1.0 General Information

1.1 *Please enter the full title of your study (Spell out acronyms):

ASSESSING SCREENING PLUS BRIEF INTERVENTION'S RESULTING EFFICACY TO STOP DRUG USE: THE ASPIRE STUDY

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

ASPIRE

2.0 Add Department(s)

2.1 List of Departments associated with this study:

<table>
<thead>
<tr>
<th>Primary Dept?</th>
<th>Department Name</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BU - BMC - 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:

Saitz, Richard, 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 in Section 3.4 below.

3.2 If applicable, please select the Protocol Staff personnel:

A) Additional Investigators

Alford, Daniel Peter, MD
Co-Investigator
Bernstein, Judith
Co-Investigator
Chaisson, Christine Ellen, MPH
Co-Investigator
Cheng, Debbie Mien-Pay, ScD
Co-Investigator
Kim, Theresa, MD
Co-Investigator
Maynie, Christine, MD  
Co-Investigator  
Meli, Seville Marquet, MPH  
Co-Investigator  
Palfai, Tibor P., PhD  
Co-Investigator  
Park, Tae, MD  
Co-Investigator  
Samet, Jeffrey, MD, MA, MPH  
Co-Investigator  

B) Research Support Staff  

German, Jacqueline Savetsky, MPH  
- Project Manager  
Gnatienko, Natalia, MPH  
- Research Assistant  
Lloyd-Travaglini, Christine  
- Data Manager/Analyst  
Palmisano, Joseph Nicholas, MA, MPH  
- Data Manager/Analyst  
Vercammen, Joseph Nicholas, MA, MPH  
- Research Assistant  
Wang, Na, MA  
- Data Manager/Analyst  

3.3 *Please add a Study Contact:*

1. German, Jacqueline Savetsky, MPH  
2. Meli, Seville Marquet, MPH  
3. Toussaint, Keshia  
4. Ventura, Alicia, MPH  
5. Wulach, Laura Alexandra, MPH

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).

3.4 If applicable, please add a Faculty Advisor:  

No Faculty Advisors have been added.

3.5 If applicable, please select the Designated Department Approval(s):  

1. Roth, Mary-Tara, RN, MSN, MPH  
   GCRC  
2. Samet, Jeffrey, MD, MA, MPH  
   Department Chair

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

No Administrative Assistants have been added.
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>
<th>Telephone</th>
<th>E-mail</th>
<th>Role</th>
</tr>
</thead>
<tbody>
<tr>
<td>Timothy Ralston</td>
<td>Boston University CRC, Dept of Psychology</td>
<td>617-353-0962</td>
<td><a href="mailto:tralston@bu.edu">tralston@bu.edu</a></td>
<td>Participating Clinician</td>
</tr>
<tr>
<td>Tracie Goodness</td>
<td>Boston University CRC, Dept of Psychology</td>
<td>617-353-0962</td>
<td><a href="mailto:tgoodness@bu.edu">tgoodness@bu.edu</a></td>
<td>Participating Clinician</td>
</tr>
<tr>
<td>Carl Kantner</td>
<td>Boston University CRC, Dept of Psychology</td>
<td>617-353-0962</td>
<td><a href="mailto:ckantner@bu.edu">ckantner@bu.edu</a></td>
<td>Participating Clinician</td>
</tr>
<tr>
<td>Leslie Wright</td>
<td>Boston University CRC, Dept of Psychology</td>
<td>617-353-0962</td>
<td><a href="mailto:wrightl@bu.edu">wrightl@bu.edu</a></td>
<td>Participating Clinician</td>
</tr>
<tr>
<td>Leah Squires</td>
<td>Boston University CRC, Dept of Psychology</td>
<td>917-362-8355</td>
<td><a href="mailto:lsquires@bu.edu">lsquires@bu.edu</a></td>
<td>Participating Clinician</td>
</tr>
<tr>
<td>Tibor Palfai, PhD</td>
<td>Boston University CRC, Dept of Psychology</td>
<td>617-353-9345</td>
<td><a href="mailto:palfai@bu.edu">palfai@bu.edu</a></td>
<td>Co-Investigator</td>
</tr>
<tr>
<td>Frank Dibert</td>
<td>Boston University CRC, Dept of Psychology</td>
<td>617-458-9230</td>
<td><a href="mailto:courage@bu.edu">courage@bu.edu</a></td>
<td>Participating Clinician</td>
</tr>
</tbody>
</table>

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).

The cost and cost-effectiveness analyses will be led by Gary A. Zarkin, PhD and Jeremy W. Bray, PhD of RTI International. Drs. Zarkin and Bray will contribute to developing instruments that will capture information for the cost study and participate in monthly conference calls. In Year 4, Drs. Zarkin and Bray will contribute to the updating of the unit cost information. In Years 4 and 5, Drs. Zarkin and Bray will lead the writing of two research papers that present the findings of the cost and costeffectiveness study. Mr. Jesse Hinde of RTI will also assist with data analysis and manuscript writing.

https://inspir.bu.edu/System_Help_Viewer.jsp?title=iRIS%3A%20Printer%20Friendly%20version%20of%20the%20Application&disppage=Study_App.jsp%3FF... 3/52
Theresa Moyers, PhD, of the University of New Mexico will consult on the assessment of the content and fidelity of the interventions implemented, particularly with regard to motivational interviewing. Nicolas Bertholet, MD, MSc of the Alcohol Treatment Center, Department of Community Medicine and Health, Lausanne University Hospital in Switzerland will contribute to manuscript writing. He will receive aggregate level data analysis only and will not have access to subject level data. Dr. Moyers will contribute towards protocol design and aggregate data analysis only and will not have access to subject-level data. RTI International (Drs. Zarkin and Bray) will receive coded, subject level data and has a signed non-engagement agreement which is included in this application.

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>Show Rev.</th>
<th>Edit/View</th>
<th>Version</th>
<th>Category</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>1.0</td>
<td>Other</td>
<td>Non-engagement agreement with RTI</td>
</tr>
</tbody>
</table>

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).

KSP Info Additional Personnel Info

No records have been added

6.0 Conflict of Interest

6.1 Conflict of Interest Disclosure

By approving this protocol, as Principal Investigator, I am confirming that the appropriate individuals have filed a BU Project Specific Disclosure (PSD) with the appropriate office. 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)

7.2 Funding Details

For instructions on how to complete this section, click on the Help icon.

**Sponsor List**

- **Sponsor Name:** NIH/National Institute on Drug Abuse (NIDA)
- **Sponsor Type:** Federal - NIH
- **Is Primary Grant Holder?** Yes
- **Contract Type:** Grant
- **BU SAP Grant Number or BMC AU Number:** 6002623
- **Award Number:** DA025068
- **Grant Title:** Efficacy/Effectiveness of Unhealthy Drug Use Screening/Brief Intervention Models
- **PI Name:**

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)
- BMC Grants Administration (OGA)
- Charles River Campus Office of Sponsored Programs (OSP-CRC)
- Other

**Funding Notifications:**

- 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.**

No electronic document has been associated.

7.5 Funding Source Info from INSPIR 1 - 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 1. If there are entries in this table, please use them to enter the funding information into the new Funding Source table.
### 8.0 Study Summary

8.1 Provide a brief summary of the project in lay terms (in 300 words or less).

The efficacy of screening and brief intervention (SBI) for drug use among primary care patients is unknown. National organizations do not recommend universal screening. But policy is at odds with the evidence: federal efforts to disseminate SBI are underway, and reimbursement codes to compensate clinicians have been developed. Thus there is a need to study SBI for drug use. The objective of the Assessing Screening Plus brief Intervention's Resulting Efficacy to stop drug use (the ASPIRE) Study, is to determine the efficacy of two models of brief intervention (BI) for decreasing drug use and consequences in primary care patients. In collaboration with a state project implementing SBI as part of a federal program, we will screen patients in a large hospital-based primary care practice for drug use.

We will then enroll up to 728 screen-positive subjects, randomly assign them to 1 of 3 groups, and follow them for 6 months (additionally up to 20 pilot subjects will first enter the study in the BI-E arm, and up to 10 pilot subjects will first enter the study in the BI-S arm). Subjects in 1 intervention group will be assigned to a standard BI model, conducted by trained health advocates implementing a Federal program locally. In another group, subjects will be assigned to an enhanced BI model that includes an optional booster contact and is conducted by master's-level counselors trained and monitored intensively. The control group will receive information (i.e., a written list of local resources to help people using drugs) and, at the end of six months, standard BI if they are still using drugs. The primary outcome is drug use at 6...
months; secondary outcomes are drug use consequences, including HIV risk behaviors at 6 months, and receipt of substance dependence treatment (among those with dependence). We will also compare costs. Results of this study re: efficacy and costs of brief intervention for drug use will be essential for making decisions about disseminating drug use SBI in primary care settings.

9.0 Study Site Information

9.1 Select one:

- Single site research conducted by BUMC investigator(s) (skip question #2 below)
- Multi-site research project - BUMC is a research site but is NOT the main study site (Skip question #2 below)
- Multi-site research - BUMC is the main research site and/or BUMC investigator is the overall PI of the entire study or the FDA sponsor (must complete #2 below)

9.2 Provide details of all other research sites involved in this study.

<table>
<thead>
<tr>
<th>Institution &amp; PI Information</th>
<th>IRB approval for site</th>
</tr>
</thead>
<tbody>
<tr>
<td>No records have been added</td>
<td></td>
</tr>
</tbody>
</table>

9.3 Institution(s) where work will be performed in the U.S: (Please skip this question for new studies - 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 corresponding table above in section 9.2 by cutting and pasting it. The box below should be left blank)

List below all other U.S. sites where study activities (e.g., recruitment, enrollment, testing procedures) will take place. For each institution that is engaged in the research (see DHHS 1/26/99 guidance memorandum on Engagement of Institutions in Research), provide their FWA number and confirm that IRB approval has 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).

No electronic document has been associated.
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 FDA approved 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 institution will rely on BUMC IRB review? ***
☐ Yes ☐ No

**If this study has or will require an IRB Authorization Agreement (IAA) where BUMC investigators will rely on IRB review by another institution, do not check YES here, but instead, go to Exempt-BUMC is Institution B and check yes there.

***If the study is Exempt, then there should not be an IAA.

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 IRB Authorization Agreement (IAA) - BUMC is Institution A

11.1 Are you requesting that BUMC be the IRB of record for investigators from BU-Charles River Campus listed on this protocol?

(Click on the Help (?) icon before proceeding to check whether this study is eligible.)

- Yes
- No

11.2 Institution B information

Provide contact information for all other institution(s) (referred to as Institution B) that will rely on BUMC IRB for IRB review in the table below. Click on the Help (?) icon for details.

Note: You don’t have to provide this information for Charles River Campus. If the other institution does not have an IRB, give name and contact info of institutional official (this is not the name of the investigators from Institution B).
11.3 Institution B Investigators

All non-BUMC investigators from the above institutions must be listed in Section 4 under "external non-BUMC investigators" including BU Charles River investigators.

☐ Yes, I have included all investigators from Institution B in Section 4 (External non-BUMC investigators) section of this application.

11.4 Funding

If investigators from one of the institutions listed above is receiving funding for this study (as the prime awardee or via a sub-award or other) please describe the circumstances below.

Boston University Charles River Campus is the recipient of a subaward from NIDA grant number R01-DA025068 (PI of subaward is Dr. Tibor Palfai).

11.5 Conflicts of Interest

Institution B investigators - Do any of the non-BUMC investigators from Institution B have a COI or potential COI? If yes, please describe the nature of the COI and whether Institution B has a COI program.

COI forms have been completed for BU CRC personnel; no conflicts of interest have been disclosed.

11.6 Describe ALL research activities and procedures involving human subjects that will be performed by the investigators from Institution B. This includes activities that will be performed at BU/BMC by Institution B investigators as well as activities that will occur at Institution B. (Example: Susan Smith MD will consent subjects, draw blood, interview subjects, analyze data.)

BU CRC psychology doctoral students (each listed with the role of "participating clinician" in Section 4) will deliver the 30-45 minute motivational interviewing-based brief intervention (BI) to subjects randomized to the Enhanced Brief Intervention arm (BI-E arm), plus an optional second "booster" session. See Section 11 for a full description of the BI-E protocol. All BIs take place at BUMC. In Year 5, BU research assistants (yet to be named) will code audio recordings of the BI session, labeled with study ID number, in order to evaluate intervention fidelity and quality of motivational interviewing.

Dr. Tibor Palfai, co-investigator, provides clinical supervision to the counselors on the BU CRC and will be involved in analyzing data (in the aggregate) and authoring manuscripts.

11.7 Describe all risks associated with the activities and procedures listed in item #6 above. Be sure to include risks related to data storage and confidentiality.
The enhanced brief intervention is considered a minimal risk activity, as the BI session is not likely to introduce harm or discomfort greater than that encountered in routine clinical care.

While BI-E counselors have access to subject's personal health information, all data is stored on BUMC computer servers and in BUMC office space. Counselors are to ensure that all subject data, including notes from counseling sessions, be stored only on a secure, web-based database maintained by the BUMC Data Coordinating Center. Data regarding BI-E sessions are labeled only with the study ID number.

11.8 PI agreement to the terms of the IAA - PI must agree to these terms.

I understand that, if this request is approved, the BUMC IRB will be the IRB of record responsible for conducting the initial and continuing review of this protocol. I understand that the decision to cede IRB review is made jointly by both IRBs and will not be the decision of the PI. The BUMC IRB, as the IRB of record, will have full responsibility for oversight of all aspects of the protocol. I will comply with the applicable policies of the BUMC IRB. I understand that this agreement is NOT considered approved until a formal IAA (Institutional IRB Authorization Agreement) is signed by the Institutional Officials of both institutions.

I understand that as PI for this study I am responsible the ethical conduct of this study including the oversight of the researchers listed on the protocol from Institution B. Oversight responsibilities include

- Ensuring that a copy of the Human Subjects Training Certificate for each investigator from Institution B has been faxed to the BUMC IRB (617-638-7234)
- Ensuring that all investigators from Institution B are listed in Section 4 (External non-BUMC Investigators Section) of this application
- Ensuring that all the investigators follow the IRB protocol as approved and make no changes to the protocol without the approval of the IRB (except to eliminate immediate harm to subjects)
- Reporting to the BUMC IRB (per policy) any adverse events or unanticipated problems involving risks to subjects or others related to the research activities conducted by the investigators from Institution B
- Reporting to the BUMC IRB any changes related to the status of the Institution B investigators
- Following all applicable HIPAA rules and using appropriate safeguards to prevent the unauthorized use or disclosure of PHI (Protected Health Information)
- Ensuring that Institution B investigators follow any determinations related to conflict of interest from BUMC or from Institution B.

☐ Yes, as PI, I agree to the above terms.
☐ No, I do not agree to these terms (at which case BUMC will not agree to serve as the IRB of record for Institution B investigators.)

11.9 Study Attachments

Here you can attach any study related documents including, but not limited to, IAA related documents. Click on the Help icon to access IAA forms that you can download into your desktop, fill them out, and then upload here.

No electronic document has been associated.

12.0 Purpose

12.1 Background/Rationale/Purpose

Provide background information, study rationale, and purpose / study objective(s) and/or hypotheses for this study.
Drug use is common, associated with numerous health consequences, and often untreated. Screening and brief intervention (SBI) hold promise for decreasing drug use and consequences. However, no studies have tested the efficacy of BI for drug use, identified by screening, among primary care patients. Without evidence, national professional organizations do not recommend universal drug SBI. But, brief interventions (BIs) have proven efficacy for addressing other substance use (e.g., alcohol), and brief valid screening tests are available. Further, large federal efforts are underway to disseminate screening, brief intervention, referral, and treatment (SBIRT), and reimbursement codes for insurers to compensate clinicians for these activities have been developed. The discrepancy between these policy developments and the available science, the promise of BI, and the severity of the drug use problem in the U.S., underscore the urgent need to test BI’s efficacy among adults in primary care.

In order for screening and brief intervention (SBI) to be effective and have widespread impact, they must be feasible in general healthcare settings, such as primary medical care offices. Standard BI models (as in the federal SBIRT programs) are currently being widely disseminated (including at BMC, though in general there is no capacity for universal screening nationally, nor locally at BMC). Enhanced, more intensive models, also feasible in general healthcare settings, have been tested (for alcohol in primary care settings) and show promise of greater efficacy though likely at greater cost. Therefore, it is important to determine whether SBI has efficacy in primary care and what costs and outcomes can be expected with different SBI models.

The specific aims of this proposed study, the Assessing Screening Plus brief Intervention's Resulting Efficacy to stop drug use (ASPIRE) Study, are to determine, in a primary care setting, the efficacy of a standard BI model and an enhanced, more intensive BI model for (1) decreasing drug use in adults; (2) decreasing drug use consequences including HIV risk behaviors in adults; and (3) increasing receipt of substance dependence treatment among adults with dependence. Aim 4 is to determine and compare the implementation and net intervention costs and outcomes of both BI models. We will achieve these aims by implementing a randomized, controlled trial in the primary care setting and by collaborating with an existing state program implementing standard drug SBI as part of the federal SBIRT initiative. We will also implement an enhanced BI based on a model tested by the investigators. More specifically, we will: -- Identify, through screening, patients with drug use in a large hospital-based primary care practice; -- Enroll up to 728 screen-positive subjects (528 with ASSIST scores of 4 or greater, up to 200 with ASSIST scores of 2-3, and up to 30 pilot subjects) in a cohort and follow them for 6 months (ASSIST is a validated drug use screening tool); -- Randomly assign subjects to 1 of 3 groups: i. a standard brief intervention (BI-S) model done by health promotion advocates as part of state implementation of a widely disseminated federal program; ii. an enhanced, more intensive brief intervention (BI-E) model that includes a booster contact, and is conducted by counselors trained and monitored intensively to perform motivational interviewing; iii. Information: a written list of local resources that can help people using drugs, with standard brief intervention offered after 6 months if they are still using drugs; -- Assess all subjects at study entry and 6 months later to determine substance use and...
consequences, including HIV risk behaviors, costs, healthcare utilization and receipt of substance dependence treatment; -- Examine the effects of BI-S and BI-E on the following outcomes: a) drug use (primary), b) drug use consequences including HIV risk behaviors (secondary), and c) receipt of treatment (among those with dependence) (secondary).

The ASPIRE study will provide information to test the following main hypotheses (for those with ASSIST scores of 4 or greater, n=528): 1. An enhanced, more intensive brief intervention model (BI-E) will have greater efficacy than screening and resource information alone for decreasing drug use, decreasing drug use consequences and HIV risk behaviors, and increasing receipt of treatment for those with dependence. 2. A standard brief intervention model (BI-S) will have greater efficacy than screening and resource information alone for decreasing drug use, decreasing drug use consequences and HIV risk behaviors, and increasing receipt of treatment for those with dependence.

The ASPIRE study will also provide information to test a number of exploratory hypotheses. One of these is to test whether among those with ASSIST scores of 2 or 3 (n=up to 200), indicating some - but lower risk - drug use, subjects who are assigned to receive BI-E or BI-S will have less drug use at follow-up than subjects assigned to screening and resource information alone. Patients with these scores are included in clinical interventions but there are no data on effectiveness in the literature.

Finally, we will explore the costs and outcomes associated with each intervention, hypothesizing that although implementation costs for BI-E may be higher, BI-E will have the lowest net intervention cost compared with control and BI-S (where net intervention costs include implementation, future healthcare and crime costs).

This proposed study, the ASPIRE Study, will assess the efficacy and costs of 2 models for brief intervention (BI) for drug use in primary care settings. This study is innovative in taking advantage of a natural experiment involving an existing collaboration between a federal SBIRT program in one state and researchers experienced at implementing studies of SBI in primary care settings. We study a standard BI (BI-S) and a likely more effective but more costly enhanced BI (BI-E) model, which will allow both determination of efficacy (sought by clinicians) and comparison of efficacy and costs (sought by policymakers). Findings will therefore be critical for recommendations about dissemination of drug use SBI in primary care. Efficacious BI models with favorable economic characteristics have the potential to significantly impact the national burden of drug use and consequences; conversely, absence of efficacy or excessive cost would inform policy addressing drug use in primary care.

13.0 Subjects

13.1 Inclusion Criteria

Specify your inclusion criteria for each cohort.

Inclusion criteria List

1. 18 years of age or older
2. Arrived for a visit in primary care

3. Fluent in English

4. ASSIST (see Section 14 for this questionnaire) specific substance involvement score of greater than or equal to (ge) 2 and (also based on the ASSIST) drug use in the past 3 months, indicating recent use of marijuana, cocaine, opioids, sedatives, meth/amphetamines, hallucinogens, inhalants, and other drugs

5. No previous MASBIRT (see grant application for definition) intervention in the past 3 months

6. Able to return to Boston Medical Center in the next 6 months for research study visits

7. Not pregnant (because care systems and resources differ greatly for such subjects)

8. Able to be interviewed by trained research staff (excluding those in acute discomfort or with significantly impaired cognition)

9. NOT participating in BMC’s Office-Based Opioid Treatment program (NOT prescribed Suboxone or Subutex and NOT expected to undergo Suboxone/Subutex induction within a week of screening)

10. Two contacts who can assist with locating the subject for follow-up

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.

13.2 Exclusion Criteria

Specify your exclusion criteria for each cohort.

Exclusion criteria List

1. NOT 18 years of age or older

2. NOT Arrived for a visit in primary care

3. NOT Fluent in English

4. NO ASSIST (see appendix for this questionnaire) specific substance involvement score of ge 2 or (also based on the ASSIST) NO drug use in the past 3 months, indicating recent use of marijuana, cocaine, opioids, sedatives, meth/amphetamines, hallucinogens, inhalants, and other drugs

5. ANY previous MASBIRT (see grant application for definition) intervention in the past 3 months

6. NOT able to return to Boston Medical Center in the next 6 months for research study visits

7. Pregnant (because care systems and resources differ greatly for such subjects)

8. UN-Able to be interviewed by trained research staff (excluding those in acute discomfort or with significantly impaired cognition)

9. Participation in BMC’s Office-Based Opioid Treatment program (prescribed Suboxone or Subutex or expected to undergo Suboxone/Subutex induction within a week of screening)
10. FEWER THAN two contacts who can assist with locating the subject for follow-up

The following data was migrated from INSPIR I (if any). Eventually, the box below will go away. So please remove your answer (if any) 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.

13.3 Subjects (Please choose the appropriate categories for your subjects.)

Gender
Both

Age
☐ Adolescent (15-17 years)
☒ Adult (18-64 yrs)
☐ Child (7-15 years)
☐ Child < 7 years
☐ Fetus
☒ 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

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
13.4 Vulnerable populations require special protections. How will you obtain informed consent, protect subject confidentiality, and prevent undue coercion?

We do not plan to specifically recruit from the vulnerable populations listed. However, subjects who are homeless, women of childbearing potential, students or employees of BU or BMC are not specifically excluded if they are otherwise eligible for the study (in many cases we will not be aware of a persons housing status, employment or potential to bear a child at the time of study enrollment). People with drug use, particularly if they suffer from drug abuse or dependence, may be considered vulnerable populations. As such, we will assure all subjects understand the elements of informed consent, and will take specific steps beyond usual clinical care to protect their confidentiality (see Sections 16 and 17). Additionally, if research staff becomes aware that a study subject is incarcerated at the time he/she is due to complete a follow-up assessment, they will contact the appropriate correctional facility in order to facilitate completion of the assessment via in-person or telephone interview. Incarcerated subjects will be presented with an additional informed consent form specifically for incarcerated subjects which will give subjects the opportunity to accept or decline study participation during incarceration.

14.0 Design/Procedure

14.1 Design

This study is:  This study is:  Data/ samples collected for this study involve:

- Investigator initiated
- Sponsor initiated

- 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
- Retrospective data/samples only
- Prospective data/samples only
- Retrospective and prospective data/samples
Categorize your research:
Other
Other:
Psychosocial, investigator initiated, single center

14.3 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.

The study is a randomized, controlled trial. We will: -Identify, through screening, patients with drug use in a large hospital-based primary care practice -Enroll up to 728 screen-positive subjects in a cohort and follow them for 6 months -Randomly assign subjects to 1 of 3 groups (probability of group assignment equal in all three groups): i. a standard brief intervention (BI-S) model done by health promotion advocates as part of state implementation of a widely disseminated federal program; ii. an enhanced, more intensive brief intervention (BI-E) model that includes an optional booster contact, and is conducted by counselors trained and monitored intensively to perform motivational interviewing; iii. information: a written list of local resources that can help people using drugs, with standard brief intervention offered after 6 months if they are still using drugs. There is no placebo group. --Assess all subjects at study entry and 6 months later to determine substance use and consequences, including HIV risk behaviors, costs, healthcare utilization and receipt of substance dependence treatment -Examine the effects of BI-S and BI-E on the following outcomes: a) drug use (primary), b) drug use consequences including HIV risk behaviors (secondary), and c) receipt of treatment (among those with dependence) (secondary).

Randomization. Subjects will be randomized to 1 of the 3 study conditions after the baseline assessment. This methodology will avoid bias by assuring allocation concealment at the time of the baseline interview. Randomization will be stratified by the presence of dependence, by the drug that concerns the subject most, and by ASSIST score (score = 2-3; score 4 or greater). Stratification will increase the likelihood of similar distribution across randomized groups of subjects with different severity, drug type used, and possibly different response to BI. Dependence will be determined during the baseline assessment with the Composite International Diagnostic Interview Short Form (CIDI-SF) that yields a diagnosis. The CIDI-SF is 94% sensitive and 96% specific; with a high pre-test probability (e.g., in subjects in this study who have all screened positive for drug use, the positive predictive value is >99%). To ensure balance with respect to the number of subjects in each group, the permuted blocks strategy will be used. Study staff will use a web-based system for randomization assignments in which they enter relevant information and receive a unique study identification number and randomization assignment. Study assessment forms will not indicate randomized group.

14.4 Procedure

Describe in detail the experimental design, including all materials and all procedures to be

https://inspir.bu.edu/System_Help_Viewer.jsp?title=iRIS%3A%20Printer%20Friendly%20version%20of%20the%20Application&disppage=Study_App.jsp%3F...
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.)

1.) METHODS:
In this study we will test 2 interventions: a standard brief intervention (BI-S) model involving 1 contact only by trained health promotion advocates and an enhanced, more intensive brief intervention model (BI-E), which includes an optional booster contact, conducted by counselors trained and monitored intensively to perform motivational interviewing (MI). Both interventions involve key elements of BI based on well-established conceptual models and evidence for efficacy: Feedback, Responsibility, Advice, a Menu of options, Empathy, and support of Self-Efficacy (FRAMES), with the counseling delivered consistent with the principles of MI. The key differences appear in the attached table ASPIRE Interventions. We will enroll up to 30 pilot subjects (20 in the BI-E arm and 10 in the BI-S arm).

2.) INTERVENTIONS:
D5.2 Standard Brief Intervention (BI-S): The standard (MASBIRT) brief intervention (BI-S) includes the known effective elements of brief intervention, and the counseling is based on the principles of motivational interviewing (MI). This brief intervention is a Brief Negotiated Interview (known as BNI), modified for use by MASBIRT in emergency, inpatient, outpatient, and primary care settings (see C4 of grant app.). The BI-S involves 4 major parts: 1) establishing rapport and asking the subject for permission to raise the topic of drug use; 2) exploring the pros and cons of use; 3) providing feedback and assessing readiness to change; and 4) advising and negotiating a plan. Before addressing drug use specifically, the health promotion advocate (HPA) gets acquainted with the subject; using a conversational tone, he/she asks patients to tell a little about themselves, describe a typical day, or discuss their goals in general. The HPA also checks whether it is OK with subjects to talk about drug use. Next, the HPA asks the subject to discuss the pros and cons of their drug use (e.g., what they enjoy and enjoy less), using reflective listening to reinforce positive behaviors and ideas and discrepancies between current and ideal behaviors. The HPA can remind subjects about problems raised on the ASSIST if no cons are raised. Next, the HPA provides feedback (based on the ASSIST score) that the subject is at risk for (score <20) or will likely experience (or may already have experienced) drug use consequences. The HPA asks about any risks that might concern the subject and then assesses readiness to change, using a 1-10 scale, to help discuss why they are more or less ready. The HPA shares, if the patient is interested, information about how specific drugs can
affect health. Finally, the HPA provides advice consistent with the subject's goals and negotiates a plan. This plan focuses on addressing the drug(s) used that is/are of greatest concern to the patient. The HPA discusses the subject's confidence to carry out the plan and reinforces resilience factors and resources available. The patient is provided with personalized feedback, including the patient's ASSIST score and interpretation, their pros and cons about behavior change, any plan for change, and resources to help achieve the plan (including the primary care physician and other specialty care resources, contact information, and appointments). Using a provider communication form, the HPA shares screening results (e.g., from preliminary discussions about referral) with the patients primary care physician (see Appendix).

HPA Training and Supervision (see Appendix and grant application section D5.2).

D5.3 Enhanced, More Intensive Brief Intervention (BI-E): Subjects in the enhanced motivational intervention (BI-E) will participate in a 30 to 45 minute brief motivational intervention in primary care and will be offered an optional brief booster, second contact. The intervention is based on the principles of MI and relies largely on strategies adapted from motivational enhancement therapy (Project MATCH). The central task of the interventionist is to engage subjects in a discussion of their drug use patterns, using an empathic, respectful, and collaborative interviewing style. The interventionist uses both a structured feedback form and open-ended questions to elicit the subjects' view of their drug use and thoughts about changing drug use patterns. Although the intervention is client-centered, it is directed toward a number of objectives including (1) enhancing the subjects' awareness about drug-related risks and problems; (2) developing a discrepancy between current drug use patterns and subject values and goals; (3) enhancing self-efficacy for change; (4) and promoting action related to decreasing drug use for those who wish to change. The intervention is designed to achieve these objectives by using a flexible brief intervention format that includes feedback, an open discussion of drug use and life goals/values, and the construction of an action plan related to drug use behavior. The specific characteristics of the intervention (e.g., content, emphasis) will be tailored to subjects' level of drug involvement (e.g., dependence or not), motivation to change, types of negative consequences, and previous experience in treatment, if any. Before meeting with subjects, interventionists will be provided with information from the assessment about the quantity and frequency of drug use, drug-related problems or consequences, and self-report of their readiness-to-change. The interventionists will also have access to the subjects' medical record to look for laboratory test results or medical and psychiatric diagnoses that may be associated with drug consumption. This information will be synthesized to create a simple, brief personalized feedback form that will be utilized as part of the intervention. Upon greeting subjects, interventionists ask permission to share information summarized in the feedback form. Subjects will be provided with information about their drug use in terms of gender specific national norms, costs, and risks for harm (including medical consequences). They will be given an opportunity to ask questions or provide comments about what they heard. The final piece of feedback will be a summary of negative consequences that were provided by subjects. This information will serve as a
transition to a more open discussion of how drug use is involved in their lives (e.g., how drug use influences the pursuit of important goals and values). This open discussion phase of the intervention typically forms the largest portion of the intervention (e.g., 30 minutes) and typically consists of motivational intervention strategies designed to enhance discrepancies about drug use and elicit change talk. In the final phase of the intervention, a drug-related action plan will be generated with subjects when relevant. This action plan may range from something as simple as "I will continue to think about my drug use" to a more elaborate formalized worksheet that includes specific actions to be taken, anticipated obstacles, and contact information. Subjects will also be asked if they want the intervention findings to be shared with their primary care team (e.g., physicians, social workers, nurses). (Note: Results of screening and whether BI was performed are routinely shared as part of clinical care. Plans and other findings may be shared in addition.) Specific requests for referrals will be handled by relevant staff (e.g., social workers) in primary care. At the end of the session, BI-E study group subjects will also be offered an optional phone contact, scheduled within 1-2 months. (A letter may be sent as a reminder.) This optional additional contact serves as an opportunity to continue counseling processes from the initial contact with the subjects and serves a case monitoring function. The additional contact is presented to subjects during the initial session as a service for them based on the concern of the interventionist. The interventionists will re-establish rapport and attempt to re-engage subjects with the issues raised in the in person session. The phone calls themselves will be recorded and assessed for fidelity in the same manner as the in-person interviews. Interventionists will also complete a checklist to summarize the content of the phone contact. As an alternative to the scheduled phone contact, BI-E subjects will be offered the option of meeting with the interventionist in person to continue to discuss drug use (second motivational interviewing session). These subjects will be provided with the counselor's phone number should they desire to initiate this contact before the scheduled contact. In-person contacts will also be recorded.

BI-E Interventionist Selection, Training, and Supervision. See grant application D5.3 for details regarding supervision.

D5.4 Control Group (Information): Subjects randomized to the control group will not receive a BI at enrollment. However, all study subjects will receive screening and its results (that they are at least at risk for drug use health hazards) along with a written list of resources available, including local options (e.g., HPAs, brief treatment, outpatient therapy, all available regardless of ability to pay). In addition, all subjects will be identified at the time of a primary care visit and thus will have the opportunity to discuss their drug use with their primary care clinician. Thus, appropriate interventions are accessible for all (including, of particular importance, for those who have dependence). Finally, after the 6-month research assessment, control subjects who continue to use drugs will be referred to an HPA in the MASBIRT program for BI.

3.) SUBJECT CONTACT: To assess outcomes, follow-up phone interviews will be conducted at 6 weeks (covering drug use, consequences and receipt of treatment) and in-person interviews at 6 months (all subjects) at the GCRU or similar location at BMC or correctional facilities in confidential space, or at a
private community location of subject's choosing (covering all topics in the baseline assessment plus additional questions assessing the influence of perceived discrimination and racial identity on health behaviors). See grant application D6.9 for details regarding follow-up strategies to minimize attrition. Hair samples (head, facial, chest, arm, axillary or leg) are taken at study entry and at 6 month follow-up from all (non-incarcerated) subjects. Recruitment, enrollment and follow-up are done at BMC (and BUMC-GCRU). If a subject is incarcerated at the time of the follow-up assessment, RAs will contact the appropriate correctional facility to schedule the assessment. Incarcerated subjects will be presented with an additional consent form for incarcerated subjects giving them the opportunity to accept or decline study participation during incarceration. Hair samples will not be assessed. Compensation will be deposited in the subject's canteen fund.

4.) DURATION OF CONTACT: The last follow-up interview is scheduled for 6 months after the date of enrollment, however, the window of opportunity to complete this assessment is 12 months from the date of enrollment. Therefore, in-person involvement for subjects could be up to 12 months, however, most subjects will be involved for only 6 months.

5.) ASSESSMENTS: Subjects will be assessed as part of this study using well-validated interview instruments, with the use of Audio-Computer-Assisted Self-Interview, testing of hair samples for drug use (all at study entry and 6 months), assessment of drug treatment utilization in a statewide database, and by audio-recording of counseling sessions. Some of the most sensitive questions (eg, sexual practices) will be asked by a computer that asks questions heard through headphones and answered by touching a computer screen. Details regarding these assessments are provided in both grant applications appended to this IRB application in sections D6.1-6.8 and in E.

Outcomes (Indicate anticipated primary and any secondary outcomes and how they will be measured):

Primary Outcome

Drug use
The primary outcome for Aim I is the percent days use (PDU) in the past 30 days for the drug that the subject identified as concerning them most at study entry. Percent days drug use will be determined using the Form 90/Timeline Followback calendar method.

Secondary Outcomes

Drug Use Consequences including HIV Risk Behaviors
Drug use consequences and HIV risk behaviors will be assessed using the Short Inventory of Problems – Drug (SIP-D) and HIV risk behaviors from the Risk Assessment Battery (RAB) and other published questions that determine unsafe sexual practices. The drug use consequences outcome will be the mean total SIP-D score. The HIV risk behavior outcomes will be the proportion reporting unsafe sex with a primary partner, other partner, or during exchange of sex for money or drugs.

Substance Dependence Treatment
Another secondary outcome is receipt of substance dependence treatment (among dependent subjects only). Screening identifies the entire spectrum of
unhealthy drug use, and the effects of BI on people with dependence are very important, even though BI is not intended as a sole treatment for this group (the goal is linkage to further care). We are interested in the proportions of subjects with dependence who report receipt of substance abuse treatment, defined broadly to include residential, any outpatient treatment (e.g., counseling or therapy), medications, employee assistance programs (EAPs), or mutual-help groups (e.g., NA).

**Additional/Exploratory Hypotheses and Outcomes**

1. For subjects with ASSIST scores of 4 or greater, an enhanced, more intensive brief intervention model (BI-E) will have greater efficacy than the standard brief intervention model (BI-S) for decreasing drug use, drug use consequences and HIV risk behaviors, and increasing receipt of treatment for those with dependence.

2. Among those with ASSIST scores of 2 or 3, subjects who are assigned to receive BI-E or BI-S will have less drug use than subjects assigned to screening and resource information alone.

3. We hypothesize intervention effects on additional outcomes (see below).

4. We hypothesize effects on outcomes of session content within brief intervention groups (see below).

**Outcomes for Exploratory Analyses**

Exploratory hypotheses 1 and 2 listed above in this section will be tested in the same manner as main hypotheses. Exploratory hypotheses 3 and 4 will be tested as described below.

**Drug abstinence**

In addition to improvements in the primary and secondary outcomes, we hypothesize that both BIs, compared with resource information alone, will increase *abstinence from* the drug of concern, both over the past 30 days by self-report and past 90 days by hair testing.

**Any drug use, Medium or heavy use**

We also hypothesize that in addition to drug use, BI will decrease the number of days of medium or heavy use based on, and as defined by, the Form 90D. We also hypothesize that both BIs will decease the frequency and any use of *any* drug (not only the drug of greatest concern), and of any drug or risky alcohol amounts.

**Intervention session content**

Finally, we hypothesize that in these primary care BIs, subjects’ commitment talk will be associated with less substance use and that motivational interviewing (MI)-consistent counselor behaviors will be related to change talk and later decreased drug use.
Hair testing: Qualitative and quantitative tests of drug use (3 month period)
Two additional outcomes will be drug use and drug abstinence by hair testing. We will test all hair samples for a 90-day window of use of marijuana, cocaine, opiates, PCP, and amphetamines. Note that other drugs of interest (e.g. prescription drugs) do not show up on this testing. Also, although we will test both qualitative and quantitative, the clinical meaning of the latter is less than clear across drugs. We will also assess the proportion of those who report recent drug use and compare it with the proportion with any drug use according to hair testing. Note that in addition to the limited types of drugs, testing may be precluded by refusal, alopecia [a medical condition resulting in no hair to assess], or processing error).

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

We anticipate recruitment will take 36 months.

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

The study began in July 2008. We anticipate completing primary analyses by May 2014.

14.5 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 it 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.

No electronic document has been associated.

15.0 Sample Size/Specimens/Data Analysis

15.1 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>758</td>
<td>758</td>
</tr>
</tbody>
</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 <code>at risk</code> during screening (e.g., blood draws, collection of identifiable information)</th>
<th>Total for this cohort</th>
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<tbody>
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No records have been added
15.2 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.

Drug use: To define the limits of the study, we present power calculations to assess the differences we will be able to detect with 90% power for the primary endpoint drug use. It is expected that 728 subjects (and an additional 30 pilot subjects) will be enrolled into the study, and at least 528 will have ASSIST scores of 4 or greater and thus be of interest for the analyses of the effects of BI on unhealthy drug use. With 528 enrolled subjects with an ASSIST score of 4 or greater, we expect to have 474 evaluable subjects (158 subjects in each of the 3 study arms) completing the 6-month follow-up, assuming 10% of subjects will be lost to follow-up. The following calculations assume 2-sided tests, with an overall significance level of 0.05. To maintain an overall type I error rate of 5%, each of the 2 main pairwise comparisons will be conducted at an alpha level of 0.025. For the purposes of power calculations, we consider a simple setting based on a Bonferroni adjustment for multiple comparisons, although in our analyses we will use the Holm sequential correction method, a less conservative approach that will result in higher power than the Bonferroni method.

Based on studies by Babor et al (of marijuana) and Bernstein et al (of heroin, cocaine), we estimate an overall standard deviation of 37 at 6 months for the variable percent days use in the past 30 days. This estimated standard deviation is based on the expectation that 40% of the sample will cite marijuana as their drug of most concern, with 31% citing cocaine, 20% opioids and 9% citing other drugs (e.g., amphetamines, benzodiazepines).

Based on these estimates, we will have 90% power to detect an absolute difference as small as 14.7% between the control group and each of the intervention arms, using a Chi-square test with continuity correction. Differences in drug use of these magnitudes are clinically important. This estimate is consistent with results reported by Babor et al, where the intervention led to an absolute decrease of 20 percentage points in percent days use at follow up. Additional estimates (for secondary outcomes) as well as full citations for the above references appear in the attachment in section S detailing outcomes and analyses.

In addition, we will enroll up to 30 pilot subjects (up to 20 in the BI-E arm and up to 10 in the BI-S arm) in order to test study procedures.

15.3 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.
Main Hypotheses (for subjects with ASSIST scores of 4 or greater): 1. An enhanced, more intensive brief intervention model (BI-E) will have greater efficacy than screening and resource information alone for decreasing drug use, decreasing drug use consequences and HIV risk behaviors, and increasing receipt of treatment for those with dependence. 2. A standard brief intervention model (BI-S) will have greater efficacy than screening and resource information alone for decreasing drug use, decreasing drug use consequences and HIV risk behaviors, and increasing receipt of treatment for those with dependence. Additional and exploratory hypotheses: 1. For subjects with ASSIST scores of 4 or greater, an enhanced, more intensive brief intervention model (BI-E) will have greater efficacy than the standard brief intervention model (BI-S) for decreasing drug use, drug use consequences and HIV risk behaviors, and increasing receipt of treatment for those with dependence. 2. Among those with ASSIST scores of 2 or 3, subjects who are assigned to receive BI-E or BI-S will have less drug use than subjects assigned to screening and resource information alone. 3. We hypothesize intervention effects on additional outcomes (see below). 4. Through coding of intervention tapes from both conditions, we will explore how interventionist and patient in-session behaviors are associated with changes in drug use. We hypothesize effects on outcomes of session content within brief intervention groups.

D9.1 Statistical Analyses D9.1.1 Overview: This study will use an intention-to-treat analysis including all subjects according to their randomized assignment. Descriptive statistics will be calculated for variables at baseline and 6 months. At baseline, all variables will be assessed to see whether there are any differences across treatment arms. Bivariate relationships will be examined using chi-square tests for categorical variables and analysis of variance or Kruskal-Wallis tests, as appropriate, for continuous variables. Exploratory correlation analyses will be performed to identify variables that may be collinear (r > 0.5); they would not be included together in multivariable regression analyses. We will use multiple regression methods for our analyses. Binary outcomes will be analyzed using logistic regression models, continuous outcomes will be analyzed using linear regression models, and count data will be analyzed using Poisson regression models. For continuous variables that are not normally distributed, median regression models will be used to analyze the data. Models will include indicator variables representing study arm and will also control for factors not balanced by randomization. We are interested in testing for all pairwise comparisons between study arms and will adjust for the multiple comparisons using the Holm sequential test procedure.

D9.1.2 Primary Analyses (for subjects with ASSIST scores of ge4): For Aim 1 we will determine whether there are intervention effects on drug use. The primary question will be examined using linear regression models, where the dependent variable is percent days drug use at 6 months. The model will include indicator variables for the treatment arms. Primary comparisons are between each brief intervention arm and control. Secondarily we will assess all pairwise comparisons and adjust for those multiple comparisons using the Holm sequential test. We will also fit multivariable models to assess the contributions of potential predictors of drug use that were not balanced by randomization. Potential confounders to be assessed include baseline...
demographic characteristics such as age, gender and race; number of dependence criteria; substance use including heavy drinking; readiness to change; health care utilization; health status; and medical and psychiatric comorbidities and symptoms. We will assess for effect modification by readiness to change (because of the use of MI in our study) and dependence using stratified analyses or by including interaction terms in regression models.

Secondary Analyses:
For Aim 2 we will examine intervention effects on drug use consequences (Short Inventory of Problems, SIP-D) and HIV risk behaviors (unsafe sex). SIP-D total scores assessed at 6 months will be analyzed using multiple linear regression models. In addition to indicator variables representing treatment group, the baseline SIP-D score will also be included as a covariate. Potential confounders not balanced by randomization will also be controlled for in the analyses. The main HIV risk behavior in this primary care sample is expected to be unsafe sex. In this sample injection drug use is not expected to be common (e.g. 5% or less). As such the HIV risk behavior outcome of interest is unsafe sex. We will record reports of injection drug use though do not expect to be able to detect differences by intervention group in that uncommon behavior in this group. We therefore do not plan to perform hypothesis testing and instead will calculate and report exact binomial confidence intervals around the proportion of subjects in each group using injection drugs. We will determine the effect of the interventions on HIV risk behaviors using multiple logistic regression models to test for intervention effects while adjusting for baseline behaviors (unsafe sex) and potential confounders not balanced by randomization.

For Aim 3 we will determine whether there are intervention effects on the receipt of drug treatment (among dependent subjects). Self-reported receipt of drug treatment at 6 months will be analyzed using multiple logistic regression models. We will determine important confounders and adjust for them in the multivariable regression models.

D9.1.3 Additional Analyses: Additional/exploratory hypotheses described above: We will repeat the primary and secondary analyses comparing the enhanced (BI-E) and standard (BI-S) brief interventions. We will also repeat the aforementioned analyses for subjects with ASSIST scores of 2 or 3. This latter analysis is done to provide estimates for future studies. We will repeat main analyses in subjects with confirmed drug use by hair sample tests at baseline. The outcome any drug use will be analyzed using multiple logistic regression. Similar to the primary analysis, we will compare use of any drug in the brief intervention arms versus control. Analyses of data obtained during the brief assessment from the 6-week research (as distinct from/not the same as the booster) telephone contact will also be conducted. Self-reported drug abstinence, consequences, and receipt of treatment (among those with dependence) will be analyzed to assess whether there appear to be early differences between groups. Finally, we will use 40% of intervention recordings to identify change mechanisms and characterize the interventions using the Motivational Interviewing Skills Code (MISC). We will examine whether motivational interviewing (MI)- consistent (counselor) behavior is associated with commitment talk (patient) and whether either is associated with later drug use. We will also assess whether the association is
moderated by intervention (BI-E, BI-S). Subgroup analyses will likely be of interest in this study. Some subgroups of interest would include people with significant psychiatric symptoms, or those with concomitant unhealthy alcohol use. These exploratory analyses are not detailed herein.
As required by the SF424 Application Guide, we note that we plan to conduct analyses of the intervention effect in gender and racial/ethnic subgroups, although power may be inadequate. There has been too little study of drug SBI to suggest whether these differences should be anticipated.
D9.1.4 Enrollment and Attrition/Missing data: Subjects who meet eligibility criteria and agree to participate will be compared with subjects who were screened and determined to be eligible but declined enrollment on data captured during screening. The 2 independent samples t-test and Fisher's exact test will be used to test for statistically significant differences between subjects who enroll and those who do not. Statistical analyses will test for significant differences between subjects lost to follow-up and those who complete follow-up. One strength of our design is that administrative data regarding some utilization outcomes will be available for subjects who are lost to follow-up; this auxiliary information can be used to help assess whether there are systematic differences in missingness patterns. If there is evidence of informative missing data, statistical adjustments will be considered in the analyses of study hypotheses, including sensitivity analyses using multiple imputation and non-ignorable nonresponse models. In situations where missing data occurs, we will document the reasons for the missing data whenever possible. The proposed study has accounted for a 10% random, non-informative loss to followup and will still have high power with this potential loss in sample size.
See grant for detailed description of outcomes, additional hypotheses and analyses, and cost outcomes and analyses.

16.0 Potential Risk/Discomforts

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

Potential risks for participants include psychological stress from randomization, from the interview or from discovering health disorders during the interviews. These are minimal risks, are not likely, and will be minimized further by selecting subjects who understand the study and are willing to participate. For example, in the HELP Study (grant application Section C2) no interviews were discontinued because of their length or subject discomfort. In at least one case (of 470) in the HELP Study (a much more severely ill population than those recruited for the proposed study), a subject reported current suicidal thoughts in response to a research question; the subject was provided with immediate psychiatric care. In thousands of additional interviews in similar research studies we have noted few instances of current suicidal thoughts expressed as a RESULT of interview questions. Nonetheless, serious mental health symptoms, including suicidal ideations present at baseline, are known to be prevalent in this population. Because we specifically assess this domain in our research interviews, we expect to identify instances of recent suicidal thoughts. When any suicidal ideations are identified via
research assessment or expressed by participants, research assistants will contact an appropriate clinician to assess the subject and provide a recommendation about further clinical care or referrals, if needed. Clinicians who will assess subjects are as follows: When assessments are conducted in clinical spaces, we approach on-site physicians (or nurses or nurse practitioners if directed by the physician) and ask them to assess subjects (these are the patient’s clinician care givers and the responsible caregivers for those patients in these sites). At that point, the subject is under clinical care. Study physicians are also available if appropriate clinical resources are not available in the primary care clinics at the time of the adverse event. For assessments conducted in research space (e.g., the GCRU), the study physicians and psychologist are contacted (Drs. Saitz, Alford, Samet, Palfai). Further, the PI and study physicians are available to respond to subject concerns with referrals as needed should the subject report new psychological distress as a result of the interview.

Loss of confidentiality by someone seeing the responses to interview assessments or any of the data collected for this study such as from state data or hair testing is potentially the most serious risk, though it is very unlikely because specific procedures will be implemented to prevent such disclosure. There is also a risk that subjects may experience loss of confidentiality when research associates make attempts to contact them for follow-up.

16.2 Provide a description of how risks will be minimized.

Risks of psychological distress from interviews will be minimized by using trained interviewers and a standardized interview process. The principal investigator and study physicians and psychologist will be available to assist subjects and make referrals as appropriate, as described above.

To assure confidentiality, each subject will receive a unique identification number and research data collection and data entry forms will be labeled only with this number, and will contain no other individual identification. Only the written informed consent forms, subject locator information, and a master list of subjects and subject study identification numbers will have the subject number and identifying information on them. There will be only one master list of names and identification numbers. These data will be kept in a secure electronic environment accessible to the principal investigator, the project manager and data managers. Tracking information will be kept similarly (accessible to research associates). Computer data will be password protected, and accessible only to research associates needing the information for follow-up purposes. When outside data sources are requested (detailed in the ICF), unique identifiers must be given to the outside agency to match the data; however, none of the information obtained for the study in the research assessments is given to these agencies. Furthermore, the agency provides no additional unique identifying information beyond that which is provided by the study upon returning the matched data.

All subjects will be well-informed of the nature of the study and provide their
consent for the study to reach them via contacts they provide and via BMC
real-time utilization records. When research associates attempt to make any
contact, all communications will be identified as coming from a Boston
Medical Center health study, not a drug abuse study. We have obtained a
Certificate of Confidentiality to further protect against loss of confidentiality.

17.0 Data & Safety Monitoring

17.1 Data and Safety Monitoring Plan (DSMP)

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

17.2 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/interviewobservational 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

Dr. Saitz the PI is responsible for monitoring adverse events. Study staff report these events when they occur and they are reviewed in real time and during weekly meetings, where the statistician, project manager and co-investigators assist with review. Monitored events include stress during interviews, breaches of confidentiality, and any unlikely complications of hair sampling.

17.3 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)

Dr. Saitz the PI is responsible for monitoring adverse events. Study staff report these events when they occur and they are reviewed in real time and during weekly meetings, where the statistician, project manager and co-investigators assist with review. Monitored events include stress during interviews, breaches of confidentiality, and any unlikely complications of hair sampling.

17.4 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.

There are no stopping rules.

17.5 Study Attachments

https://inspir.bu.edu/System_Help_Viewer.jsp?title=iRIS%3A%20Printer%20Friendly%20version%20of%20the%20Application&disppage=Study_App.jsp%3F... 29/52
Here you can attach any Data and Safety Monitoring Plan documents including BUMC DSMP template, DSMB charter, and any other related documents.
No electronic document has been associated.

17.6 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:

18.0 Potential Benefits

18.1 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.)

There may be no benefits to subjects from participation in this study. Subjects in the intervention groups may benefit by decreasing their drug use and consequences; this may also be the case in the control group who will receive information and resources. All subjects may benefit from discussing their health with an interviewer. Potential benefits for incarcerated subjects remain the same. Continued participation in this study will not influence decisions about parole.

19.0 Potential Benefits - Cont.

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

Society, medical science and the health care system may benefit if the intervention is proven effective because it would suggest that drug SBI should be implemented more broadly.

At the end of the study period, continuation of the BIs cannot be guaranteed. However, efforts will be made to secure clinical funding for this program if it is effective, from internal or external sources. The BMC (hospital) has a history of supporting similar programs in the past (Project ASSERT, see grant application C4) to identify patients in the Emergency Department and link them to addiction treatment services). As a result, the continued support of
the program, particularly if proven effective, is a real possibility. In addition, control group subjects will be offered brief intervention if they continue to use drugs.
Data collected as part of this study will be made available to investigators who are part of the study team, or who join the study team. In addition data will be shared with other investigators who propose meritorious analyses to the study publications committee, obtain appropriate regulatory approvals (including IRB and HIPAA Privacy Committee review and approval) and cover costs of data sharing. These investigators will collaborate with study investigators on these analyses. This sharing and these additional analyses promise to allow exploration of additional scientific questions.

19.2 Risk to Benefit Ratio

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

The principal risk of the study is loss of confidentiality and the occurrence of this risk is not likely. Anticipated benefits exist for individual subjects who may benefit from counseling or even from screening (which has led to improvements in some studies). Most importantly, the knowledge resulting from the study has potential to help many if drug SBI is proven effective (and if it is not, to redirect efforts in drug use prevention and treatment to where they may be more effective).
The risks to subjects are reasonable in relation to anticipated benefits and in relation to the importance of the knowledge expected to result from the study. If the intervention were effective, this knowledge would be significant because it would suggest that drug SBI should be disseminated, and it will provide specific information on which BI should be disseminated (BI-S or BI-E) or at least inform health providers about the costs and benefits. This could significantly improve the care of patients at risk for drug problems. As stated above, the principal risk of the study is loss of confidentiality and the occurrence of this risk is not likely. Anticipated benefits exist for individual subjects who may benefit from counseling, or even from screening (which has led to improvements in some studies). Most importantly, the knowledge resulting from the study has potential to help many if drug SBI is proven effective (and if it is not, to redirect efforts in drug use prevention and treatment to where they may be more effective).

20.0 Recruitment Procedures/Materials

20.1 Recruitment Procedures

Who will recruit subjects for this study?
☐ PI
☑ 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.

BMC clinical staff (MASBIRT Health Promotion Advocates [HPAs]) will make patients who are potentially eligible aware of the study and will refer patients to research staff, though these HPAs are not study staff and are not implementing research procedures. All recruitment and enrollment will be at BMC. Immediately after "prescreening", the researcher will be called to come and see the patient for further screening and then consent if eligible and interested.

Subjects will be recruited at BMC primary care clinics in private space. Only patients who have arrived for a primary care visit and who have not received a MASBIRT BI in the past 3 months (known from MASBIRT electronic clinical records) and who are not patients of the OBOT program (confirmed with OBOT program records by Research Assistants [RAs]) will be approached and referred to the study.

Pilot subjects: To test procedures, we will recruit pilot subjects as described above and by calling subjects of the AHEAD study (protocol H-23464) who have given specific consent to be contacted for other studies for which they may be eligible (see AHEAD ICF, pg 6). Subjects will be informed about the purpose of the call (see Pilot Script-Phone) and if interested, undergo screening. Eligible subjects will be scheduled for an in-person visit to complete the relevant pilot procedures.

20.2 Recruitment Material

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

20.3 Recruitment using the StudyFinder website

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).

☐ Yes
☐ No

20.4 Screening

Will there be any screening procedures done to determine subject eligibility in this study?

☐ Yes ☐ No
20.5 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).

No electronic document has been associated.

21.0 Screening Procedures

21.1 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:

There are two stages of screening that determine study eligibility. Currently, for clinical purposes not related to this study, HPAs screen patients presenting for care for drugs, alcohol, and tobacco (using “prescreening” items), and for those with any affirmative answers, the ASSIST questionnaire.

Prescreening for drug use (based on validation in this setting) is "In the past 3 months, how often have you used marijuana, cocaine, heroin or other drugs, or narcotic pain medications, sedatives (benzos), or amphetamines without a doctor's prescription or in greater amounts than prescribed?" An affirmative response to prescreening is consistent with a score of ge 2 on the ASSIST (an eligibility criterion). Thus, patients who respond affirmatively will be offered a referral to speak with a study RA immediately after completing prescreening, prior to completing the remaining portion of the MASBIRT screening and prior to any BI. This is the first stage of screening. In the event an HPA is not available, the RA will prescreen the patient using identical methods.

Patients who prescreen positive on the drug use questions and are interested in the study are then asked the remaining screening questions by a study RA. This second stage of screening is screening that occurs for both research (part 1) and clinical (part 2) purposes. First, the remaining inclusion criteria are assessed solely for research purposes (part 1). Eligible patients then complete the remaining portion of the MASBIRT screener in its entirety (part 2, typically asked for clinical purposes, as described above), which includes detailed questions about recent drug use, including the ASSIST questionnaire. Patients will be returned to the HPA for clinical care if at any point they choose to not participate in further screening or in the trial or are determined to be ineligible.

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

After prescreening positive for drug use, subjects are assessed for research study eligibility: today's date, gender, age/year of birth, language fluency, pregnancy, willing/able to return to BMC, and whether they could provide 2 contacts if enrolled in the study.

If subjects meet these criteria, they then complete the MASBIRT questionnaire in its entirety (which includes the ASSIST instrument).

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

No identifier appears on screening forms retained for research purposes. All screening data will be kept in order to describe those who enroll and do not (external validity) but these data will be anonymous except for subjects who enroll in the study and provide written informed consent (at which time they will be labeled with a study ID).

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.)

Patients will be returned to the HPA for clinical care if at any point they choose to not participate in further screening or in the trial or are determined to be ineligible. Very few patients are likely to drop out after enrollment.

***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.

21.2 Study Attachments
Here you can attach any screening forms and screening related documents.
No electronic document has been associated.

22.0 Consent Procedures

22.1 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.

For eligible subjects, Research Assistants will seek written informed consent to participate in the trial, enroll the subject, and complete baseline assessments before randomization. RAs will explain all study procedures in language understandable to the study population, will stress the voluntary nature of research, and will provide an opportunity for subjects to review the ICF in full before agreeing to participate. Patients who choose not to participate in eligibility screening or in the trial will return to the HPA for clinical care. At enrollment, subjects are specifically asked for permission to contact them should they become incarcerated. Research staff learns that subjects are incarcerated by notification from the subject or subject's contact person, or by contacting correctional facilities directly. Incarcerated subjects will be presented with an additional informed consent form specifically for incarcerated subjects which will give subjects the opportunity to accept or decline study participation during incarceration. Incarcerated subjects will be informed that participation in the study is not related to decisions about parole. Subjects will also be asked during enrollment for their written consent to contact them about future studies for which they may be eligible.

22.2 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):

22.3 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)

We do not seek a waiver of consent for the study as a whole but for the
portion of the screening process for study eligibility that is not already done as part of clinical care (e.g. part 1 of the second stage - research screening, including language fluency, willingness/ability to return to BMC, and the remaining items listed above in Section 20 as part 1 of the second stage screening). In addition, we will check clinical records to confirm participation in the OBOT program prior to or during screening. This information is recorded anonymously by research staff, without identifiers recorded on the screening data form. Once eligible, if subjects wish to consider study enrollment, they will undergo full written informed consent. As such, there is no more than minimal risk for that screening. Subjects will be told the purpose of the screening (to assess study eligibility) and that their participation is voluntary. When MASBIRT staff that routinely implement the prescreening for clinical care are not available, research staff will complete that prescreening as well. In that case, the prescreening remains minimal risk, as it is what occurs in standard clinical practice, and will also be recorded in accordance with current clinical practice. Note: The MASBIRT questionnaire (stage 1 and part 2 of stage 2), which is currently administered as part of standard clinical practice, is not recorded anonymously by the MASBIRT program in accordance with their clinical protocols. However, all data retained for research purposes by the research team (e.g., to compare enrolled vs unenrolled patients to better assess external validity) will be recorded anonymously, without identifiers. Identifying information will be stored only for those subjects who enroll in the study and provide written informed consent as described above.

Below please find a "script" or text that staff researchers use to support their informed consent conversations (this was an attachment in INSPIR I as part of the approved protocol):

**Purpose of the Study**

- This study will look at whether brief discussions affect drug use and/or health for people who use drugs or are at risk for consequences of drug use.

**What Happens in This Research Study**

- If you decide to be in this study, you will be interviewed today, have a hair sample tested for recent drug use, your health records reviewed and you may meet with someone else, either now or later to have a conversation about your drug use. Today’s procedures will take up to two hours. You will be interviewed again 6 weeks from now for about 10 minutes by phone or in person and for a third and last time six months from now for approximately an hour and a half. You will also have a hair sample tested at this last interview.
- You will be compensated $50 for completing all baseline procedures today, including the interview, hair test and the brief discussion, $10 for the brief 6-week interview, and $75 for the 6-month interview and hair
test.
- You will be assigned to one of three groups at random (by chance, like rolling dice). If you are in the first group, you will have a conversation with a healthcare worker for about 10 minutes about drug use and related resources.
- If you are in the second group, you will have a conversation with a counselor who will first review your medical record and some of your research interview answers so that they can better help you and so that you don't have to answer the same questions again. You will have up to two discussions about drug use and related resources for about 30-45 minutes each, the second discussion by phone or in person over the next few weeks.
- If you are assigned to meet with someone else today, that person and your doctor will know the results of the screening questionnaire, and they may let your doctor know about any treatment plans you make.
- If you are in the third group, your current screening questionnaire will not be shared with your doctor, and you will be referred to someone at BMC at your six-month research interview if appropriate.
- Discussions will be audio-taped for research purposes only. Your doctor and other staff in your primary care office will not listen to the audio tape. Research interviews with me will not be audio-taped.

**Risks and Discomforts**

- You may have stress from being assigned to a group at random or from talking about your health, including very sensitive personal issues during the interviews.
- You may find it inconvenient to take time for the interview or to be contacted by study staff reminding you of a research interview.
- If you are in one of the first two groups and meet with someone else to discuss your drug use, a summary of your screening questionnaire will be in your medical record. Anyone you permit to review your medical record might see this summary information and think that you use drugs or have consequences of drug use.
- Although research records are confidential, there is always the possibility that a mistake could be made, allowing personal data to be leaked. However, in 18 years of doing these studies, this has never happened, and it is extremely unlikely in this study.

**Potential Benefits**

- You may find it helpful to answer questions and talk about your health problems.
- If you meet with someone else, you might be more likely to get drug treatment that could improve your health as it relates to using drugs.
- However, you may not receive any benefit from participating.
Costs to Subject

- It will not cost you any money to be in the study.

Confidentiality

- We will be asking you a number of very personal questions, but your answers will always be kept separate from your name and identifying information. Also, your hair test results and audio tapes of discussions will not be labeled with your name.
- Any information kept on paper is kept in a locked file cabinet and electronic files are kept within a highly secured database.
- Other people or groups who may see your information include the Hospital administration or the people who fund this study.
- Even under subpoena, the courts will not have access to any of the information that you give us for this study. Police and parole and probation officers will not have access to any of the information either.
- There are only two exceptions to this rule, and those are for 1) child abuse and 2) plans to harm yourself or someone else. If you report either of these things in your answers to us, we are required by law to report that information.

Your Rights

- All research is completely voluntary. You have the right to refuse to take part in this study.
- You can enroll in the study and later drop out by informing the research staff but you will not be able to take back information that has already been collected.
- Your decision will not affect any health care or benefits you normally receive.
- By signing this form, you are agreeing that you have read and discussed this form with me and have decided to be in this research study.
- If you have any questions or concerns about participating in this study, contact numbers for the research staff are located in the informed consent document.

Incarceration

- We would like to be able to contact you if you become incarcerated during this study. Would you be willing to be contacted by a member of the research team if you become incarcerated during this study?
Other Studies

- Would you be willing to be contacted for future studies?

Purpose of the Study

- This study will look at whether brief discussions affect drug use and/or health for people who use drugs or are at risk for consequences of drug use.

What Happens in This Research Study

- If you decide to be in this study, you will be interviewed today, have a hair sample tested for recent drug use, your health records reviewed and you may meet with someone else, either now or later to have a conversation about your drug use. Today’s procedures will take up to two hours. You will be interviewed again 6 weeks from now for about 10 minutes by phone or in person and for a third and last time six months from now for approximately an hour and a half. You will also have a hair sample tested at this last interview.
- You will be compensated $50 for completing all baseline procedures today, including the interview, hair test and the brief discussion, $10 for the brief 6-week interview, and $75 for the 6-month interview and hair test.
- You will be assigned to one of three groups at random (by chance, like rolling dice). If you are in the first group, you will have a conversation with a healthcare worker for about 10 minutes about drug use and related resources.
- If you are in the second group, you will have a conversation with a counselor who will first review your medical record and some of your research interview answers so that they can better help you and so that you don’t have to answer the same questions again. You will have up to two discussions about drug use and related resources for about 30-45 minutes each, the second discussion by phone or in person over the next few weeks.
- If you are assigned to meet with someone else today, that person and your doctor will know the results of the screening questionnaire, and they may let your doctor know about any treatment plans you make.
- If you are in the third group, your current screening questionnaire will not be shared with your doctor, and you will be referred to someone at BMC at your six-month research interview if appropriate.
- Discussions will be audio-taped for research purposes only. Your doctor and other staff in your primary care office will not listen to the audio tape. Research interviews with me will not be audio-taped.
Risks and Discomforts

- You may have stress from being assigned to a group at random or from talking about your health, including very sensitive personal issues during the interviews.
- You may find it inconvenient to take time for the interview or to be contacted by study staff reminding you of a research interview.
- If you are in one of the first two groups and meet with someone else to discuss your drug use, a summary of your screening questionnaire will be in your medical record. Anyone you permit to review your medical record might see this summary information and think that you use drugs or have consequences of drug use.
- Although research records are confidential, there is always the possibility that a mistake could be made, allowing personal data to be leaked. However, in 18 years of doing these studies, this has never happened, and it is extremely unlikely in this study.

Potential Benefits

- You may find it helpful to answer questions and talk about your health problems.
- If you meet with someone else, you might be more likely to get drug treatment that could improve your health as it relates to using drugs.
- However, you may not receive any benefit from participating.

Costs to Subject

- It will not cost you any money to be in the study.

Confidentiality

- We will be asking you a number of very personal questions, but your answers will always be kept separate from your name and identifying information. Also, your hair test results and audio tapes of discussions will not be labeled with your name.
- Any information kept on paper is kept in a locked file cabinet and electronic files are kept within a highly secured database.
- Other people or groups who may see your information include the Hospital administration or the people who fund this study.
- Even under subpoena, the courts will not have access to any of the information that you give us for this study. Police and parole and probation officers will not have access to any of the information either.
- There are only two exceptions to this rule, and those are for 1) child
abuse and 2) plans to harm yourself or someone else. If you report either of these things in your answers to us, we are required by law to report that information.

Your Rights

- All research is completely voluntary. You have the right to refuse to take part in this study.
- You can enroll in the study and later drop out by informing the research staff but you will not be able to take back information that has already been collected.
- Your decision will not affect any health care or benefits you normally receive.
- By signing this form, you are agreeing that you have read and discussed this form with me and have decided to be in this research study.
- If you have any questions or concerns about participating in this study, contact numbers for the research staff are located in the informed consent document.

Incarceration

- We would like to be able to contact you if you become incarcerated during this study. Would you be willing to be contacted by a member of the research team if you become incarcerated during this study?

Other Studies

- Would you be willing to be contacted for future studies?

Purpose of the Study

- This study will look at whether brief discussions affect drug use and/or health for people who use drugs or are at risk for consequences of drug use.

What Happens in This Research Study

- If you decide to be in this study, you will be interviewed today, have a hair sample tested for recent drug use, your health records reviewed and you may meet with someone else, either now or later to have a conversation about your drug use. Today’s procedures will take up to two hours. You will be interviewed again 6 weeks from now for about
10 minutes by phone or in person and for a third and last time six months from now for approximately an hour and a half. You will also have a hair sample tested at this last interview.

- You will be compensated $50 for completing all baseline procedures today, including the interview, hair test and the brief discussion, $10 for the brief 6-week interview, and $75 for the 6-month interview and hair test.
- You will be assigned to one of three groups at random (by chance, like rolling dice). If you are in the first group, you will have a conversation with a healthcare worker for about 10 minutes about drug use and related resources.
- If you are in the second group, you will have a conversation with a counselor who will first review your medical record and some of your research interview answers so that they can better help you and so that you don’t have to answer the same questions again. You will have up to two discussions about drug use and related resources for about 30-45 minutes each, the second discussion by phone or in person over the next few weeks.
- If you are assigned to meet with someone else today, that person and your doctor will know the results of the screening questionnaire, and they may let your doctor know about any treatment plans you make.
- If you are in the third group, your current screening questionnaire will not be shared with your doctor, and you will be referred to someone at BMC at your six-month research interview if appropriate.
- Discussions will be audio-taped for research purposes only. Your doctor and other staff in your primary care office will not listen to the audio tape. Research interviews with me will not be audio-taped.

**Risks and Discomforts**

- You may have stress from being assigned to a group at random or from talking about your health, including very sensitive personal issues during the interviews.
- You may find it inconvenient to take time for the interview or to be contacted by study staff reminding you of a research interview.
- If you are in one of the first two groups and meet with someone else to discuss your drug use, a summary of your screening questionnaire will be in your medical record. Anyone you permit to review your medical record might see this summary information and think that you use drugs or have consequences of drug use.
- Although research records are confidential, there is always the possibility that a mistake could be made, allowing personal data to be leaked. However, in 18 years of doing these studies, this has never happened, and it is extremely unlikely in this study.

**Potential Benefits**
• You may find it helpful to answer questions and talk about your health problems.
• If you meet with someone else, you might be more likely to get drug treatment that could improve your health as it relates to using drugs.
• However, you may not receive any benefit from participating.

Costs to Subject

• It will not cost you any money to be in the study.

Confidentiality

• We will be asking you a number of very personal questions, but your answers will always be kept separate from your name and identifying information. Also, your hair test results and audio tapes of discussions will not be labeled with your name.
• Any information kept on paper is kept in a locked file cabinet and electronic files are kept within a highly secured database.
• Other people or groups who may see your information include the Hospital administration or the people who fund this study.
• Even under subpoena, the courts will not have access to any of the information that you give us for this study. Police and parole and probation officers will not have access to any of the information either.
• There are only two exceptions to this rule, and those are for 1) child abuse and 2) plans to harm yourself or someone else. If you report either of these things in your answers to us, we are required by law to report that information.

Your Rights

• All research is completely voluntary. You have the right to refuse to take part in this study.
• You can enroll in the study and later drop out by informing the research staff but you will not be able to take back information that has already been collected.
• Your decision will not affect any health care or benefits you normally receive.
• By signing this form, you are agreeing that you have read and discussed this form with me and have decided to be in this research study.
• If you have any questions or concerns about participating in this study, contact numbers for the research staff are located in the informed consent document.
Incarceration

- We would like to be able to contact you if you become incarcerated during this study. Would you be willing to be contacted by a member of the research team if you become incarcerated during this study?

Other Studies

- Would you be willing to be contacted for future studies?

Purpose of the Study

- This study will look at whether brief discussions affect drug use and/or health for people who use drugs or are at risk for consequences of drug use.

What Happens in This Research Study

- If you decide to be in this study, you will be interviewed today, have a hair sample tested for recent drug use, your health records reviewed and you may meet with someone else, either now or later to have a conversation about your drug use. Today’s procedures will take up to two hours. You will be interviewed again 6 weeks from now for about 10 minutes by phone or in person and for a third and last time six months from now for approximately an hour and a half. You will also have a hair sample tested at this last interview.
- You will be compensated $50 for completing all baseline procedures today, including the interview, hair test and the brief discussion, $10 for the brief 6-week interview, and $75 for the 6-month interview and hair test.
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not be shared with your doctor, and you will be referred to someone at BMC at your six-month research interview if appropriate.

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Risks and Discomforts

- You may have stress from being assigned to a group at random or from talking about your health, including very sensitive personal issues during the interviews.
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Potential Benefits

- You may find it helpful to answer questions and talk about your health problems.
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- Any information kept on paper is kept in a locked file cabinet and
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- Other people or groups who may see your information include the Hospital administration or the people who fund this study.
- Even under subpoena, the courts will not have access to any of the information that you give us for this study. Police and parole and probation officers will not have access to any of the information either.
- There are only two exceptions to this rule, and those are for 1) child abuse and 2) plans to harm yourself or someone else. If you report either of these things in your answers to us, we are required by law to report that information.

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- You can enroll in the study and later drop out by informing the research staff but you will not be able to take back information that has already been collected.
- Your decision will not affect any health care or benefits you normally receive.
- By signing this form, you are agreeing that you have read and discussed this form with me and have decided to be in this research study.
- If you have any questions or concerns about participating in this study, contact numbers for the research staff are located in the informed consent document.

Incarceration

- We would like to be able to contact you if you become incarcerated during this study. Would you be willing to be contacted by a member of the research team if you become incarcerated during this study?

Other Studies

- Would you be willing to be contacted for future studies?

22.4 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.
22.5 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.

22.6 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>
</tr>
</thead>
<tbody>
<tr>
<td>No records have been added</td>
<td></td>
</tr>
</tbody>
</table>

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.

No electronic document has been associated.

The following two text boxes are read only. They are data migrated from INSPIR I (if any) to assist you in answering the rest of this section above.

Translation of the entire Consent Form

Spanish

Short Form Consent Document

23.0 Confidentiality

23.1 Confidentiality

Will research data include elements which will allow the subjects to be identified?

☐ Yes ☐ No

Confidentiality of the Data

State what steps will be taken to maintain confidentiality of data and privacy (or anonymity) of subjects. Specify whether study data will be identified by specific subject identifiers (name, medical record numbers, etc.) or by study IDs that can be linked to subject identifiers via a master-code or key.

Screener information is recorded anonymously. Subject forms are identified
with a study ID and the key that links the ID to the identifiers is kept in a password protected file or locked cabinet. Subject tracking information is kept similarly. To assure confidentiality, each subject will receive a unique identification number and research data collection and data entry forms will be labeled only with this number, and will contain no other individual identification. Only the written informed consent forms, subject locator information, and a master list of subjects and subject study identification numbers will have the subject number and identifying information on them. There will be only one master list of names and identification numbers. These data will be kept in a secure electronic environment accessible to the principal investigator, the project manager, data managers and research assistants (all at BUMC). Tracking information will be kept similarly. During tracking, any contacts will be told that subjects are being contacted to follow-up in a health study; the nature of the study will not be disclosed. Computer data will be password protected, and accessible only to research assistants needing the information for follow-up purposes. When outside data sources are requested, unique identifiers must be given to the outside agency to match the data; however, none of the information obtained for the study in the research assessments is given to these agencies. Furthermore, the agency provides no additional unique identifying information beyond that which is provided by the study upon returning the matched data. A Certificate of Confidentiality has been obtained from the National Institute on Drug Abuse to protect from release of data even under court order or subpoena. All of these procedures are likely to be effective, based on our experience with similar studies. This protocol is the same for incarcerated subjects.

Please check all that apply:

- [ ] Study data will be anonymous. All data will be RECORDED as anonymous. There will be no way to link data to individual subjects, even temporarily AND subjects’ identities cannot be reasonably ascertained via deductive disclosure.
- [x] Study data will be coded. All study documents will be identified by a unique study ID. The unique study ID will be linked to subject identifiers via a mastercode or key. Access to the mastercode/key will be limited to the researchers. The mastercode/key that links study data to identifiers will be stored separately from the study data and protected (locked, separate flash drive, etc.)
- [ ] Study data will contain certain identifiers such as dates including dates of birth, medical record numbers, etc. Data will not contain social security numbers.
- [x] Study data will contain high risk identifiers (e.g. social security numbers) or very sensitive information with subject identifiers such as HIV status, psych diagnosis, illegal drug use, etc.
- [ ] There is an alternate plan for how subjects will be identified in study documents. Please specify in text box below.

The Massachusetts Department of Public Health will be given subject identifiers for the purpose of obtaining substance abuse treatment utilization data. They will not retain those identifiers. The data will be used to match any data they have on our research subjects and provide that data to the investigators. They will not have access to research information other than the fact that the subject is in this study and their identifiers needed to match electronic records. The BU CRC will have access to audiotapes labeled with study ID numbers, and the counselors will keep records of their brief counseling sessions that will be identified and kept at BMC.
Release of identifiable data.
Indicate who will be PROVIDED with identifiable research data (including "coded" data). Be sure to include study sponsors, students, outside institutions, etc. (Note: in most instances NIH and other study sponsors are not provided identifiable study data but they have access to study data on-site for monitoring and auditing purposes. The IRB and the other institutional officials also have access to study data for audit and quality assurance purposes. These do not have to be listed below) Include any release of study data into registries or research databases.

### Who gets data

- Research assistants and staff and investigators (BMC) listed on our protocol
- BUMC psychology doctoral students (study clinicians listed on our protocol)
- Massachusetts Dept of Public Health

### Type of data

- anonymous
- coded data with no mastercode/key
- data with some identifiers (e.g. dates)
- data with high risk identifiers or sensitive information

### Additional Information.
The Massachusetts Department of Public Health will be given subject identifiers for the purpose of obtaining substance abuse treatment utilization data. They will not retain those identifiers. The data will be used to match any data they have on our research subjects and provide that data to the investigators. They will not have access to research information other than the fact that the subject is in this study and their identifiers needed to match electronic records. The BU CRC will have access to audiotapes labeled with study ID numbers, and the counselors will keep records of their brief counseling sessions that will be identified and kept at BMC.

### Storage and destruction of study data
Where will research data be kept? How will such data be secured? How long will it be kept? How and when will it be destroyed?

- Note: Federal regulations require that study data be maintained by the investigator for a minimum of three years following the COMPLETION of the study. FDA regulations may require that study data be retained for significantly longer.

Research data will be kept in files in locked file cabinets and locked offices of the PI, coinvestigators and research staff, as well as on password protected computers and institutional computer network drives of the research team and the Data Coordinating Center. Data will be kept indefinitely. This protocol is the same for incarcerated subjects.
Certificate of Confidentiality
Will you obtain a Certificate of Confidentiality for this study?
(Note: If a CoC will be obtained then CoC language is required in the consent form. See IRB website for more information about CoCs.)
☐ Yes ☐ No

23.2 Study Attachments
Here you can attach the Certificate of Confidentiality (CoC) and any Confidentiality related documents. No electronic document has been associated.

24.0 HIPAA Compliance

24.1 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:
- [ ] 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

24.2 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. No electronic document has been associated.

25.0 Cost/Payment

25.1 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.

Subjects will be asked to present in person for one study research follow-up visit. As such they may incur travel costs. They will also be asked to return phone calls to study staff which may lead to costs for subjects. Their insurance will not be responsible for research related costs. All research procedures will be paid for by the study.
Research associates will accept collect phone calls, will have a toll free number, and will be available by beeper and cell phone. Subjects will be given 3 stamped self-addressed cards to send if their contact information changes (sent to subjects if they are not reachable). For further detail please see grant application budget justification, grant application human subjects section and follow-up plans section (in grant application research plan).

25.2 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 will be given study keychains and cardholders with the project acronym and study phone numbers, and we will offer cafeteria meal coupons during in-person assessments. Public transport passes or taxi/parking vouchers will be offered for those attending any visits in person (when arranging the visit, given at the time of the visit). Subjects are compensated when they complete baseline study procedures ($50), the 6-week research contact ($10) and six-month follow-up study procedures ($75) with cash or equivalent voucher. If they withdraw, they are compensated for the procedure they complete. Incarcerated subjects will have compensation deposited in their canteen fund. $2 will be provided any time a subject verifiably updates their contact information and for birthdays and some holidays in order to enhance affiliation with the study and improve retention (added to compensation at follow-up or in the form of a local business certificate (eg Dunkin Donuts).

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

26.0 Biological Sample Collection

26.1 Add New Samples

Sample Collection

Sample

Select a sample type:
Other
Other:
Hair, not including roots

What is the purpose of the sample collection?

Hair analysis of cocaine, opioids (codeine, morphine, oxycodone, and heroin), amphetamines (methamphetamine and MDMA [methylenedioxymethamphetamine]), PCP, and tetrahydrocannabinol will be obtained to assess recent use of these substances; this objective measure of drug use will be compared to patient self-report.

For blood draws, specify the amount drawn at each visit and across the course of the subject’s entire participation time.

Is there the possibility that cell lines will be developed with this sample? If you answer yes, then the cell line disclaimer language will appear on your consent form(s). Please review your consent form(s) in section Q before submitting.
☐ Yes ☐ No
Sample will be obtained from:
☒ Directly From Subject
Pathology Department
Clinical Labs
Research Labs
Other:

<table>
<thead>
<tr>
<th>Will the sample be stripped of identifiers? An identifiable sample is any sample accompanied by codes or data that could facilitate 1) re-contacting the subject or 2) gaining access to identifiable private information about the subject.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes ☐ No</td>
</tr>
</tbody>
</table>

**If sample will be released outside BU/BUMC:**

<table>
<thead>
<tr>
<th>Will sample be released to anyone not listed as an investigator on the protocol? Will the information be identifiable, coded or de-identified? If coded, who will hold the code? How will it be secured? When/how will it be destroyed?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes. The samples will be sent to Psychemedics for testing. They are a laboratory that tests hair samples for drugs. They have a great deal of experience with chain of custody and confidentiality because of the nature of the testing they do. The samples will be sent with a study ID number but without any other identifiers. BMC PI and research staff hold the codes/key to the study ID. The codes/key will be secured as described in detail in previous sections. The samples will be destroyed after testing by the testing laboratory using standard procedures. The data (results) will not be destroyed.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Will sample material be sold or transferred to any third parties? If so, describe the recipient. Will the information be de-identified? If so, describe how.</th>
</tr>
</thead>
<tbody>
<tr>
<td>The sample material will not be transferred to any third parties other than for testing as described above.</td>
</tr>
</tbody>
</table>

**If sample will be banked for future use:**

<table>
<thead>
<tr>
<th>Where will the sample be banked and for how long? Will the subject be re-consented for future use?</th>
</tr>
</thead>
<tbody>
<tr>
<td>The sample will not be banked.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Does the banking institution have an IRB approved policy for the distribution of samples?</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
</tr>
</tbody>
</table>

**If the entire sample will NOT be used during the course of this research study:**

<table>
<thead>
<tr>
<th>Will the remaining sample be discarded? If not what will be done with the remaining sample after study completion and how long will the sample be kept?</th>
</tr>
</thead>
<tbody>
<tr>
<td>The remaining sample will be discarded.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Will samples be made available to the research subject (or his/her medical doctor) for other testing?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes ☐ No</td>
</tr>
</tbody>
</table>

**If a subject withdraws from the study:**

<table>
<thead>
<tr>
<th>Will the subject have the option to get the remaining portion of his/her sample back?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes ☐ No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Will the remaining sample be discarded? If not, will it be kept anonymously? What will happen to the sample if the subject revokes authorization?</th>
</tr>
</thead>
<tbody>
<tr>
<td>If the subject withdraws from the study, the remaining sample will not be discarded. It will be kept confidentially (identified by study ID number) but will not be kept anonymously. If the subject revokes authorization the sample will be discarded.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Will data obtained from the sample be deleted? What will happen to the data if the subject revokes authorization?</th>
</tr>
</thead>
</table>
If the subject withdraws from the study, no further testing will be done. All data already collected and tested with their consent will be maintained as agreed to.

Will study data or test results be recorded in the subject's medical records?
☐ Yes ☐ No

Will results of specific tests and/or results of the overall study be revealed to the research subject or his/her doctor?

No.

Please identify all third parties, including the subject's physician, to receive the test results.

N/A

27.0 Study Attachments

27.1 Attach here any remaining study documents other than the ones listed below.

<table>
<thead>
<tr>
<th>Show Rev.</th>
<th>Edit/View</th>
<th>Version</th>
<th>Category</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0</td>
<td>Other</td>
<td>11/25/2013</td>
<td>Non-engagement agreement with RTI</td>
<td></td>
</tr>
</tbody>
</table>