-list control condition with a two-week no-intervention wait list followed by a two-week micro-randomized EMI-II. This study design will allow for testing the initial effectiveness on both proximal and distal smoking reduction outcomes.
Hypothesis (1): Participants receiving EMA + EMI-II will show greater reductions in self-reported smoking than participants assigned to a wait-list only control.
Hypothesis (2): Self-reported cigarette smoking during the next EMA following II presentation will be lower relative to cigarette smoking reported in EMAs that do not proximally follow II delivery.

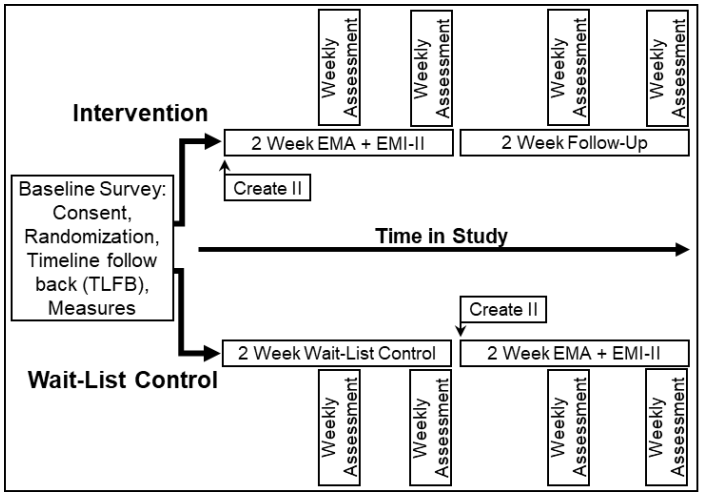
3. Study Design

Describe all study procedures, materials, and methods of data collection:

All study procedures will be conducted remotely using the internet and mobile phones. No in-person visit is required for any study procedures.

Based on information provided in the study ads (posted on social media sites such as Facebook), interested individuals will be directed to an eligibility screening questionnaire through Dartmouth's Qualtrics system and may call or email study staff with questions. Those who meet the eligibility criteria for the study based on the online screening will be verified by phone. After the phone verification, participants will be sent a baseline assessment.

The first page of the baseline features a consent form (electronic through Qualtrics via an "agree" answer choice) and be offered an electronic copy to download. Consenting participants will complete baseline questionnaires, including demographics and psychological/behavioral assessments (as described in the assessments described below). We expect the baseline assessments to take approximately 30 minutes of participants' time. During the baseline, participants will be randomized to either an intervention/follow-up condition or a waitlist-control/intervention condition. Each condition (intervention, wait-list, follow-up) will last for approximately 14 days, and participation in each condition will last for approximately four weeks after completing the baseline assessment.



During the approximately four-week study period, participants will be asked to complete an online survey each week. This will be the only study activity during the wait-list condition and the follow-up condition.

During the 14-day intervention period (the details of which are below), participants will complete mini-surveys presented using ecological momentary assessment (EMA; questions/questionnaires asked at a given time point outside of a laboratory setting via a mobile device). EMAs will be sent to participants via text message (i.e., short message service [SMS]) scheduled using the Chorus platform (see Chorus information document). The EMAs will assess conditions surrounding smoking and smoking behavior (see EMA Questions for content). We will ask participants to respond to EMAs for 14 consecutive days. We will prompt them five times daily to inquire about smoking risk behavior and recent nicotine use. Prompts will be sent during the participant's waking hours. A randomly selected 40% of EMAs will include one of the participant's Implementation Intention messages as the final item, permitting repeated delivery of the intervention content in real time.

Study participants will be compensated at the end of their study period via Amazon gift card or MasterCard gift card.

The following supplemental materials will be uploaded to the Rapport website:
- Consent form
- Screening questionnaire
- Baseline assessment
- Weekly survey questions
- EMA questions
- Sample study ads
- Procedural checklist
- Sample emails
- Confirmation phone call script
- Participant compensation visual
- Chorus information

We expect materials such as the study ads, procedural checklist, participant compensation visual, confirmation phone call script, and emails to evolve over time based on participant feedback. Contact information and links within these documents will be updated once they are finalized.

4. Analysis

Describe any qualitative tests and measures as well as quantitative methods:

<u>Aim 1</u>
Hypothesis 1: At least 75% of participants who start the EMA + EMI-II component will complete the two-week active study period. To determine feasibility, the number of participants who complete the two-week EMI-II period will be divided by the number of participants who start the EMI-II period.
Hypothesis 2: Participants will rate the acceptability of the EMI-II at least a 3.5 out of 5 on average. Acceptability will be calculated by determining the mean score on the AIM.

<u>Aim 2</u>
Hypothesis 1: **Participants receiving EMA + EMI-II will show greater reductions in self-reported smoking than participants assigned to a wait-list control.** Test by comparing rates of smoking with generalized linear mixed-effects models within the negative binomial family, this accounts for the interdependence of observations within subjects and accounts for the count data of the outcome. Here the rate of change in the number of combustible cigarettes reported in the timeline follow-backs will be

examined by testing an interaction between time and condition. A significant interaction would suggest a differential change in the number of combustible cigarettes smoked across the intervention conditions. The intervention will be tested by including the baseline assessment, as well the change across weeks 1 and 2 of the study (comparing active EMI-II for the intervention group and no-intervention for the wait-list control). **Hypothesis 2: Self-reported cigarette smoking during the next EMA following II presentation will be lower relative to cigarette smoking reported in EMAs that do not proximally follow II delivery.** Test by constructing multilevel dynamic structural equation models nesting the response from the microintervention compared to the no-intervention periods. Robust maximum likelihood estimation will be utilized to account for the ordinal nature of the data.

5. Study Progress Monitoring

Note: appropriate monitoring may include periodic assessment of the following:

- data quality
- timelines
- recruitment and enrollment

Provide a description of the methods which will be used to determine the progress of the study, including periodic assessments of data quality, timelines, recruitment, and enrollment as appropriate:

The PI will be dedicated to ensuring that timelines, recruitment and enrollment, and data quality meet expectations throughout the study. Any issues will be reviewed and handled appropriately. The PI will be in charge of recruitment and enrollment. Participants may call or email with any questions. The PI will be available for questions throughout the study period, and participants will be informed that they may withdraw from the study for any reason at any time. The PI plans to monitor data quality on an approximately daily basis, with potential assistance from other team members.

Poor compliance regarding any study assessments will first be addressed through reminders sent to the participant's mobile phone (e.g., text message) or email address or by telephone call. If poor study compliance persists, the participant may be withdrawn from the study, and an additional participant will be enrolled.

6. Risks & Benefits

Note: Risks may be physical, psychological, social, legal, economic, to reputation, or others.

a. Describe any potential risks, their likelihood and seriousness:

The proposed study is expected to provide minimal risk to participants, though the greatest risk is anticipated to be loss of confidentiality. There may also be a slight risk that participants may try to answer text-message prompts while driving or operating machinery, but we will instruct participants that they will have adequate time to respond to each prompt. There are no other clear physical or psychological risks associated with participation in this study.

b. Confirm that risks to subjects have been minimized, by use of procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk:

We confirm that risks to participants have been minimized, consistent with sound research design. We will take multiple steps to lower the likelihood of a breach of confidentiality. First, all data will be collected using subject codes, rather than names, and the code key linking names and identities will be stored separately from any data collected. Second, participants will complete the baseline surveys and weekly assessments of smoking using a HIPAA-compliant, online survey software package (Qualtrics), and common email messages will be scheduled and sent in advance using this

HIPAA-compliant system. Data from EMAs will be collected using short message service (SMS; i.e., text message), which is encrypted by network providers. Data will be stored behind password protection. Data will be maintained on a HIPAA-compliant, cloud-based server and secondarily backed-up on an encrypted hard drive. (see also Section 13).

c. Describe why all the risks to subjects are reasonable in relation to both anticipated benefits and the knowledge expected to be gained from the study:

Prior research suggests that single-session II interventions help individuals reduce their smoking. The proposed study will extend II by adding delivery via text message, potentially increasing dose and enhancing temporal and contextual relevance. This research will examine the feasibility, usability, and potential efficacy of this intervention. Positive findings from this evaluation would suggest an accessible method for delivering a smoking cessation intervention and would provide pilot data for a line of research aimed at identifying momentary personal and contextual factors that interact with intervention components, eventually allowing for better personalization and adaptation of smoking cessation interventions. It thus may inform more efficient, cost-effective care. Given the importance of the knowledge to be gained, the risks to the participants are reasonable, as the risks are minimal and plans for protection against these risks are in place.

7. Unexpected Events or Incidental Findings

Note: It may be important to consider the potential for certain unanticipated events to occur, for example:

- finding an anomaly in a MRI
- discovering child abuse
- causing distress in interviews of a sensitive nature

Describe potential events and provide a plan of action:

If any participants express any emotional disturbance, distress, and/or desire for further help, we will provide them with resources available for assistance and local counseling.

8. Deception

Does any part of this study involve deception or withholding of information from participants?

☐ **Yes** ☒ **No**

If Yes, provide an explanation which addresses the following:

- A description of the deception being used
- Why the deception is necessary
- A plan for debriefing, or providing subjects with the pertinent information after participation

N/A

9. Equitable Participant Selection

a. Estimated number of participants at Dartmouth CPHS reviewed sites:

For this study, we propose a sample size of up to 100 participants who smoke cigarettes recruited from the United States, including U.S. districts and territories.

We propose the sample size above to reach the study analytic sample size of up to 65 participants. The proposed sample size accounts for participants who sign consent but participate minimally.

b. Provide a justification of the proposed sample size

Power calculations suggested that with a low intraclass correlation coefficient, there is greater than 80% power to detect Aim 2 Hypothesis 1 with a medium effect. Power calculations from a micro-randomized trials power calculator suggested that there would be greater than 90% power to test Aim 2 Hypothesis 2.

c. Define the target population:

We are recruiting people who smoke cigarettes. To be eligible for the study, potential participants must:

- Be at least 18 years old
- Be located in the United States
- Smoke at least 15 tobacco cigarettes per day on average
- Express interest in quitting or reducing smoking
- Have a cell phone with access to test messaging
- Be willing to send and receive text messages related to smoking
- Not be currently receiving behavioral treatment/therapy for smoking cessation
- Not currently on psychotropic medications for smoking cessation
- Not currently pregnant, nursing, or planning to become pregnant

Past attempts by our study team to recruit a similar sample using similar online methods resulted in a disproportionate number of screen-ins from non-Hispanic, White women. We may selectively recruit and enroll for this study based on gender, race and/or ethnicity to form a sample that is more representative of the population of interest. We may do so by targeting ads based on gender, race, and/or ethnicity and by selectively enrolling (based on gender, race, and/or ethnicity) those who have screened into the study.

d. Vulnerable populations

Note: Certain populations are considered vulnerable to coercion and undue influence and are provided with additional protections when participating in a research study.

Identify any of the below populations which you plan to recruit for this study. In addition, complete the form(s) linked with each population as necessary and upload on the 'Supporting Documents' page in Rapport.

☐ Pregnant Women, Fetuses and Neonates
☐ Children
☐ People with impaired decision-making capacity

The following populations may also be considered vulnerable to coercion or other undue influence:

- Prisoners
- People who are economically disadvantaged
- The elderly
- People who are illiterate or do not speak English
- Students and employees

Describe any other potentially vulnerable population(s) and the additional protections provided to them:

N/A

10. Recruitment

Describe method(s) of recruitment. Associated advertisements and other materials to be used for recruitment should be uploaded to the 'Consent Forms and Recruitment Materials' page in Rapport.

Study advertisements will be posted online (e.g., Facebook, Instagram) using sample targeting available on the online platform. Our team has had great success with similar recruitment strategies in prior research studies.

11. Informed Consent, Assent, and Authorization

All forms discussed in this section should be uploaded to the 'Consent Forms and Recruitment Materials' page in Rapport

a. Please describe the consent and/or assent process, addressing the following:

- Who will obtain consent/assent from participants
- Where the consent/assent process will take place
- The timeframe for providing information potential participants about a study, having the consent form signed, and beginning study activities
- Any precautions taken to minimize the possibility of coercion or undue influence
- The forms which will be used as well as any aids used to simplify scientific or technical information
- How comprehension will be ensured

All descriptions in the informed consent form are written at an 8th grade reading level. The consent document includes descriptions about: background of the study, study procedures, risks and discomforts, benefits, payment for participation, voluntary nature of participation, privacy and confidentiality, and contact information for the research team. The consent form will be presented to prospective study participants online.

Individuals who wish to participate in the study will be asked to carefully read the consent form. If they have any questions about the study, they can email/call the study staff before consenting and at any time afterward. Individuals who provide consent for participation in the study will be offered an electronic copy of the form. Their screening information, agreement to participate, contact information, and baseline data will be saved in Qualtrics. Study participants will be informed that they can withdraw from the study for any reason at any time.

b. Waiver(s) or alteration(s) may be requested for research that involves no more than minimal risk.
Indicate requested waiver(s) or alteration(s) below. In addition, complete the corresponding section of the Waivers and Alterations Request Form and upload it to the 'Consent Forms and Recruitment Materials' page in Rapport.

- ☐ For the informed consent *process*
- ☐ For the *documentation* of informed consent
- ☐ For the HIPAA Authorization to use and/or disclose PHI
- ☐ For a waiver of the requirement for medical record documentation

12. Compensation or Gifts

Please describe any payments, gifts or reimbursements participants will receive for taking part in the study:

Compensating participants for active study participation will help ensure exposure to the intervention.

Participants will be compensated according to the following schedule.

$20 for baseline assessment*

$10 for each weekly survey* × 4 weeks = up to $40

$1 for each EMA* × 5 EMAs per day × 14 days = up to $70

$10 bonus per week for completing minimum of 32 EMAS (~90% of 35 total EMAs in the seven-day period) × 2 weeks = up to $20

Total: up to $150 over approximately four-week study period

Note that these values are based on the maximum compensation possible. Each item marked with an asterisk must be completed in its entirety to receive the study payment. Participants will be compensated at the end of their study period (after completing the final weekly survey).

The opportunity for compensation expires three months after the end of the participant's study period. Each participant who is unable to be reached (e.g., after three tries) for compensation will be notified of this expiration date.

13. Privacy of Participants

Note: Methods used to obtain information about participants may have an effect on privacy. For example:

- Consent discussions or interviews held in public which concern sensitive subjects or behaviors
- Observations of behavior, especially illicit behavior, in quasi-public settings

Describe any activities or interactions which could lead to a breach of privacy and provide a plan to protect participant privacy:

All data collected for this study will be collected online. There is a risk of breach of privacy associated with online data collection methods. We will take multiple steps to lower the likelihood of a breach of privacy (see also Section 6b). First, all data will be collected using subject codes, rather than names, and the code key linking names and identities will be stored separately from any data collected. Second, participants will complete the baseline surveys and weekly assessments of smoking using a HIPAA-compliant, online survey software package (Qualtrics), and common email messages will be scheduled and sent in advance using this HIPAA-compliant system. Data from EMAs will be collected using short message service (SMS; i.e., text message), which is encrypted by network providers. Data will be stored behind password protection. Data will be maintained on a HIPAA-compliant, cloud-based server and secondarily backed-up on an encrypted hard drive.

14. Confidentiality of Data

Note: Any person engaged in research collecting information that could cause financial, social or legal harm to participants may apply for a Certificate of Confidentiality. Certificates of Confidentiality are issued by

the National Institutes of Health (NIH) to protect identifiable research information from forced disclosure. They are intended to allow the investigator and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.

a. If disclosed, could any of the data collected be considered sensitive, with the potential to damage financial standing, employability, insurability, or reputation?

☐ **No** ☒ **Yes**

If Yes, describe the data or information, the rationale for their collection, and whether a Certificate of Confidentiality will be obtained:

This study asks questions about cigarette smoking behaviors, which could potentially be sensitive for some participants. This study is covered by a Certificate of Confidentiality from the National Institutes of Health.

b. Describe the safeguards employed to secure, share, and maintain data during the study, addressing any of the following which may apply:

- Administrative, ie. coding of participant data
- Physical, ie. use of locked file cabinets
- Technical, ie. encrypted data systems

We will take multiple steps to lower the likelihood of a breach of privacy (see also Sections 6b, 13). First, all data will be collected using subject codes, rather than names, and the code key linking names and identities will be stored separately from any data collected. Second, participants will complete the baseline surveys and weekly assessments of smoking using a HIPAA-compliant, online survey software package (Qualtrics), and common email messages will be scheduled and sent in advance using this HIPAA-compliant system. Data from EMAs will be collected using short message service (SMS; i.e., text message), which is encrypted by network providers. Data will be stored behind password protection. Data will be maintained on a HIPAA-compliant, cloud-based server and secondarily backed-up on an encrypted hard drive.

c. Describe the plan for storage or destruction of data upon study completion:

Study participants will be informed that research data collected about them will be stored until they are no longer useful. It is estimated that the data will possibly be useful for 10 years, but the data may be useful and may continue to be retained indefinitely. Data will be maintained on a HIPAA-compliant, cloud-based server and secondarily backed-up on an encrypted hard drive.