### 1.0 General Information

* Please enter the official title of your study:

Patient Navigation and Financial Incentives to Promote Smoking Cessation: a Randomized Controlled Trial

* Please enter the Study Nickname you would like to use to reference the study:

Patient Navigation and Financial Incentives

* This field allows you to enter an abbreviated version of the Study Title to quickly identify this study.

### 2.0 Add Department(s)

2.1 List departments associated with this study (Note: The primary department should accurately reflect the primary Department or Section of the PI - click on (?) icon for instructions)

<table>
<thead>
<tr>
<th>Primary Dept?</th>
<th>Department Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>☑</td>
<td>BU - MED - General Internal Medicine</td>
</tr>
</tbody>
</table>

### 3.0 Assign key study personnel (KSP) access to the study

3.1 * Please add a Principal Investigator for the study:

Karen Elizabeth Lasser, MD, MPH

Select if applicable

- Student
- Resident
- Fellow

If the Principal Investigator is a Student, Resident, or Fellow, the name of the Faculty Advisor must be supplied below.

3.2 If applicable, please select the Research Staff personnel:

A) Additional Investigators

   Lisa Marie Quintiliani, PhD

   Co-Investigator

B) Research Support Staff

   Jana Florian, BS

   Research Assistant

   Nicole Marie St. Omer Roy, BA

   Research Assistant

   Ve Truong, Health Science

   Research Assistant

3.3 Please add a Study Contact:

   Orlaith Heymann, MA

   Karen Elizabeth Lasser, MD, MPH
Ve Truong, Health Science

The Study Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g. The study contact(s) are typically either the Study Coordinator or the Principal Investigator themselves). If the PI is a student, resident, or fellow, the Supervising Principal Investigator MUST be entered here.

3.4 If the PI is a student, resident, or fellow, you MUST add the Supervising Principal Investigator here:

3.5 Please ONLY list the PI's Department Chair/Section Chief below. The system will automatically route for signoff to any additional "Special Routing" approvals, so please do not list those here.

Jeffrey Samet, MD, MA, MPH
Department Chair/Section Chief

**Add the name of the individual authorized to approve and sign off on this study from your Department (e.g. the Department Chair or Dean). This should be someone other than the Principal Investigator himself.

3.6 If applicable, please select the Administrative Assistant(s)

List here anyone performing administrative tasks only (not engaged in research and having no contact with subjects or identifiable data; where certification/recertification and COI disclosure form are not required)- Click on (?) icon for more info.

4.0 External non-BU/BMC Investigators

4.1 In this section, only list non-BU/BMC investigators (not a full-time or permanent part-time employee of BMC, BU, BPHC, etc.). Any BU/BMC personnel should be listed in the KSP section (3rd section)

List here all non-BU/BMC persons working on the protocol who will be engaged in the research on behalf of BU/BMC. This includes all persons who are conducting research under an Authorization Agreement (IAA) with BU/BMC IRB.

<table>
<thead>
<tr>
<th>Name</th>
<th>Institution</th>
</tr>
</thead>
</table>

No External Personnel has been attached to this Study

4.2 Does this study involve participation of non-BUMC investigators who are determined to be “not-engaged” in the research?

☐ Yes ☐ No

If you answered Yes above, indicate in the text box below; the names of the non-BUMC investigators, all study activities they will be performing, the names of their institutions, and why they are determined to be NOT-Engaged in the research (based on the OHRP engagement guidance).

Scott Halpern, MD from the University of Pennsylvania is a consultant who will provide expertise on financial incentives. He will have no contact with study subjects, and will only review analyses of deidentified data in aggregate.

Lori Pbert, PhD from the University of Massachusetts is a consultant who will provide expertise on smoking cessation. Similarly, she will have no contact with study subjects, and will only review analyses of deidentified data in aggregate.

4.3 Study Attachments
Click on the link below to attach any necessary documents related to external non-BU/BMC personnel.

<table>
<thead>
<tr>
<th>Version</th>
<th>Title</th>
<th>Category</th>
<th>Last Modified By</th>
<th>Date Last Modified</th>
<th>Checked Out</th>
<th>View Document</th>
</tr>
</thead>
</table>

No Document(s) have been attached to this form.

5.0 Investigator Information from INSPIR I

5.1 This section had been migrated from INSPIR I. - If this is a new study, please skip this section (click Save and Continue). - If this is a study that was migrated from INSPIR I, DO NOT ADD ANY MORE INVESTIGATORS IN THIS SECTION. YOU CAN ONLY DELETE INVESTIGATORS HERE. All BU/BMC personnel should be listed in the KSP section (3rd section), and all non-BU/BMC investigators should be listed in the External non-BU/BMC Investigators section (4th section).

<table>
<thead>
<tr>
<th>KSP Info</th>
<th>Additional Personnel Info</th>
</tr>
</thead>
</table>

No records have been added.

6.0 Conflict of Interest

6.1 Conflict of Interest Disclosure

I confirm that all those responsible for the design, conduct, or reporting of the proposed program, including at minimum, all Senior/key personnel in the grant application, have completed the financial interest disclosure forms and submitted them to the COI office as provided under the Boston University Policy on Investigator’s Conflicts of Interest or Boston Medical Center Policy: Significant Financial Conflicts of Interest in the Conduct of Research. I understand that this is a continuing obligation as new individuals join my research team in the future.

☑ Agree

Of the BU PSDs submitted, have any significant financial interests been disclosed?

☐ Yes ☐ No

If yes, please specify who has disclosed a COI.

7.0 Funding Source

7.1 Funding Source

What is the source of your research funding. If you have multiple sources of funding (including sub-awards), check all that apply.

☐ Unfunded Student Research
☐ Dept/Internally Funded
☐ Government
☐ Industry
☑ Foundation/Other
☐ Training Grant (e.g. T32, K-award)
For instructions on how to complete this section, click on the Help icon.

<table>
<thead>
<tr>
<th>Sponsor Name</th>
<th>Sponsor Type</th>
<th>Contract Type</th>
<th>BU SAP Grant Number or BMC AU Number</th>
<th>Award Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>American Cancer Society</td>
<td>Private - Non-profit</td>
<td>Grant</td>
<td>RSG-14-034-01-CPPB</td>
<td></td>
</tr>
</tbody>
</table>

Sponsor Name: American Cancer Society
Sponsor Type: Private - Non-profit

Project Period:

Is Institution the Primary Grant Holder: No

Award Number: RSG-14-034-01-CPPB

Grant Title: Patient Navigation and Financial Incentives to Promote Smoking Cessation

Award Recipient: If Award Recipient is not the same as identified on the study.

7.3 Grants Office

In the check boxes below, please indicate which grants office is handling your award/sub-award.

- [ ] BU Office of Sponsored Programs (OSP-med)
- [X] BMC Grants Administration (OGA)
- [ ] Charles River Campus Office of Sponsored Programs (OSP-CRC)
- [ ] Other

Funding Notifications:

- [X] I have received a Notification of Award (NoA)
- [ ] I have received a Just In Time notice (JIT)
- [ ] I have received a fundable score for this study.

7.4 Study Attachments

Click on the Help (?) icon for information on what you're required to attach in this section.

<table>
<thead>
<tr>
<th>Version</th>
<th>Title</th>
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</tr>
</tbody>
</table>

No Document(s) have been attached to this form.

7.5 Funding Source Info from INSPIR I - STOP! Do not complete this section below; this section will soon be removed. Please complete section 7.2 above instead.

This table is read-only. It will only be populated if this study was migrated from INSPIR I. If there are entries in this table, please use them to enter the funding information into the new Funding Source table above.

<table>
<thead>
<tr>
<th>Funding Type</th>
<th>Sponsor Name</th>
<th>Award #</th>
<th>PI of Award</th>
<th>Industry Protocol Number</th>
</tr>
</thead>
</table>
8.0 Study Summary

8.1 Provide a brief lay summary of the project in lay terms (in 500 words or less).

Cigarette smoking is a significant health threat. To eliminate disparities in cancer burden, smoking rates must be reduced among populations where smoking is disproportionately concentrated: those with low socioeconomic status (SES). We will apply two methods that are being used in the field of health disparities to the challenge of promoting smoking cessation among low SES smokers. These include: 1) Patient navigation; patient navigators are often lay persons, working as paid employees, who guide patients through the health care system and 2) Financial incentives; We propose to provide monetary incentives: $250 for smoking cessation within 6 months after study enrollment, and $500 for an additional 6 months of abstinence after the initial cessation. We will recruit/randomize 352 smokers to a randomized controlled trial comparing the combination of Patient Navigation (delivered over 6 months) and Financial Incentives versus Enhanced Traditional Care control condition (smoking cessation brochure/list of cessation resources). The RCT will take place among adult daily smokers seen in the past year at BMC primary care practices, with a primary outcome of smoking cessation at one year. Follow-up by telephone, for both groups, will occur 6, 12, and 18 months after enrollment.
been or will be obtained for each site engaged in the research. This does not include multi-center studies, unless the PI is the PI for all sites in this study.

9.4 Does this study involve Community Based Participatory Research?

☐ Yes  ☐ No

9.5 Indicate below if any recruitment, consenting, and/or study interventions/procedures/data collection will take place in any of the following places (check all that apply)

☐ Boston Healthnet Community Health Centers (click on ? icon for listing)
☐ MD offices or clinics (not part of BUMC campus)
☐ Subjects' places of residence including nursing homes, assisted living facilities, etc.
☐ Community centers or other 'community' locations (homeless shelters, daycare, etc.)
☐ International sites
☐ Veterans Administration (VA)

9.6 Study Attachments

Here you can attach any study sites related documents.
Attach IRB approval letters from other institutions (If you answered question #2).

<table>
<thead>
<tr>
<th>Version</th>
<th>Title</th>
<th>Category</th>
<th>Last Modified By</th>
<th>Date Last Modified</th>
<th>Checked Out</th>
<th>View Document</th>
</tr>
</thead>
</table>

No Document(s) have been attached to this form.

10.0 Navigation Menu

Please note: Questions in the Navigation Menu section determine which subsequent sections will be displayed and which ones will be hidden. If later you make any change to the Navigation Menu section, you will need to click on the "Save and Continue to Next Section" button throughout the whole application to display any new required section or hide any sections that are no longer required.

10.1 Emergency Use

Is this application for an EMERGENCY USE of an Investigational Drug or Device?

☐ Yes  ☐ No

10.2 Individual Patient IND or Humanitarian Use Device

Is this application for an FDA approved Individual patient (single use) IND or Humanitarian Use Device?

☐ Yes  ☐ No

10.3 Review Path Determination

☐ This project meets the regulatory definition of Not Human Subject Research (NHSR). Examples are Quality Assurance, Quality Improvement projects, or studies involving obtaining data/tissue.
☐ BUMC has delegated IRB review to another institution (BUMC is Institution B). (Please note: this relationship requires an Authorization Agreement.)
☐ According to the Engagement of Institutions in Research guidance by OHRP, neither BUMC (Boston University, Boston Medical Center) nor affiliated institutions/organizations for which the BUMC IRB has oversight responsibilities is “engaged” in human subjects research.
☐ This study fits into one or more of the Federal Exempt categories.
☐ None of the above. This study requires Expedited review or the review of the Full Board.

10.4 IRB Authorization Agreement (IAA) - BUMC is Institution A

Does this study have or require an IRB Authorization Agreement (IAA) where investigators from another
### 10.5 International Research

Are any BU/BMC investigators involved in any way in any research activities at any non-US (international) sites, including oversight of international research activities?

- [ ] Yes
- [ ] No

### 10.6 HIPAA Compliance

Is the PI a member of the covered entity and the study involves the collection of protected health information (PHI)? Is any investigator or member of the study staff, whether a member of the covered entity or not, using (i.e., accessing, recording) and/or disclosing PHI as part of this research? If your answer to either question is YES then select Yes below.

- [ ] Yes - This study is subject to the HIPAA Privacy Rule
- [ ] No - This study is HIPAA Exempt

### 10.7 Genetics

Does this research involve genetic testing, gene therapy, or collection of genetic information?

- [ ] Yes
- [ ] No

### 10.8 Biological Samples Collection

Does this study involve collecting, banking, and/or distributing biological samples?

- [ ] Yes
- [ ] No

### 10.9 Drugs/Biological Agents

Does this study involve administering drugs or biological agents?

- [ ] Yes
- [ ] No

### 10.10 Device

Does this study involve testing or use of a medical device?

- [ ] Yes
- [ ] No

### 10.11 Repositories

Will you be collecting data or samples that will be placed into a repository, or will you be establishing a repository (either as a new protocol or to be added to an existing protocol)? (Do not check yes if this protocol involves ONLY obtaining samples FROM a repository to conduct this research)

- [ ] Yes
- [ ] No
10.12 StudyFinder Listing

Do you agree to have the study title, summary, and PI name and e-mail address listed on StudyFinder, a publicly viewable medical campus website for general publicity and collaboration purposes? (If you also want to use StudyFinder to recruit subjects, there is another question to answer in the Recruitment section.)

☐ Yes ☐ No

11.0 Purpose

11.1 Background/Rationale/Purpose

Provide background information, study rationale, and purpose / study objective(s) and/or hypotheses for this study.

Cigarette smoking is a highly significant health threat, responsible for > 480,000 deaths in the US each year, many due to cancer, and is the largest cause of preventable morbidity and mortality in the US. Primary care settings provide an opportunity to reach large proportions of low-income smokers, as 61% of such smokers are engaged in medical care. The proposed project addresses this under-utilization of available smoking cessation services which is occurring despite considerable interest among low-income patients about quitting/receiving help with quitting. This intervention has the potential to increase the reach of existing services and in turn, to improve the public’s health.

Patient financial incentives, while not yet used as standard of care for health promotion, are in the research stage for various types of conditions. Financial incentives are effective in promoting smoking cessation; but have not been extensively studied among low SES smokers. Financial incentives are a behavioral economic intervention that is effective in promoting smoking cessation, increasing cessation rates 3-fold compared to no incentives. We believe financial incentives merit further study, particularly in low SES populations. Incentives for completing smoking cessation programs/achieving abstinence may be particularly effective among low SES smokers because they: 1) can alleviate some of the financial strain that prevents low SES smokers from quitting (studies have shown that the stress from financial problems prevents patients from quitting, even though quitting smoking could save people large amounts of money); 2) promote short-term abstinence among smokers with mental illness and substance use, many of whom are low SES smokers; 3) provide a substitute reinforcer for smoking (e.g., in lieu of hobbies, physical activity, work satisfaction) often absent in environments of low SES smokers and 4) provide extrinsic motivation for patients to quit smoking, and may be particularly effective among low SES smokers, many of whom in our recent pilot study were found to have low levels of intrinsic motivation. Our strategy is to combine financial incentives with patient navigation, as the latter may “supercharge” the former, for the two interventions may work in complementary ways. We posit that incentives will augment people’s willingness to connect with a navigator, and the navigator will put people in touch with resources/environments in which the incentives can work.

Patient navigation holds promise as an intervention to reduce cancer disparities, but alone may be insufficient to promote smoking cessation. Patient navigators are often lay persons from the community who guide patients through the health care system so that they receive appropriate services. While patient navigation has been shown to be an effective intervention to reduce health care disparities, prior patient navigation studies have been limited to the realms of cancer screening and diagnosis. Preliminary findings from our pilot RCT of patient navigation to promote smoking cessation among low SES and minority primary care patients at Boston Medical Center suggest that a more potent intervention may be needed. While a patient navigator was able to link 37% of patients to treatment, she was unable to contact or meaningfully connect with 53% of patients. Thus, financial incentives may be used to increase participant motivation to connect with patient navigators.

Combining financial incentives with patient navigation may be an effective approach to promote cessation among low SES and minority smokers. Multicomponent interventions have shown the most promise in changing health behaviors in general, and in reducing health disparities. Barriers to behavior change among socially disadvantaged persons may be so large that no single intervention can be effective. We have therefore chosen to implement two intervention components, financial incentives and patient navigation, which have shown some promise in smoking cessation, and are currently being applied in the health disparities field to other health conditions.

Our objectives and hypotheses are:

**Specific Aim I**: To determine whether patient navigation and financial incentives increase the rates at which primary care patients engage in smoking cessation treatment.

H1: Compared to control patients, those assigned to the intervention will be more likely to engage in smoking cessation treatment at six months post-enrollment.

**Specific Aim II**: To determine whether patient navigation and financial incentives increase the rates at which primary care
patients quit smoking (our primary outcome), defined as biochemically confirmed cessation at twelve months using salivary cotinine levels.

H1: Compared to ETC patients, those assigned to the patient navigation/financial incentives intervention will be more likely to be abstinent at 12 months post-enrollment.

12.0 Subjects

12.1 Inclusion Criteria

Specify your inclusion criteria for each cohort.

<table>
<thead>
<tr>
<th>Order Number</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>smoked ≥10 cigarettes/day in the past week</td>
</tr>
<tr>
<td>2</td>
<td>age ≥ 18</td>
</tr>
<tr>
<td>3</td>
<td>have a PCP in the Shapiro Building (general internal medicine) at BMC</td>
</tr>
<tr>
<td>4</td>
<td>telephone access</td>
</tr>
<tr>
<td>5</td>
<td>English speaking</td>
</tr>
<tr>
<td>6</td>
<td>able and willing to participate in the study protocol and provide informed consent.</td>
</tr>
</tbody>
</table>

12.2 Exclusion Criteria

Specify your exclusion criteria for each cohort.

<table>
<thead>
<tr>
<th>Order Number</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>planning to move out of the area within the next six months</td>
</tr>
<tr>
<td>2</td>
<td>cognitive impairments that preclude participation in study activities</td>
</tr>
<tr>
<td>3</td>
<td>severe illness or distress</td>
</tr>
<tr>
<td>5</td>
<td>actively using evidence-based smoking cessation treatment</td>
</tr>
<tr>
<td>6</td>
<td>transient residence or lack of a telephone for follow-up assessments.</td>
</tr>
</tbody>
</table>

The following data was migrated from INSPIR I (if any). Eventually, the box below will go away. So please remove your answer from the box below and place it in the above text editor (green button) by cutting and pasting it. The box below should be left blank.
12.3 Subjects (Please choose the appropriate categories for your subjects.)

Gender

Both

Age

☑ Adult (18-64 yrs)
☑ Geriatric (65+ yrs)
☐ Other/unknown (specify in the box below)

Race/Ethnicity:

☑ All Ethnic Groups
☐ American Indian or Alaskan Native
☐ Asian or Pacific Islander
☐ Black (Not of Hispanic Origin)
☐ Hispanic
☐ Mixed Race or Ethnicity
☐ White (Not of Hispanic Origin)
☐ Other or Not Available (specify in the box below)

Languages: Remember that informed consent forms and all other written documents must be given in a language understandable to the subject. List all languages in which you are planning to obtain informed consent. Once the English version of the consent form is approved in INSPIR, please submit an Amendment with applicable translated consent & attestation forms prior to use.

Languages

Languages: English

Which if any of the following vulnerable populations will be recruited as subjects?

☐ BU Undergraduate Students
☐ BUMC Students
☐ Children
☐ Children who are wards of the State
☐ Cognitively Impaired
☐ Emergency Department Patients
12.4 Vulnerable populations require special protections. How will you obtain informed consent, protect subject confidentiality, and prevent undue coercion?

Only smoking cessation medications that are safe in pregnancy will be offered to/discussed with any subjects who are known to be pregnant. Women of child bearing potential will be informed if any smoking cessation medications are potentially unsafe in pregnancy. In general, it the patient’s PCP who will be prescribing smoking cessation medications.

13.0 Design/Procedure

13.1 Design

This study is:

- Investigator initiated
- Sponsor initiated

This study is:

- Social/behavioral/educational research only (no biomedical interventions)
- Involves biomedical interventions and/or FDA regulated products (biomedical only)
- Combines biomedical and social behavioral aspects
- Chart/record/data base review only
- Repository only

Data/samples collected for this study involve:

- Retrospective data/samples only
- Prospective data/samples only
- Retrospective and prospective data/samples

13.2 Design - Read only. Migrated form INSPIR I.

Categorize your research:

Other:

13.3 Discuss the research design including but not limited to such issues as: probability of group assignment, potential for subject to be randomized to placebo group, who is responsible for the randomization at local site, use of control subjects, etc.

We will conduct a randomized controlled trial (RCT), randomizing 552 patients to the intervention condition (patient navigation and financial incentives) or an enhanced traditional care (ETC) control condition. Our primary outcome is biochemically confirmed smoking cessation at 12 months. Our intervention is based on motivational interviewing principles (e.g., tailored to participant’s level of confidence and importance of quitting) and behavioral economics to encourage patients to utilize smoking cessation resources (e.g., quit lines, discussing smoking cessation with their PCPs, smoking cessation groups).

Randomization to the study conditions will be by individual patient. We will randomize patients to condition using the Urn Randomization Program, which allows for randomization of participants to two randomization groups while balancing on additional variables. To ensure equivalence across treatment conditions, we will stratify random assignment on the basis of stage of change since this would likely impact study outcomes (e.g. the percent of persons who increased motivation to quit,
engaged in treatment resources, and were abstinent). There is a risk of contamination between patients assigned to the navigation + incentives arm and those assigned to the ETC arm. We will minimize this risk by having the navigator based centrally in the Section of General Internal Medicine; she would only have a presence in the clinics when meeting a newly enrolled participant. S/he will be trained to work only with the patients assigned to the navigation + incentives arm.

13.4 Procedure

Describe in detail the experimental design, including all materials and all procedures to be performed in sequential order as they will be performed. Clarify which procedures/test articles are investigational and which are part of standard clinical care. This description may include:

1. methods
2. specific information concerning experimental interventions, such as dose and frequency of drug (and placebo) administration, or deception/debriefing process for social behavioral studies
3. number, frequency and duration of subject contacts (visits, telephone calls, mail outs, emails)
4. entire duration of participation for a single subject
5. any additional requirements of the subject (post treatment follow-up, diary cards, questionnaires, etc.

(Note: For multiple sites, indicate which of the procedures will be done at any other sites other than BUMC (see Study Site Information). Attach, in the Study Attachments section, copies of any surveys, questionnaires, and other data collection instruments.)

Enhanced traditional care (ETC) control condition. Patients randomized to the ETC control condition receive a low literacy smoking cessation brochure and a list of hospital and community resources for smoking cessation. The study research assistant will give these materials to all participants at the time of study enrollment regardless of study condition, as this intervention content is common to both treatment conditions. This control condition standardizes the provision of information regarding evidence-based smoking cessation resources, allowing for a more rigorous evaluation of the Patient Navigation/Financial Incentives intervention. In routine clinical care at Boston Medical Center, medical assistants ask all patients in the primary care practices about their smoking status, which is documented in the medical record. In usual care at BMC, patients do not receive a low literacy smoking cessation brochure or a list of hospital and community resources for smoking cessation. The brochure and list of resources are an enhancement of usual care and are provided to ETC control subjects upon enrollment.

All participants (those in ETC control condition, and patient navigation and financial incentives condition, described below) will complete assessments at baseline, 6, 12 and 18 months (please see attachment). Measurements assess the primary and secondary outcomes of the study, and potential mediating and moderating variables as well as process variables. A blinded, trained research assistant will administer survey assessments at the primary care practices (baseline) and over the telephone (6, 12, and 18-month). All assessments require < 30 minutes to complete. Participants will receive incentives for completion of 6-, 12- and 18-month assessments.

For participants in the patient navigation and financial incentives condition, we will assess participants’ perceived impact/helpfulness of each intervention component at the 6-month assessment.

Participants in both study groups who self-report ≥7 days of abstinence at the 6, 12, or 18 month follow-up period will be asked to meet with a research assistant at the clinic or the participant’s home to provide a saliva sample via oral swab for cotinine analysis (or a urine test if they are on nicotine replacement therapy). The saliva swab is a painless procedure that takes a few seconds.

Patient navigation and financial incentives condition

Patient navigation. Patients randomized to the intervention condition will receive a low literacy smoking cessation educational brochure and a list of hospital and community resources for smoking cessation (again, this intervention content is common to both treatment conditions). At the time of enrollment, intervention patients will be introduced to the patient navigator either in person or by telephone. The intervention patients will receive navigation from one of two trained navigators, based centrally in the Section of General Internal Medicine. Our two navigators will have completed high school, and will have had extensive experience doing community health outreach. Patients will receive up to four hours of patient navigation, largely
Description of the patient navigation interactions. The first patient navigation meeting will often take place before or after a patient’s medical appointment. Depending on the participants’ availability, this meeting could take place on the day of enrollment or on a subsequent date. The meeting will be guided by a script that has already been developed (see attachment). The script uses motivational interviewing (MI) strategies to do the following: (1) assess stage of change for smoking cessation; (2) assess and reinforce any prior abstinence from smoking and/or any efforts made to reduce or quit smoking; (3) explore the patient’s motivation to quit smoking, drawing on recent illness, financial situation, and family situation as appropriate; (4) advise about the risks of smoking/benefits of quitting; (5) discuss past experience with utilizing cessation support; (6) describe/discuss options for smoking cessation -- quitline, PCP visit, smoking cessation groups -- discussing the process and success achieved with each program, exploring the pros and cons of each option tailored to the patient’s needs; (7) determine how the navigator can facilitate access to the preferred approach; (8) explore barriers to accepting a cessation referral (e.g. lack of trust, cost, misconceptions about treatment (e.g. that NRT is more harmful than cigarettes); (9) brainstorm strategies to address barriers; (10) elicit commitment to accept referral to smoking cessation treatment, if patient is willing, and (11) elicit commitment to accept another navigation call/meeting and discuss timing. The navigator can also connect participants to resources to assist with problems that keep them from stopping smoking, such as insurance, housing, or financial problems. The patient navigator may also be in touch with the participant’s primary care provider, asking him/her to place a referral to a smoking cessation group, for example. The navigator will also document in the medical record any referrals that she has made to smoking cessation resources outside of Boston Medical Center.

Subsequent navigator-patient interactions follow a similar format, and will take place either in person or over the phone, according to the participant’s preference. The length of the first meeting will vary depending on the individual participant, but should take no more than one hour.

Navigator training and evaluation. The Education Coordinator at the Brief Negotiated Interview-Active Referral to Treatment (BNI-ART) Institute at BU School of Public Health, an experienced MI trainer with expertise in training patient navigators, will deliver a standard, validated MI training program to the navigators. This training will take place over 5 days and will focus on developing MI skills and delivery of the navigator intervention. MI skills will be learned through didactics, demonstrations, role-plays, reading assignments, and video. The navigators will be evaluated on both process (helpfulness, warmth, empathy), and content (intervention adherence). The navigators will practice the intervention protocol with two to three “practice” participants and achieve proficiency prior to delivering the intervention. Training will also include information about tobacco dependence and treatment, barriers to treatment engagement among low SES and minority patients, and treatment resources. Following training, Drs. Lasser and Quintiliani will meet weekly with the navigators to discuss difficult cases, and monthly to ensure skill maintenance by reviewing audiotapes of interactions and providing corrective feedback. Every other month, the Education Coordinator at BNI-ART will also review a randomly selected audiotape to provide an ‘external’ perspective on the navigator’s performance and provide that feedback to Drs. Lasser and Quintiliani and both navigators. The Education Coordinator will not be engaged in the research, and thus is not listed on the protocol.

Preserving internal validity/treatment fidelity, and program tracking. The intervention is manual-based. After each patient interaction, the navigators complete a checklist of intervention components that were delivered. We will use these checklists to ensure that the intervention is delivered as intended, and to estimate intervention “dose” and treatment exposure. We will audiobuffer one interaction per participant with permission from the participant; Drs. Lasser and Quintiliani will monitor tapes for protocol adherence, auditing at least 50% of the tapes at the beginning of the intervention period, until adherence to the checklist reaches a proficiency threshold, and between 20-50% toward the end of the intervention period, to ensure continued adherence.

Financial incentives. The navigators will be aware that participants are eligible to receive financial incentives, but will not provide them to patients. The research assistant will provide incentives following assessments and biochemically confirmed cessation (described above; and a certificate of completion if a participant has attended a smoking cessation group). The financial incentives will be similar to those used by Volpp et al in an earlier successful smoking cessation study: $250 for cessation of smoking within six months after study enrollment, as confirmed by a salivary cotinine or urine
anabasine/anabatine test, and $500 for abstinence for an additional six months after the initial cessation, as confirmed by a salivary cotinine or urine anabasine/anabatine test. Study staff will mail money in check form to patients who have successfully quit smoking or completed a smoking cessation group. Other studies (e.g. those that are NIH funded) of financial incentives to promote healthy behaviors among low SES participants are currently using checks to compensate patients.

4. entire duration of participation for a single subject

   1. 18 months.

5. Any additional requirements of the subject (post treatment follow-up, diary cards, questionnaires, etc.

As noted, above, all participants will complete assessments at baseline (in person), and at 6, 12 and 18 months (over the telephone; please attachments for each assessment). Measurements assess the primary and secondary outcomes of the study, and potential mediating and moderating variables as well as process variables. A blinded, trained research assistant will administer survey assessments at the primary care practices (baseline) and over the telephone (6, 12, and 18-month). All assessments require < 30 minutes to complete. Participants will receive incentives for completion of 6-, 12- and 18-month assessments. We will assess participants’ perceived impact/helpfulness of each intervention component through surveys (including open-ended questions) following the intervention.
Outcomes (Indicate anticipated primary and any secondary outcomes and how they will be measured):

Our primary outcome is **smoking abstinence at 12 months post-enrollment**. Because smokers who successfully quit for even a short period are more likely to quit long-term, we will measure the point prevalence of self-reported smoking cessation that is confirmed biochemically at 12 months. We define this outcome as no smoking within the past 7 days as defined by self-reported abstinence in the past 7 days AND biochemical validation of abstinence. Those who self-report ≥7 days of abstinence at the 6, 12, or 18 month follow-up period will be asked to meet with a research assistant at the clinic or the participant’s home to provide a saliva sample via oral swab for cotinine analysis, which is the measure of choice because of its sensitivity and specificity. Salimetrics, LLC, State College, PA will conduct salivary cotinine analysis. If a participant is using nicotine replacement therapy, the test of choice is a urine test for anabasine/anabitine. Participants will receive $15 dollars to provide a saliva or urine sample. We categorize as smokers all patients who 1) self-report abstinence, but are identified as smokers via biochemical validation (cotinine level greater than 15, or positive anabasine/anabitine ), 2) self-report abstinence, but refuse biochemical verification, or 3) cannot be located.

We will also study whether linkage to/utilization of smoking cessation treatment at 6 and 12 months post-enrollment mediates the hypothesized primary outcome (smoking cessation). We have designated this outcome as a dichotomous variable, Y/N, based on a) completion of ≥1 quit line counseling session (based on report from MA DPH Quitworks program, or self-report if another quitline is used); OR b) ≥1 PCP visit in which smoking cessation treatment is discussed (medical record review of progress notes); OR c) completion of ≥1 session of a BMC smoking cessation group (medical record review or self-report if another group is used). We will also examine use of cigars or chewing tobacco as a secondary measure.

Estimated Duration of Enrollment (Indicate how long will it take to recruit the required sample size):

We estimate that it will take 8 months to recruit 552 patients, based on our recruitment experience from the pilot study.

Estimated Duration of Entire Study (Indicate estimated duration from initial IRB approval through data analysis to close of study):

We estimate the study will take 5 years; 2.5 years to complete the intervention and assessments, and an additional 2.5 years to conduct data analyses and write manuscripts.

13.5 Study Attachments

*You must attach to this application all surveys, interviews, questionnaires, focus group outlines, etc. that will be used in this study. The IRB must review these materials as part of its review. If these items are included as part of the grant application they do not have to be submitted again. Failure to provide this information could result in a delay in IRB review. If some of the materials are not finalized- submit the DRAFT versions. The final versions will need to be approved by the IRB via an amendment PRIOR to use.*

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No Document(s) have been attached to this form.

14.0 Sample Size/Specimens/Data Analysis

14.1 Sample Size (Click on the Help icon for instructions)
How many subjects (or records, or specimens, or charts) will be enrolled in this study?

<table>
<thead>
<tr>
<th>Subjects under BU/BMC PI (click on the Help icon for instructions)</th>
<th>For multi-center studies only - Total worldwide subjects, including subjects under BU/BMC PI</th>
</tr>
</thead>
<tbody>
<tr>
<td>552</td>
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</table>

**Subjects under BU/BMC PI Sample Size Calculations (Table's grand total should equal to the Subjects under BU/BMC PI sample size):**

If this protocol involves more than one cohort or study phase please specify anticipated sample size for each cohort /study phase.

<table>
<thead>
<tr>
<th>Cohort (study group)</th>
<th>Consent and/or fully participate in study</th>
<th>Expected dropouts, withdrawals, and terminations</th>
<th>Screened and not enrolled - for studies where subjects were placed ‘at risk’ during screening (e.g., blood draws, collection of identifiable information)</th>
<th>Total for this cohort</th>
</tr>
</thead>
<tbody>
<tr>
<td>ETC control group</td>
<td>276</td>
<td>188</td>
<td>0</td>
<td>464.00</td>
</tr>
<tr>
<td>Patient navigation + financial incentives arm</td>
<td>276</td>
<td>188</td>
<td>0</td>
<td>464.00</td>
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</tbody>
</table>

**14.2 Sample Size Justification**

Indicate why you chose the sample size proposed. Provide your sample size calculations. If this is a pilot study, this justification does not necessarily require a formal sample size calculation, but should provide a rationale for choosing the sample size proposed (e.g. to estimate a mean to a certain accuracy, to determine if the response rate is above a certain percentage, etc.) Note: Once the IRB approves a certain study sample size then you may not enroll beyond that sample size without first obtaining approval from the IRB. **** In determining your sample size be sure to allow for screen failures and study drop-outs. Explain how many evaluable subjects you will need to end up with to answer your study question and how many subjects you will need to enroll and consent to achieve this number. The IRB counts study subjects starting when they are screened/consented.

We have based our power calculations on estimates of the outcomes from prior research. While we will recruit more than 176 participants per study arm to account for a possible exclusion of non-smokers are the consent has been completed, we have powered the study to account for a 50% potential loss to follow-up of 176 participants per study arm, based on estimates from other studies. With an estimated sample size of 88 per study arm, we will have 88% power to detect a 5% vs. 20% difference in cessation rates between the 2 groups, with a one-sided alpha of .05.

**14.3 Data Analysis**

Provide a description of your plan for data analysis. State the types of comparisons you plan (e.g. comparison of means, comparison of proportions, regressions, analysis of variance). Which is the PRIMARY comparison/analysis? How will the analyses proposed relate to the primary purposes of your study? If you are doing qualitative research please state how comparisons will be made.

We will first run analyses to assess baseline comparability of the intervention and ETC control group. In this analysis we will examine number of prior quit attempts in each group. If necessary, we will control for any baseline differences in subsequent analyses.
We will then examine descriptive statistics of the primary outcome, smoking cessation at 12 months. For categorical outcomes of engagement and cessation, we report percentages and 95% confidence intervals, for continuous outcomes we examine means, standard deviations, and ranges. In order to determine if the patient navigator/financial incentives condition achieves greater smoking cessation at 12 month follow-up compared to ETC participants, we will compare groups using chi-square tests and note differences that are statistically significant at the =0.05 level. Analyses will be based on intent-to-treat. Because participants may receive varying “doses” of the patient navigation intervention, we will also analyze the intervention effect according to the total amount of time the navigator spends with each participant, and whether participants received a “minimum dose” of the intervention, defined as at least one in-person meeting with the navigator. We will use multiple logistic regression to control for potential confounders identified in bivariate analyses as well as variables of a priori clinical significance (gender, age, race, ethnicity, and insurance). We will utilize odds ratios with 95% confidence intervals to determine the relative magnitude of the adjusted association for each variable. Independent variables with strong correlations may result in collinearity. To address collinearity, we will construct separate models, each with one of the variables, and assess both the C statistic and the coefficients for the other variables in the model. We expect the majority of missing data to be due to dropouts due to moving or failure to remain in the study. We will investigate whether missing data is associated with patient characteristics. While data may not be missing completely at random, it may be reasonable to assume that data are missing at random. If this is the case, multiple model based imputation methods originally developed for sample survey data is applicable to clinical trials with dropouts.

15.0 Potential Risk/Discomforts

15.1 Lists the possibilities for risks of harm or discomfort to subjects as a result of their participation in the research.

This study entails a risk of breach of confidentiality and privacy for completion of study surveys, self-reported smoking behaviors during follow-up, and/or biochemical test results. Due to the financial interventions in this study, we will be collecting social security numbers (only from the study arm which receives financial incentives for smoking cessation) so that we can complete W-9 forms for participants receiving incentives. Accidental disclosure of social security numbers could lead to identity theft.

We will be asking participants about stress, chaos, and hassles in their life. There is a very small risk that answering some of these questions may cause participants some distress.

Donation of salivary or urine samples for cotinine (or anabasine/anabitine) testing poses minimal risk. It is a simple sample of a few milliliters of saliva that can be obtained in seconds, or a standard urine test. Risk involved is limited to that of inconvenience and disclosure and breach of confidentiality.

15.2 Provide a description of how risks will be minimized.

We will use commercial-grade encryption to protect social security information in transit. Social security numbers will only be used to generate W-9 forms and will be deleted once they are no longer needed. Names and addresses will be stored in encrypted databases. These data will be viewable only by the research assistant. All other researchers will be able to view only participant ID numbers.

In our pilot study we asked subjects about stress, chaos, and hassles. We did not observe that participants experienced distress. We believe the risk is minimal. Moreover, these questions are routinely asked in clinical care.

Urine and saliva samples will be coded with an identification number before being sent off-site for testing.

Patient navigators will be collecting data that may be personal and/or sensitive—they will receive training in how to handle these data securely (e.g. subject logs in excel spreadsheets will be de-identified and kept on a password-protected computer) A list of numeric identifiers and subject names will be kept in a locked file cabinet in the navigator’s office.

The PI with the assistance of the trained research assistant will perform all electronic medical record reviews, 6 and 12 months after the subject has signed the informed consent and enrolled in the study. She will review records for the following information:

1) whether the subject has had a PCP visit in which smoking cessation treatment is discussed
2) Whether subject attended ≥ 1 session of a BMC smoking cessation group
3) Whether subject was prescribed a medication for smoking cessation during the study period (nicotine, bupropion, or
She will abstract data into a standard electronic form with a numeric identifier for each subject. The list of numeric identifiers and subject names will be kept on a password protected BMC computer in the PI's office.

### 16.0 Data & Safety Monitoring

**16.1 Data and Safety Monitoring Plan (DSMP)**

**CLICK ON THE HELP ICON (?) FOR MORE INFORMATION ABOUT DSMPS**

**16.2 Adverse events (AEs), serious adverse events (SAEs), Unanticipated Problems (UPs). (Check all that apply)**

- [ ] AEs, SAEs, are defined in an attached detailed protocol.
- [ ] This is not a drug/device study or an intervention study. Only AEs/SAEs and UPs that are related or possibly related to the research will be collected and reported.
- [ ] This is a survey/interview/observational study. The only risks are related to confidentiality. No AEs/SAEs will be reported unless they meet the definition of an UP. Security/confidentiality breaches will be reported to the IRB as UPs.
- [ ] A DSMP has been created using the BUMC DSMP template and attached in the Study Attachments section below.
- [ ] Other definitions will be used for AEs/SAEs, and UPs. Describe below.
- [ ] We will NOT follow the BUMC policy for reporting AEs/SAEs and UPs. Describe alternate plan below.

*Unless specified the expectation is that BUMC policy will be followed for reporting AEs, SAEs, and UPs. Click here for link to BUMC policy*

This is a randomized controlled trial that is of minimal risk. The only risks are related to confidentiality. No AEs/SAEs will be reported unless they meet the definition of an UP. Security/confidentiality breaches will be reported to the IRB as UPs.

Because this is a minimal risk randomized controlled trial, we will not convene a data safety and monitoring board. The sample size is too small to warrant any interim analyses. The principal risk subjects face is loss of confidentiality.

**16.3 Frequency of monitoring. How often will the data be monitored by the entity/entities selected in question above? Provide additional details in the text box below.**

- [ ] DSMB/DMC/Independent Monitor will provide written reports annually
- [ ] DSMB/DMC/Independent Monitor will provide written reports every 6 months
- [ ] Other details about monitoring activities including by CRO & sponsor (describe below)

**16.4 Stopping rules: for individual subjects and for the study as a whole. Not all studies require stopping rules. Describe any stopping rules in the box below.**

Because the study is minimal risk, we will not implement stopping rules.

**16.5 Study Attachments**

Here you can attach any Data and Safety Monitoring Plan documents including BUMC DSMP template, DSMB charter, and any other related documents.
16.6 Read-only. This question was migrated from INSPIR I. Outside/Independent Monitors

**For some studies, for example, those that are moderate to high risk, the IRB may require data/safety review by an outside monitor. (check all that apply)**

This study is a minimal risk study and no independent monitoring is required.
☐ Yes  ☐ No

This study will have an independent Data and Safety Monitoring Board. If yes, attach the DSMB charter.
☐ Yes  ☐ No

This study will have an independent Data Monitor. If yes, insert information about the monitor in the box below.
☐ Yes  ☐ No

This study will be monitored by a clinical research monitoring organization CRO. If yes, specify details in the box below.
☐ Yes  ☐ No

Independent Data Monitor and/or CRO Details:

---

17.0 Potential Benefits

17.1 Describe potential benefit(s) to be gained by the individual subject as a result of participating in the research.
(Payments to subjects should not be included in this section.)

Potential participants will be informed that they may or may not derive direct benefit from participation in the research. Participants’ chances of achieving smoking cessation due to participation in this research study may be improved because all arms, including the Enhanced Traditional Care arm, entail the provision of features that may promote cessation that would not otherwise be available to participants per usual care at BMC. Participants may benefit from this study by being counseled by a patient navigator, who can help them become involved in smoking cessation programs. If participants achieve cessation, they would benefit by reducing their risks for many tobacco-related diseases.

---

18.0 Potential Benefits - Cont.

18.1 Describe potential benefit(s) to society and scientific/medical knowledge in the research.

This research is being conducted with the primary goal of producing knowledge, and so the primary benefits to be gained are those related to the knowledge that the research may produce. An accurate understanding of the effects of this intervention on improving access to smoking cessation programs and leading to smoking cessation itself is crucial in reducing disparities.

---

18.2 Risk to Benefit Ratio

**Describe how risks to subjects are reasonable in relation to anticipated benefits:**

In light of the tremendous benefits to public health and individual smokers of developing more effective smoking cessation programs, as well as our efforts, outlined above, to mitigate all risks associated with this study, we believe that this study
presents a highly favorable risk-benefit ratio for participation.

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<tr>
<th>19.0 Recruitment Procedures/Materials</th>
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<tr>
<td>19.1 Recruitment Procedures</td>
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</table>

Who will recruit subjects for this study?
- [ ] PI
- [x] PI's Staff
- [ ] Research subject (e.g., recruitment of family member into genetic studies)
- [ ] Third Party

Third Party Info:

Describe in detail how the research population will be identified and your methods for contacting potential subjects. If this study is a chart review or medical record review, explain how you will identify potential records to be reviewed.

The recruitment procedure is as follows: Research assistant 1) distributes study fact sheet in waiting room of the BMC general internal medicine primary care clinics; 2) invites patients to participate in the screening process to determine eligibility; 3) administers a brief pre-screening survey to determine eligibility; the screening does not involve collection of any PHI. Only responses without identifiers will be recorded for assessment of eligibility. 4) obtains written informed consent for eligible and interested patients. 5) confirm smoking status in EMR or carbon monoxide meter. 6) and then administers baseline assessment measures. We estimate that we can recruit 552 patients, as a full-time research assistant will be able to recruit 12 patients per week over eight months.

We will also employ a second recruitment strategy; the BU RESPECT registry. We attach an e-mail that will be sent out BMC patients who are part of the RESPECT registry.

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<tr>
<th>19.2 Recruitment Material</th>
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Add any recruitment material that will be used in the table below. If a video, submit the tape. If a website, provide the URL.

No records have been added.

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<th>19.3 Recruitment using the StudyFinder website</th>
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The BUMC Study Finder is a medical campus website that lists research studies for public view. If you are using Study Finder to recruit subjects, you should complete the Study Finder Form in the Submission Forms section of INSPIR.

**Will you be listing your study in Study Finder to recruit subjects?** If “yes,” select “yes” below and complete the Study Finder Form (located in the Submissions Forms section of the Study Management view of INSPIR II - click on the (?) icon for instructions).
19.4 Screening

Will there be any screening procedures done to determine subject eligibility in this study?
- Yes
- No

19.5 Study Attachments

Here you can attach any study related documents including, but not limited to, recruitment material related documents.

Please attach copies of materials such as: posters, flyers, newspaper ads, script for telephone recruitment (if any).

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No Document(s) have been attached to this form.

20.0 Screening Procedures

20.1 Indicate in the text boxes below if any screening procedures will be done to determine subject eligibility. The information in this section should be consistent with the Design/Procedure Section (specifically how will you screen people to determine that they meet the inclusion/exclusion criteria.)

**Describe all screening procedures that will be conducted for this study:**

When study staff interacts with interested individuals, study staff will ask if they can ask questions to screen him or her for eligibility.

**What data will be collected during the screening procedure(s):**

Study staff will ask potential participants if they smoked >10 cigarettes/day in the past week, if they are currently trying to quit smoking, if they speak English, if they plan to move within the next 6 months, if they are 18 years of age or older, if they have a telephone, and if they have a general internal medicine PCP at BMC;

**What data will be retained during the screening procedure(s):**

For those who are eligible, we will retain name, study id, contact information, and eligibility status (yes/no). For those who are not eligible, we will retain their study ID, eligibility status (no) and reason they were ineligible.

**Will subjects be consented prior to screening?**

- Yes
- No

**What will happen to subjects’ data if subjects “screen out”**?
(If you expect a certain number of subjects to “screen out” be sure to allot for these subjects in the Sample
Size/Data Analysis section.

Subjects who screen out will only have their study ID and reason for being ineligible recorded.

***Note:

In most instances, if identifiable data will be recorded as part of the screening, informed consent is required. The IRB will determine whether verbal consent is allowed or whether written consent is required for screening.

20.2 Study Attachments

Here you can attach any screening forms and screening related documents.

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No Document(s) have been attached to this form.

21.0 Consent Procedures

21.1 Consent Procedures

Will informed consent be obtained for this research?

☐ No (skip the follow up question below)
☐ Yes (answer the follow up question below)

If yes, describe in detail the informed consent process, i.e. who will obtain consent and where, how long will subjects have to consider participating, is consent required prior to eligibility screening. If children will be enrolled, describe the assent process.

The research assistant will ask the participant if he/she can be asked a few screening questions, informing the participant that no information will be recorded in an identifiable way. After being found eligible, the research assistant will review the consent document with the potential participant. Following the consent document, she will describe the study and answer any questions the participant may have. She will then ask all those who are willing to participate to sign the form. If a person would like to think about it, they will be asked to contact us within 1 week if they are still interested in participating. The consenting procedure will take place in a private exam room in the primary care clinic.

If a participant calls in about the study, e.g. from the ReSPECT registry, we will set up a time for the participant to come in and meet with the research assistant to learn more about the study.

21.2 Verbal Consent/Assent - Waiver of Documentation of the Informed Consent

Will this research include an informed consent process, but require a Waiver of Requirement for Documentation of Consent?

☐ Yes  ☐ No

If yes, please explain in the text box below how your study meets one of the two criteria in 45 CFR 46.117(c) (see ? for criteria):

21.3 Waiver of Informed Consent Process

Will this research require a Waiver of Informed Consent?

☐ Yes  ☐ No
If you are requesting that the IRB approve a Waiver of Consent (you will not obtain informed consent) indicate this in the text box below. Explain specifically why you will not obtain consent. Provide as much information as possible to allow the IRB to make a determination based on the required criteria 45 CFR 46.116(d)(1-4). (Click on ? for criteria)

21.4 Assent (from Minors)

Indicate in the text box below if you intend to obtain assent from minor subjects. As a rule the IRB requires verbal assent for minors 7-11 years of age and written assent from minors ages 12-17. Note: if verbal consent is approved by the IRB for the parents/adult subjects (see the Verbal Consent/Assent section above), then verbal assent may be allowed also for 12-17 year olds. ** Be sure to discuss any plans for obtaining consent/assent from pregnant minors.

21.5 Consent by Substituted Judgment

Indicate in the text box below if you intend to obtain consent from a legally authorized representative for cognitively impaired/decisionally impaired subjects. Be sure to include information about how you will ascertain whether or not subjects are capable of consenting themselves and how you will determine who may provide consent for them. ***Note: consent can only be obtained from someone other than the subject with specific IRB approval.

21.6 Non-English Language Consent Forms:

Will this study require one or more non-English language consent forms?

☐ Yes ☐ No

If you answered yes above, for each Non-English language you listed in the Subjects section, add the language to the table below and indicate which consent document you will use:

<table>
<thead>
<tr>
<th>Language</th>
<th>Translation</th>
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**Non-English Language Consent Attachments**

Attach here any documents and forms related to the non-English language consent process, click on the (?) icon for instructions and related forms. Attach here such documents as the Request For Use of Short Consent Form Process, the Short Consent Form in English, and the Short Consent Form in any of the available non-English languages.

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23.0 HIPAA Compliance

23.1 HIPAA

Indicate below all forms that apply to the research. (All forms selected below, except for the HIPAA Authorization, need to be downloaded from the (?) help icon, filled out, and attached to the protocol in the Study Attachments section below)

- HIPAA Authorization (PI will include HIPAA Authorization language in the Consent Form)
- Waiver of Authorization Form
- De-identified Data Form
- Limited Data Set Form
- Preparatory to Research Form
- Decedent Research Form

23.2 Study Attachments

All HIPAA forms selected above, except for the HIPAA Authorization, need to be attached to the protocol in this section. Click on the Help (?) icon for a list of these forms, then click on the form’s link to download and save a copy on your desktop. After completing the form, upload it in this section.

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24.0 Cost/Payment

24.1 Cost

What costs / potential costs will subjects incur (include travel, parking, medication, etc.)? How will the cost of research visits / procedures be covered? Will the subject (or the subject’s insurance) be responsible for any research related costs? If yes, state specifically which items the subject (or the subject’s insurance) will be responsible for and the cost of each.

The subjects will not be responsible for any research-related costs.

24.2 Payment / Course Credit

Payments

If subjects will be paid (money, gift certificates, coupons, etc.) to participate in this research project, please note the total dollar amount (or dollar value amount) and distribution plan (one payment, pro-rated payment, paid upon completion, etc.) of the payment. Describe any other reimbursement that will be provided to
subjects, (i.e. travel, parking, public transportation, etc.). Explain specifically how and when these reimbursements for expenses will be paid. Specify your plan for reimbursement if a subject withdraws from the study.

Subjects in both study arms will receive an incentive of $15, $20, and $25 for completion of the 6, 12, and 18-month assessments, respectively. Participants will receive an additional $15 for completion of the cotinine assay test (or a urine test if they are using nicotine replacement therapy), at the six, twelve and eighteen month follow-up assessments.

At each assessment, there will be a “retention lottery” across both study arms. Each participant will choose a number from 1-100 upon recruitment, e.g., “17.” A number from 1-100 will be randomly generated at every assessment period. If the randomly drawn number was “17” (a 1 in 100 chance), the person would win $100. If more than one participant chooses the same number, each will win $100. To minimize loss to follow-up rates at each assessment, all participants will be entered into the lottery regardless of whether they quit smoking. Participants who withdraw from the study will not be included in the lottery.

For the intervention group, participants will receive $100 for completion of a smoking-cessation program, $250 for biochemically confirmed smoking cessation within 6 months after study enrollment, and $400 for biochemically confirmed abstinence for an additional 6 months after the initial cessation.

Course Credit - If student subjects will receive course credit for their participation in this study. Explain below.

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25.0 Study Attachments

25.1 Attach here any remaining study documents that you have not attached in previous sections.

<table>
<thead>
<tr>
<th>Version</th>
<th>Title</th>
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No Document(s) have been attached to this form.