Study Title: Testing the Effectiveness of a Graphic Novel Health Education Curriculum for Patients with Addiction

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Treatment Research Institute—Institutional Review Board

SUMMARY OF HUMAN SUBJECTS RESEARCH PROTOCOL

Please address all applicable points to create a complete and succinct synopsis of the protocol. Use language, insofar as is possible, that can be understood by an external, non-scientist layperson, and provide meanings for all acronyms used. **Form must be typewritten.**

(Maintain subheadings in body of text.)

Title of project: Testing the Effectiveness of a Graphic Novel Health Education Curriculum for Patients with Addiction

Funding Source and Funding Dates (Start and End Dates): Patient Centered Outcomes Research Institute (PCORI), 10/1/2014 – 6/30/2017

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1. Introduction and rationale for study

This project addresses an important service gap in treatment for substance use disorders (SUDs). The U.S. has invested heavily in developing treatments for substance abuse resulting in a variety of replicable, empirically-supported treatments (ESTs). Unfortunately, most providers do not use these ESTs due to cost, complexity, and training burden, and therefore show very low rates of EST adoption. Poor treatment quality is reflected in patient dissatisfaction with SUD treatment, often leading to poor retention in treatment. The most recently available Treatment Episode Data Set indicates that only a minority of clients complete intensive outpatient (39%) or outpatient (40%) treatment. Many patients are leaving SUD treatment early because they do not perceive that their concomitant psychosocial needs are taken seriously or addressed quickly enough. Furthermore, ESTs with the strongest, most consistent evidence-base are currently absent from the majority of outpatient treatment programs; for example, medication assisted treatment (MAT) approaches for alcohol use disorders have been established to be efficacious in reducing relapse, but their use is not widespread due to lack of awareness, patient reluctance to take medication, and misplaced concerns that these medications are addictive.

Patients who drop out from treatment are perceiving a mismatch between what they perceive they need and what their treatment programs are providing. This project aims to focus counselor and patient attention on the important healthcare and treatment decisions they need to make at the beginning of treatment, including raising patient awareness concerning previously ignored treatment options such as MAT. This study deploys a strategy to develop and evaluate a training-efficient, multimedia patient-centered Health Education Toolkit to promote shared decision making between counselors and patients.

2. Specific aim(s)

***Aim 1*:** An existing evidence-based toolkit intervention will be adapted and redesigned by a patient and provider team into an engaging, narrative graphic novel curriculum useful in substance abuse counseling. The proven behavioral interventions will be augmented with health education material focused on MAT and HIV risk reduction. Together, these materials will comprise the Health Education Toolkit. The Health Education Toolkit (**TK**) will employ a shared decision making model to encourage 1) increased recovery engagement by patients, and 2) patient engagement in deciding whether to initiate and adhere to MAT.

Aim 2: We will provide training and support to increase patient access to MAT for alcohol-related SUDs at a centrally located Federally Qualified Healthcare Center.

Aim 3: We will assess the feasibility and acceptability of the HET Toolkit to estimate whether exposure to the Toolkit (**TK**) can reduce substance use and increase engagement with MAT. We will conduct a three-month, randomized controlled trial of 50 patients with active alcohol SUDs enrolled in inpatient and outpatient treatment to obtain estimates of effect on the following exploratory hypotheses:

Exploratory Hypothesis 1: Patients randomized to the **TK** will participate in shared decision making conversations with their counselors at higher rates than patients randomized to treatment-as-usual sessions (**TAU).**

Exploratory Hypothesis 2: Patients randomized to the **TK** will report greater satisfaction and acceptability with their individual sessions than patients randomized to **TAU.**

Exploratory Hypothesis 3: Patients randomized to **TK** treatment sessions will demonstrate a) larger reductions in substance use (drug and alcohol) and b) increases in abstinence measured by urine-confirmed, self-reported days using over the 3-month follow-up compared to patients randomized to **TAU**.

Exploratory Hypothesis 4: Patients assigned to the **TK** condition will demonstrate improved ASI Alcohol Severity Scores relative to patients assigned to **TAU**.

Exploratory Hypothesis 5: Patients randomized to **TK** will attend more specialty substance abuse intervention and treatment sessions over the 3-month follow-up period than patients randomized to **TAU**.

Exploratory Hypothesis 6: Patients randomized to **TK** will initiate MAT for alcohol dependence at greater rates than patients randomized to **TAU**.

3. Endpoint(s) to be measured

Patient variables that will be measured include client satisfaction, treatment integrity, drug and alcohol use and problems, intervention and treatment engagement, health and medical functioning, and psychosocial functioning.

4. Number of subjects to be enrolled per year and in total. These numbers should incorporate numbers screened and consented to reach enrollment.

We anticipate screening approximately 100 patients who are attending substance abuse treatment at two participating sites. We expect approximately 50% of screened patients will meet eligibility

criteria and consent to take part in the study (about 50 patients). Of those patients consented, we expect approximately 50 participants will be enrolled to participate in the study (n=25 per condition).

Year 2: We anticipate we will screen and enroll 20 participants
Year 3: We anticipate we will screen and enroll 30 participants

We will also enroll 31 counselor participants. Approximately 12 of these counselor participants will also be recruited for a focus group in Year 3.

In Year 3 we will also recruit approximately 30 patients for focus groups in order to further determine the feasibility and acceptability of the Toolkit.

5. Considerations of statistical power in relation to enrollment

The purpose of this study is to determine the feasibility and acceptability of the Health Education Toolkit while collecting preliminary data is to establish effect sizes. These effect sizes will be used determine the sample size for a future fully powered clinical trial; therefore, statistical power is not relevant to this protocol.

6. Explain procedures that will involve the subject

We will work with 31 counselors from 1 inpatient and 2 outpatient substance abuse treatment site (note that one treatment site was able to enroll counselors but not clients prior to closing study recruitment). We will travel to the substance abuse treatment sites in order to present the study and recruit counselors. After presenting the study, we will obtain written informed consent for those counselors who are willing to participate in the study (the recruitment process for counselors is described in more detail in section 9 below). We then will randomly assign counselors to the toolkit (**TK**) or treatment-as-usual (**TAU**) group. Randomization will be *within-sites*, and ordered in matrices to ensure that the study conditions are evenly distributed within the treatment site. We will then screen and recruit clients who are attending individual treatment sessions with these counselors to participate in the study (recruitment process for clients is described in more detail in section 9 below). As part of their treatment experience, all patients who provide informed consent will continue to receive all other standard substance abuse treatment at the participating treatment sites.

Intervention Procedures

Health Education Toolkit (TK): Counselors in this condition will receive brief training in the use of the Health Education Toolkit and will run a 4 to 6-session, 4 to 6-week individual therapy series using the Toolkit. The toolkit will be developed by a project-specific Patient and Counselor Team (PACT) that will meet on a monthly basis in the first year of the study. The PACT will consist of approximately 10 patients and counselors who will work with the research team to compose characters, plot points, storyline, and content emphases for a four-volume graphic novel curriculum within the following working parameters: 1) the curriculum will be in a narrative, fictionalized graphic novel format in four serial volumes appropriate for use in substance use treatment sessions over four to six weeks; 2) the curriculum will include learning supplements and talking points for counselors to use in running therapy sessions using the curriculum; 3) at least 50% of the content will focus on or highlight issues related to integrating the use of medication (psychiatric, relapse preventive) in recovery, including an introduction to Vivitrol; 4) other curriculum content will include, but not be limited to, psychoeducation on HIV risk and risk reduction strategies; 5) characters will demonstrate racial, ethnic, and socioeconomic diversity; and 6) each volume will contain at least three patient response exercises that can be used in the therapy session.

TK Workshop Training: We will use our developed 3-hour training workshop which focuses on using the Toolkit. The workshop is divided between didactic information, demonstration, and brief skill practice via role-play. Counselors are given a brief introduction to the benefits of exposing their patients to the health and treatment option information in the TK, and the elements of the Toolkit are introduced. Counselors are shown how they can prepare each module, and are taken through the self-prep process for Module 1. Counselors briefly practice the Toolkit-specific skills of engaging in shared decision conversations surrounding the treatment options brought up by the curriculum, with a particular focus on engaging clients in their thought processes around the use of medication in treatment. TK counselors will be provided with Counselor Checklists and prompts to use them to stay on topic when conducting their therapy sessions. Finally, TK counselors will be encouraged to follow-up on discussion topics brought up by their clients in sessions.

Toolkit Condition: The TK sessions will be conducted with a more focused agenda than typical individual treatment sessions. TK sessions will begin with a review of any assignments the patient completed since the last session. TK counselors will then lead the session in a reading and/or review of the graphic novel content slated for that session (typically one to two volumes will be covered in each individual session so that the entire four-volume toolkit can be covered in about 4 to 6 weeks of individual sessions). The TK counselor will process the narrative content with the participant, and then move to application, which would typically cover opening up discussion topics regarding becoming more assertive and responsible for one's recovery, and deciding what other supplemental treatment goals a patient might want to consider, or other services a patient might pursue. In particular, TK counselors will look for opportunities to revisit the concepts laid out in that week's module, and to engage clients in discussions regarding how to decide whether medication (psychiatric, relapse preventative) is right for them. Each module includes corresponding interactive journaling content that patients can access in the graphic novel workbooks, which emphasizes important content and application points. The Toolkit condition will consist of 4 to 6 individual therapy sessions, 1 conducted each week for a 4 to 6-week period.

Toolkit Booster Trainings: In addition to the initial orientation training, TK counselors will receive three brief (~30 minute) booster trainings from a TRI expert TK trainer. These sessions will focus on concrete ways that the counselors can improve their use of the Health Education Toolkit. These booster trainings will occur after the counselor has treated 1, 3, and 5 patients respectively. The counselor's checklists will be reviewed and in particular, the counselor will be provided booster training on using core homework assignments (Schedule Planning, Change Plans, and Shared Decision Making conversations).

Treatment as Usual (TAU): In the TAU condition, counselors will receive a control training of the same length and intensity on recovery topics that are covered in the Health Education Toolkit, but will not be immediately equipped with the Toolkit. They will then run 4 to 6 individual sessions throughout a 4 to 6-week TAU span with each of their patients enrolled in the study.

TAU Workshop Training: Our control training intervention compares to the TK training in that it presents new, didactic information; TAU counselors will be presented with discussion topic points on the areas covered by the Health Education Toolkit (medication facts, setting work and education goals, etc.). TAU counselors will attend a 3-hour workshop that introduces the talking points, and provides orientation on how to best to cover the talking points in therapy sessions. Counselors will be encouraged to study the talking points as they see fit to prepare to run a 4 to 6-session series over 4 to 6 weeks. Counselors will be given latitude to talk over these topics in any order they choose.

TAU Condition: Counselors will lead a 4 to 6-session series on similar topics over a 4 to 6-week period, but without the Toolkit aids (graphic novel volumes).

TAU Booster Trainings: In order to provide an attention control training that matches the amount of time that TK counselors will be trained, TAU counselors will also receive three brief (~30 minute) booster trainings from a TRI expert trainer. During these sessions, the counselor and trainer will discuss the counselor's experience running individual sessions for this study.

Participant Baseline Procedures

Patients and counselors will be recruited following the procedures outlined in section 9 below. Following informed consent (described below in item 9), a Research Assistant will complete an assessment battery with participating counselors. As a part of this assessment, counselors will be paid $25 in cash for completing the Baseline Interview. Participating clients in the recruited counselor's caseload will also provide informed consent, and will complete a baseline assessment including a self-report of drug use, urine screen, and other measures. Patient participants will be paid $40 in cash for completing the Baseline Interview. Additionally, participants will receive an additional $10 in cash for providing three verified collateral contact they provide on the Locator Form. Research staff will attempt to contact each collateral provided on the Locator Form, and a collateral contact will be considered verified if research staff are able to establish contact with the person.

Participant Follow-up Procedures

We will complete a 6-month follow-up assessment with counselor participants. This assessment will take place at the counselor's treatment site. We will also complete follow-up assessment interviews with patient participants at 6 weeks, and 3 months after intake. (Note: We also completed a 6-month assessment interview with 2 participants due to a miscommunication with staff following the funder's decision to end recruitment and close out the randomized trial). We will use patient-provided information on the Locator form to contact participants. Research staff will use participant tracking software to ensure that they are alerted when call windows open at each assessment point (6 weeks and 3 months). Research staff will call participants at the times and numbers indicated on their Locator Form as the best time to reach them. For participants who are more difficult to reach, call times and call numbers will be alternated. Participants will also be mailed reminder notices informing them of an upcoming interview, as well as thank you notes for completing interviews. Research staff will also attempt to contact participants via any other mechanisms that the participant consented to on the Locator (e.g. email, Facebook, home address). For participants who are unreachable, messages will be left at all contacts that the participant consented to on the Locator Form, and postcards will be sent to contacts that we cannot reach on the phone. Should contact persons indicate that they have lost track of the participant, research staff will search for the patient using available public search mechanisms (www.whitepages.com, etc.). When participants are reached by telephone, research staff will schedule the date and time of the interview, and will update the Locator Form in case the patient's contact information has changed.

In addition to contacting patient participants to complete their scheduled assessments, we also contacted four participants between the 3-month and 6-month assessments (at approximately 4.5 months) to verify their contact information prior to receiving notice from our funder to end recruitment and close out the randomized trial. Participants that we are able to establish contact with and who verify or update the information on their Locator Form will receive either a $5 gift card to a retailer in the community via mail, or $5 cash in person at a time and location convenient to both the participant and RA (e.g. the participant's treatment program where RAs will travel to frequently).

Confidentiality. We have devised IRB-approved procedures to safeguard patient confidentiality while attempting to locate participants. Research assistants will call participants from either a study provided cell phone or from TRI's office phone. TRI's calling system blocks the name "Treatment Research Institute" off of its listing, preventing the incoming phone from accessing TRI's name. If a participant registers more significant confidentiality concerns, research staff will call from blocked cell phone numbers that do not display the return number. When messages are left for the participant on recording devices or with collaterals, research staff members report that they are trying to reach the participant to complete a "health care survey" that the participant volunteered for. Additional protections for patient follow-up can be found in the Human Subjects Protections section (item 11).

Follow-up assessments will take place in-person, generally at the participant's treatment site. If patient participants have been discharged from their respective treatment site, follow-up assessments will be done in person either at another mutually agreed upon location, such as the Public Health Management

Corporation (PHMC)'s Care Clinic (a Federally Qualified Health Center), or at one of The Wedge's substance abuse treatment program sites. If the participant is not able to travel to any of these sites or their treatment site, then we will meet them in a safe, neutral location such as a restaurant or public library. The assessment battery will be similar to that collected at Baseline (see Participant Measures below), and we will collect a urine sample. Participants will be provided with a payment of $40 in cash for the 6-week and 3-month assessments. The two participants mentioned above received $50 in cash for the 6-month assessment. If a participant is incarcerated at any follow-up point research staff will not attempt to contact the participant while incarcerated.

Expanding Patient Access to MAT

Few community treatment programs (including some that will serve as research sites for this study) offer MAT as a treatment option for patients. As part of this project, we will work with the Public Health Management Corporation's (PHMC) Care Clinic to offer MAT for alcohol SUDs. PHMC is a regional public health institute that serves close to 200,000 patients annually and includes more than 250 programs in 70 locations, one of which is the Care Clinic, a Federally Qualified Health Center (FQHC) where study patients may be referred. The medical staff at the Care Clinic will establish a routine protocol for treating patients with Vivitrol. Staff at the Care Clinic will evaluate patients for suitability following standard medical guidelines, and dispense Vivitrol to study participants as well as non-study patients provided the patient is suitable, medically eligible, and is covered by their insurance. Behavioral health staff will interview prospective patients to determine whether they are suitable for Vivitrol MAT, and medical staff will oversee their medical treatment. It is important to note that this protocol at the Care Clinic will not be considered research, or part of the present research project. The purpose of our research is to determine whether patients exposed to the Health Education Toolkit in a SUD treatment setting become more likely to seek out and initiate MAT for alcohol SUDs. No patient will be assigned to Vivitrol, or asked to take it as part of this protocol. With a patient participant's permission, our team will be given a release to confirm when study participants are evaluated for and initiated on Vivitrol, but this permission is at the patient's discretion and not mandatory to participate in the current research project.

Focus Groups

We will conduct a series of focus groups to obtain feedback from counselors and patients about the Toolkit. The feedback from these focus groups will be used to inform feasibility and acceptability and further refine the Toolkit materials. Specifically, we will be seeking feedback on usefulness, perceived helpfulness, and opinions on ways to improve the curriculum.

We will hold 2 to 3 focus groups with 5 to 10 patients each and 2 focus groups with 5 to 7 counselors each. We will ask counselors assigned to the Toolkit condition who have used the Toolkit with clients to participate in a counselor focus group. We will also ask counselors to refer clients with whom they have used the Toolkit. As we will be looking for feedback on all of the graphic novel books, we will ask counselors to make referrals based on the various books those clients received. Though we expect that some of these clients may already be enrolled in the study, we anticipate that many will be new clients (not previously enrolled in the clinical trial) in order to represent the full curriculum.

Each focus group will last two hours, and refreshments will be provided. Participants will be reimbursed $50 for their time for each focus group. Recruitment and consent procedures are outlined in detail in section 9.

7. Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data.

Patient Screening Instruments

Alcohol Use Disorders Identification Test (AUDIT). The AUDIT (Babor et al., 2007) was developed by the World Health Organization to serve as a brief screening instrument and includes questions on frequency and alcohol problems and dependence (Allen et al., 1997, Reinert & Allen, 2002, Saunders et al., 1993).

DSM-V SUD Diagnosis: MINI Plus 5.0. The MINI is a short structured diagnostic interview developed in the United States and Europe for DSM-IV and ICD-10 psychiatric disorders (Sheehan et al., 1998). The MINI has become the structured psychiatric interview of choice for psychiatric evaluation and outcome tracking in clinical psychopharmacology trials and epidemiological studies. We will modify the MINI to meet DSM-V criteria for SUD. In DSM-V, the 7 DSM-IV items for dependence and 4 items for abuse have been merged into a single entity of 11 items called a "Substance Use Disorder" but with the following two changes - the abuse item of recurrent legal problems will be removed and an item for craving or strong desire to use will be added (American Psychiatric Association, 2013). A diagnosis of SUD requires 2 or more of the 11 items, and SUDs have three levels of severity: 2-3 items = mild, 4-5 = moderate, and 6+ = severe; any diagnosis of SUD results in study eligibility. We also included two pre-screening questions to assess for past 60 day alcohol use.

Patient Outcomes

Quick Drinking Screen and ASI Drug Grid: This instrument contains items from two established instruments: the Quick Drinking Screen (QDS), and the Addiction Severity Index (ASI). The QDS is a six question screener that estimates the frequency and quantity of drinking. Two comparison studies found high levels of agreement between the QDS and the Timeline Followback, the "gold standard" in drinking measurement (Roy et al. 2008, Sobell et al, 2003). We also included the Follow-up Assessment Drug Grid and overall drug use questions from the ASI (see below) in order to assess for both alcohol use and other substance use. *Administered at 6 weeks only.*

Urine testing: Urine drug testing will be done using kits that test for cocaine, opiates, amphetamines, methamphetamines, benzodiazepines, cannabis, barbiturates, and PCP. These will be purchased from ACON International. These kits provide a rapid (5-minute) on-site urine test. *Administered at BL, 6 weeks, 3 months, 6 months.*

Non-Study Medical and Other Services (NSMOS): This questionnaire was adapted from the Treatment Services Review (McLellan et al., 1992) for patients in medical settings. The NSMOS counts substance abuse treatment, medical services, visits to medical offices, hospitalizations, and emergency room visits received that were not a part of the assigned treatment. *Administered at BL, 6 weeks, 3 months, 6 months.*

PHMC Utilization Review: PHMC Care Clinic will maintain records on patients from the study who are referred for Vivitrol evaluation. By prior patient consent, the Care Clinic will release records on whether a study patient attended an appointment for a Vivitrol evaluation, the determination of appropriateness for Vivitrol, and whether the patient actually received the initial dose and subsequent doses (if any) of medication.

HIV Risk Assessment (HIV-RA): The HIV Risk Assessment provides a brief self-report measure of HIV testing history and sexual risk and uses the preceding three months as the time interval of interest. The HIV-RA was developed Lisa Bond, PhD, and David Metzger, PhD, experts in the field of HIV risk behaviors. *Administered at BL, 6 weeks, 3 months, 6 months.*

Addiction Severity Index-6th Edition Modified Version (ASI6-Modified): The ASI is a multi-dimensional interview used to measure the substance use, health, and social problems of those with alcohol and other drug problems, both at admission to treatment and subsequently at follow-up contacts (McLellan et al., 1992; McLellan et al., 1980). We are using an abbreviated version of the ASI-6 that eliminates many of

the items that do not contribute to our primary hypotheses and takes approximately 20 minutes to complete. We will use only the ASI domains for medical, drug use, alcohol use, and psychological status for covariate analysis. The ASI-6 produces *Recent Status Scores* in each of these four areas, which have demonstrated high levels of inter-rater, test-retest, and concurrent reliability (Cacciola et al., 2011). Our modified version also includes items from the QDS (see above) in order to obtain consistent and reliable estimates of alcohol use. *Administered at BL, 3 months, and 6 months.*

EQ-5D-5L: The EQ-5D™, a trade mark of the EuroQol Group, is a standardized measure of health outcomes. It takes only a few minutes to complete, and it provides a simple descriptive profile and a single index value for health status. *Administered at BL, 6 weeks, 3 months, 6 months.*

Client Shared Decision Making Questionnaire: The Shared Decision Making Questionnaire (SDM-Q client version; Kriston et al., 2010) is a validated 9-item questionnaire that measures the process of shared decision making between clinicians and patients. We adapted this measure to apply to substance abuse treatment decision making. This version of the questionnaire measures shared decision making from the patient's perspective. *Administered at BL, 6 weeks, 3 months, 6 months.*

Client Satisfaction Questionnaire: The Client Satisfaction Questionnaire was developed for this study and assesses the extent to which participants perceived the intervention to be helpful and useful. It contains both closed- and open-ended questions in order to obtain information that will help us further refine the intervention for dissemination. *Administered at 3 months only.*

Client Fidelity Checklist: The Client Fidelity Checklist will indicate the content areas that were covered in group and individual treatment during the intervention period and across the follow-up period, and it will detect any between-condition contamination. In particular, the checklist will confirm whether patients have been exposed to any treatment content delivered in a graphic novel format. *Administered at 6 weeks, 3 months, 6 months.*

Counselor Measures

Counselor Background Form (CBF): The CBF was developed for this study and assesses the demographics and work/training histories of each participating counselor. Additionally, for this study, we have added questions on counselor's experience with medication assisted treatment. *Administered at baseline only.*

Counselor Satisfaction Form: The Counselor Satisfaction Form was developed for this study and assesses the extent to which counselor participants perceived the intervention to be helpful and useful. It contains both closed- and open-ended questions in order to obtain information that will help us further refine the intervention for dissemination. *Administered at 6 months only.*

Counselor Shared Decision Making Questionnaire (SDM-Q): The Shared Decision Making Questionnaire (SDM-Q counselor version; Simon et al., 2006) is a validated 9-item questionnaire that measures the process of shared decision making between clinicians and patients. We adapted this measure to apply to substance abuse treatment decision making. This version of the questionnaire measures shared decision making from the clinician's perspective. *Administered at baseline and 6-months.*

Counselor Evidence-Based Practices Questionnaire: The Evidence-Based Practices Questionnaire (Abraham et al., 2009). measures counselors' attitudes and familiarity with a range of evidence-based practices, such as MAT, CBT, and MET. *Administered at baseline and 6 months.*

Counselor Fidelity Checklist: The Counselor Fidelity Checklist will indicate the content areas that were covered in treatment during the intervention period. It will measure counselors' adherence to their assigned intervention, and it will help detect any between-condition contamination. *Ongoing; completed after each study treatment session.*

8. Describe characteristics of the subject population, such as their anticipated number, age ranges, sex, ethnic background, and health status. The study should employ a study design with gender and race representation appropriate to the purpose of the research. Strong justification must be provided for exclusion of broad population groups. Identify the criteria for inclusion or exclusion. Explain the rationale for the use of vulnerable populations as research subjects (i.e., prisoners, pregnant women, disabled persons, drug users, children).

Research participants will be patients currently receiving treatment at one of our participating inpatient or outpatient substance abuse treatment sites. We expect that 350 participants will enroll in the study. We will not exclude any potential participant based on race or gender, and members of gender and minority groups, the elderly, and disabled will be included in the research in the same proportion as they are represented in the populations of patients served at the participating treatment sites. We anticipate that the demographic characteristics associated with the client participants will be similar to the characteristics of the clients we have recruited in the Philadelphia area in the past; clients are, on average, 30% female, 36% Black, 51% White, 13% other minorities, and 15% Hispanic. Elderly subjects and those with medical problems will be included in the research as long as they are able to give competent, informed consent and understand the content of the research instruments. Participants with disabilities will be accommodated. We will monitor gender and minority representation to ensure that it is representative of the target population, and we will over-sample any gender and racial groups that are significantly under-represented.

9. Describe plans for recruitment of subjects, including advertisement and posters and the consent procedures to be followed, including the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects and the methods of documenting consent.

Counselor Recruitment

We will travel to the inpatient and outpatient substance abuse treatment sites in order to present the study and recruit counselor participants. After presenting the study, interested counselors can schedule a time with research staff to consent into the study. At this scheduled time, research staff will obtain written informed consent and will then administer an assessment battery as part of the Baseline Interview. Research staff will only work with treatment sites whose administrators agree that they will not impose any negative consequences on counselors who choose not to participate in the study. We then will randomly assign counselors to the toolkit (**TK**) or treatment-as-usual (**TAU**) group, and counselor participants will schedule a time to complete the initial training on their assigned condition. Counselors will be paid $25 for measures completed at the Baseline Interview, $75 for the initial training, $25 for each of the 3 booster trainings, $20 for each set of 5 fidelity checklists up to $200, and $25 for measures completed 6-months post Baseline Interview. Counselors can earn up to $400 throughout the course of the study.

Client Recruitment

Immediately after a counselor completes training (either TK or TAU), we will work with the counselor to schedule a date within the next two weeks to present the study to patients who are on his or her caseload. On the scheduled day, research staff will travel to the treatment site and will present the study to those patients who attend individual therapy sessions with the counselor. Patients who are interested in the study will be asked to complete a brief verbal screening consent. We will administer the AUDIT; patients who score a 16 or above (criteria for moderate to severe alcohol use disorder) will receive further screening. We will then administer the MINI (modified for DSM-V criteria). Patients must meet criteria for current alcohol SUD (i.e., positively endorse at least 2 of the 11 items on the MINI) and have experienced 6 days of alcohol use in the past 60 days in order to be eligible. To maximize

generalizability and practical relevance of our findings, only patients who are unable to provide valid informed consent will be excluded. We expect to recruit 50 patients.

Inclusion and Exclusion Criteria

Inclusion Criteria: (a) patient is on the caseload of a participating counselor, (b) patient is 18 years or older, (c) a screening score of at least 16 on the AUDIT, (d) patient meets criteria for a substance use disorder as defined by DSM-V assessed via the MINI Plus 5.0, (i.e., endorsement of at least 2 of the 11 items on the MINI), (e) the patient has enrolled in the treatment program within 4 weeks prior to the date of consent and (f) patient reports 6 days of alcohol use in the past 60 days. Each participant must meet all the inclusion criteria in order to be enrolled in the study.

Exclusion Criteria: (a) the patient reports plans to leave the Philadelphia greater metropolitan area within the next 6 months; (b) the patient is not English-speaking; (c) the patient is mandated to attend inpatient treatment (i.e. considered a prisoner), or (d) if the patient is unable to provide valid informed consent by correctly describing the key components of consent to the RA.

Research staff will work with participating counselors to identify patients on their caseload who have enrolled in treatment within the past 4 weeks. Patients who are identified as potential study participants will be asked to complete a screening consent with an RA. We are requesting a waiver of written documentation of consent for the screening process. According to 45 CFR 46.117(c), written documentation may be waived if "the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from breach of confidentiality." For patients who are found ineligible through the screening process, the screening consent form would be the only written document linking the patient to the research, thus a requirement for written consent would paradoxically be the only real danger to loss of privacy and confidentiality for participants who agree to be screened. We will provide an information sheet (i.e. a screening consent) to patients prior to screening that contains informed consent information, and we will obtain verbal consent that the patient is willing to participate in the screening. For patients who consent to screening, the RA will administer the AUDIT, MINI, and 8-week TLFB to determine if they meet inclusion criteria. Patients who meet the inclusion criteria and are interested in participating will be asked to provide written informed consent. Study research assistants (RAs) will fully explain the study procedures to eligible patients, and will obtain informed consent from those interested in participating.

During the informed consent process, patients will be fully informed of the procedures, the nature of the study conditions, inclusion and exclusion criteria for the study, and the compensation associated with participating in the study. They will be informed that all research data collected in the study will be kept strictly confidential and that we have applied for or obtained an NIH Confidentiality Certificate that will shield the research data from a subpoena or court order. The only exceptions to confidentiality (clearly specified in the consent form) will pertain to information related to medical emergencies, disclosure of current child/elder/dependent abuse or neglect, or imminent risk of death or serious injury to the participant or others. Finally, these individuals will be informed of all known potential risks and benefits of participation, their right to refuse or revoke consent at any time, and the names and phone numbers of responsible individuals they may contact for additional information or to register complaints about study procedures. They will also be asked to complete a brief consent quiz to ensure their understanding of the study requirements, the risk and benefits, and their human subject protections. All items answered incorrectly will be reviewed with the participant to ensure adequate understanding. This process will continue until participants demonstrate at least a 95% understanding of the essential elements of the informed consent document. Potential participants will then be asked if they have any questions and will be asked to sign the informed consent form to document their agreement to participate. They will receive a duplicate copy of the consent form for their records. The original signed consent form will be kept in a locked filing cabinet only accessible to staff working on this study.

Focus Groups

We will recruit Counselor focus group participants from already enrolled counselors assigned to the Toolkit condition. Counselors must have used the Toolkit with at least one of their clients in order to be eligible for the focus group. We will recruit Client focus group participants from counselor referral. We will ask counselors who meet the criteria for our focus group to refer clients who received at least part of the Health Education Toolkit as a part of their care. Clients must have received at least part of the Health Education Toolkit as a part of the care in order to be eligible for the focus group. A member of the TRI research team will speak individually with each prospective focus group participant and explain the procedures of the focus group (types of people participating, activities the group will engage in, and the fact that the group will be audio-recorded). Counselors and clients willing to participate will be scheduled for the appropriate group.

We are requesting a waiver to document informed consent for individuals participating in the focus groups according to **45 CFR 46.117(C)(2)** which states documentation may be waived if "the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context." At the beginning of each focus group meeting, TRI staff will provide a copy of the Focus Group Information Sheet to all participants and will fully explain the focus group procedures. Participants will be asked to provide verbal informed consent to participate, and will be told that they can stop participation at any time by leaving the focus group room.

10. Discuss whether risks to the subject are 'minimal' or 'greater than minimal.' List the major risks of subject participation. Describe any possible benefits of subject participation. Are the risks to subjects reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result?

The risks to subjects enrolled in this study are minimal. There are three anticipated potential risks associated for both counselor and patient participants enrolled in this study.

1. Perception of coercion: It is possible that some participants may feel coerced to participate in the research study. Our previous studies with similar populations indicate that this is a rare event.
2. Discomfort answering research questions and/or providing biological data: Participants may experience mild and transitory psychological discomfort from completing research measures that deal with emotionally laden material or from providing urine samples. The probability of these risks and the magnitude of the anticipated harm are likely to be small. These events have *not* been encountered in any of our previous studies using similar assessments.
3. Harm from Breach of Confidentiality: Participants are at risk for harm as a result of being identified as a study participant or as someone with an alcohol or drug problem. The likelihood of this occurring is small and was not encountered in our previous studies.

Benefits to participants: Participants in this study may benefit from receiving an intervention which is designed to educate patients about their treatment options and encourage self-efficacy to access treatment modalities that best address patients' needs, including alcohol-related MAT. This project will also yield considerable information on behavioral changes associated with the Health Education Toolkit intervention.

Importance of Knowledge to be Gained: The aim of this project is to test the impact of a Health Education Toolkit in increasing patient knowledge, increasing treatment modalities accessed, and reducing substance use. The Toolkit series will be designed to communicate pertinent health information to SUD patients in a format that is engaging and easily understood. If this Health Education Toolkit proves to be effective, patients will demonstrate detectable reductions in substance use, higher

engagement rates with supplemental treatments including MAT, and increased knowledge about treatment options.

The risks associated with participating in this study are reasonable given the benefits and importance of knowledge to be gained.

11. Describe the procedures for protecting against or minimizing any potential risks, including physical, psychological, legal and confidentiality risks, and assess their likely effectiveness. Where appropriate, discuss provisions for insuring necessary medical or professional intervention in the event of adverse events to the subjects and for monitoring the data collected to insure the safety of subjects. Also, where appropriate, describe alternative treatment and procedures that might be advantageous to the subjects.

1. Perception of coercion: Research staff will be trained to describe the study to eligible counselors and patients, including the risks and benefits, prior to offering an invitation to participate in the study. Research staff will clearly state that the counselor's decision to participate is voluntary and will not affect their employment at the site. Similarly, we will state that a patient's decision to participate is voluntary and that it will not impact the services they receive at their treatment site. Patients will be told that treatment site staff have no vested interest in their participation and will receive no benefit if they choose to participate. All potential participants will be told that if they feel any pressure to participate from any treatment site staff, they can voice this concern to the PI or other TRI research staff, and the PI will discuss this matter with the site's director and/or other appropriate individuals.
2. Discomfort answering research questions and/or providing biological data: Individuals enrolled in any study may experience mild and transitory emotional discomfort when answering the questions posed in interviews and on questionnaires, or providing a urine sample. All participants will be informed about these possible risks before signing the consent form. In order to minimize discomfort with providing a urine sample, the sample will not be collected under observation. The research staff will complete a training regarding monitoring and addressing emotional distress among research participants, as well as an additional training on the urine collection process which will include suggestions for decreasing participant discomfort. Participants will be told that they can choose not to respond to a question that they find upsetting and can withdraw from participation at any time without negative consequence.
3. Harm from Breach of Confidentiality: Data collected in the study will be kept strictly confidential and will not be shared with anyone outside of the research team. The only exceptions to confidentiality, which will be clearly specified in the consent form, will be for information related to medical emergencies, current child abuse or neglect, or imminent risk of death or serious injury to the participant or others. All research materials will be coded with a research number and will contain no other identifying information. Information collected on paper (e.g., consent forms, HIPAA forms, Locator Forms) will be stored in locked filing cabinets at TRI, and computer spreadsheets will be saved in password-protected files. Participants will be assigned a study identification number which will be affixed to all collected data. Linkage between participant identity and identification numbers will be stored in a password protected electronic file available only to the PI and designated research staff. All research instruments will be computerized for this study, and the data will be entered via the Web into a secure server located at the University of Pennsylvania's Data Management Unit. All computers have security codes and password protections to prevent unauthorized access. Efforts to contact participants for telephone check-ins or follow-up appointments will make no mention of the study until it is established that the participant has been reached. Access to participants' telephone numbers, addresses, and other contact information will be limited only to research staff members who need to contact a participant for study purposes.

Digital audio recordings of the focus groups will be coded/saved with the date of the session and an identification code; no personal identifying information will be placed in the filename or intentionally dictated into the audio recording. Research staff who are responsible for transcribing the interview content will also be responsible for ensuring that identifying information does not appear in the transcript. Once the transcript is completed and checked for accuracy, the audio recording will be erased from the computer.

Should any breaches of participant confidentiality occur, they will be reported to the relevant IRB, DSMB, and PCORI officials.

12. Describe procedures for reporting Serious Adverse Events (SAEs) and Adverse Events (AEs), and Unanticipated Problems. Include the definition of SAEs and AEs.

Serious Adverse Events (SAEs) for client participants will be defined as death; a life threatening event such as drug overdose, suicide attempt, or inpatient hospitalization (including substance abuse or psychiatric hospitalizations) due to drug/alcohol overdose, suicidal behavior, or psychiatric distress; or an event that extends an existing hospitalization as defined above. Childbirth, pre-planned elective procedures, and unrelated medical events that require hospitalization will not be considered SAEs. No SAEs are expected as a result of the study procedures or intervention. Client participants in this study are individuals attending therapy in substance abuse treatment, and are thus, as a population, at risk for relapse to substance use or clinical worsening. Although we do not believe the study procedures or intervention places clients at increased risk for clinical worsening, we will review and report events of clinical worsening that lead to a substance abuse or psychiatric hospitalization. These events are not anticipated to occur more often than the baseline rate in this population.

We do not expect and we will not report any Serious Adverse Events for counselor participants, as participating in this study would put them at no related risk for medical or psychiatric distress.

Adverse Events (AEs) for clients will be defined as: report of coercion to participate in the study; significant discomfort from answering research questions or providing urine samples such that the participant decides to stop their participation; risk of harm resulting from a breach of confidentiality; or suicidal thoughts. For client participants, we will also report significant returns to drug/alcohol use defined as a 50% or higher increase of drug/alcohol use compared to baseline, and significant increases in psychiatric symptoms compared to baseline. Clinically insignificant events are not considered AE's. Examples of clinically insignificant events include mild viral illness (e.g., colds, flu, and runny nose), common headaches, minor scratches, and mild symptoms or problems associated with medical conditions not related to drug use (e.g., back pain). Clients in substance abuse treatment often enter treatment with various medical and/or psychological problems which may continue during the course of treatment, and new problems often develop. As per the definition of AEs, only significant worsening of baseline psychiatric or drug/alcohol abuse status or new problems will be reported as AEs.

Adverse Events (AEs) for counselors will be defined as report of coercion to participate in the study; or significant discomfort from answering research questions such that the participant decides to stop their participation.

In prior research, the AEs listed above have been known to occur. However, due to the protections we have put in place we do not anticipate a report of coercion to participate in the study, significant discomfort from answering research questions or providing urine samples, or harm resulting from a breach of confidentiality to occur. Substance abuse and psychiatric disorders are often chronic relapsing diseases, and therefore we anticipate a small percentage of clients will report an increase in drug/alcohol use or psychiatric symptoms during their participation in the study. However, as stated above we will only report these if they are a significant increase from baseline.

All adverse and serious adverse events occurring during the study are documented on a form, reviewed and signed by the PI or Co-I and reported to TRI and other applicable IRBs. All non-fatal

adverse events that meet the above definition of "Severe" are reported to the IRBs within 48 hours of our awareness of the event. Fatal SAEs are reported to the IRBs and relevant PCORI Office within 24 hours of our awareness of the event. A summary of all SAEs and AEs that occurred during the previous year will be including the annual progress report to the relevant IRBs.

13. If this study is a chart review, indicate the time frame of data to be collected (from when to when). Also, will the data be collected anonymously (meaning that only aggregate data will be collected, and there will be no names or codes maintained to match the data with the original files)?

Not Applicable

14. Children, defined as individuals under the age of 21, must be considered for potential enrollment in every study as subjects unless there are scientific or ethical reasons for excluding them. See below for the permissible exclusionary circumstances listed in the NIH Policy. If no exclusion applies: 1) discuss your plan for the inclusion of children; 2) justify the age range of children to be enrolled; 3) indicate the expertise of the research team with regard to children; 4) describe the facilities for the children; 5) indicate the number of children to be enrolled to give sufficient power for meaningful analysis; 6) describe how the assent process for children 7 to 17 years of age will be carried out.

Justify your exclusion based on one of the exclusionary circumstances listed:

- The research topic is irrelevant for children
- Children are barred by law from participation because of the risk
- Study is redundant; knowledge is being obtained in another study or is already available
- Separate age-specific children study is preferable
- Rarity of disorder makes inclusion of children extremely difficult
- The limited number of available children are already enrolled in a nation-wide pediatric disease network
- Study design precludes direct applicability to children
- Insufficient adult data to judge potential risk for children
- Study design is a follow-up of an adult study

As the NIH definition of children includes all persons less than 21 years old, we will include children between the ages of 18 and 21 in this investigation. Based on previous enrollment in studies in the Philadelphia treatment system, we expect that 5-8% of our clients will be between the ages of 18-21. We will exclude potential participants who report that they are younger than the age of 18.

15. This study involves research to be performed at:

The specific sites are listed below. Each participating site will sign a site letter of agreement. We will also work with PHMC's Care Clinic as described above. The PI and Study Coordinator will be responsible for obtaining FWA's at all sites prior to any data collection.

	Program	**City/State**
1	Wedge Medical Center	Philadelphia, PA
3	PHMC Care Clinic	Philadelphia, PA
4	Presbyterian Medical Center	Bensalem, PA

5	Kirkbride	Philadelphia, PA

Reminder: It is Principal Investigator's responsibility to obtain copies of FWAs for each performance site.

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