Financial Incentives to Promote Stimulant Abstinence in a Community-Based Syringe Exchange Program

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Human Subjects Research Protocol

PROTOCOL SUMMARY

Project Title: Financial Incentives to Promote Stimulant Abstinence in a Community-Based Syringe Exchange Program

Protocol Version Date (10/10/23)

Principal Investigator: Tyler G. Erath, Ph.D.; Stephen T. Higgins Ph.D.

Check the type of the review:

[ ] Full convened meeting - The IRBs employ the convened meeting review process for review and approval of studies that are more than minimal risk.

[x] Expedited review - The IRBs employ the expedited review process for approval of studies that are determined to be minimal risk and only involves activities such as; prospective collection of biological specimens for research purposes by noninvasive means (blood collection, salvia, nail clippings), collection of data through noninvasive procedures (ultrasounds, MRI, physical sensors) and research on behavior such as perception, cognition, motivation, identity, language and communication.

PURPOSE AND OBJECTIVES

Purpose: The importance of the research and the potential knowledge to be gained should be explained in detail. Give background information.

The use of methamphetamine and other psychomotor stimulants is both pervasive and increasing in the United States. Between 2015 and 2019, the rate of overdose deaths involving psychomotor stimulants has increased 180% (Han et al., 2021). Currently, there are no Food and Drug Administration-approved medications for stimulant use disorder (StimUD) available due to small and inconsistent effects observed for the medications evaluated to date (Brandt et al., 2021). However, contingency management (CM), an empirically support treatment for substance use in which individuals earn positive reinforcers for adherence to verifiable behaviors, is a very efficacious strategy in reducing cocaine and methamphetamine use for individuals with StimUD (Bentzley, et al 2021; Bolivar et al., 2021).

To date, the research supporting CM for treatment for individuals with StimUD has been primarily conducted in settings where individuals are presenting for treatment. Recruitment in these studies is typically characterized as targeted toward "treatment seeking" individuals. However, many substance users are not interested in treatment, but do see value in harm reduction activities, including syringe exchange, and the importance of these services has recently been acknowledged by US health leaders. In addition to an array of harm reduction services, there is evidence that some individuals receiving these services will enter treatment if that treatment is offered within the "low barrier" environment of the harm reduction facility. However, limited research has been conducted examining interest treatment services in syringe exchange programs (McMahan et al., 2020).

Syringe exchange is one of the most widely implemented harm reduction interventions for individuals who use drugs in the US. Individuals who are actively using drugs by injection are encouraged to visit a harm reduction site and get a supply of new syringes and be given information and other health services relevant for individuals who inject drugs (e.g., hepatitis and HIV testing). The population of individuals who use these services may be using opioids (heroin, prescription opioids, fentanyl) or stimulants (cocaine/methamphetamine) or any other drugs by injection. Participants receive information about available treatments for those individuals who desire to reduce/stop their drug use. In fact, at the Safe Recovery program, the site of the proposed project, there is a low barrier buprenorphine program for individuals who use opioids and would like to receive buprenorphine but who don't want to enter a formal treatment program. At present there is no comparable treatment for those individuals who use stimulants. This proposed project is a first attempt to explore the interest in CM as a treatment for their stimulant use disorder.

The purpose of this study is to examine the potential utility of a CM intervention for individuals with

StimUD who already participate in a low-barrier community-based syringe exchange program. To our knowledge, this will be the first study to specifically assess the potential efficacy and acceptability of a CM intervention for psychomotor stimulant abstinence among individuals who participate in a syringe exchange program. In addition, this study seeks to examine intervention implementation in a natural setting with a community-based service provider who will be implementing the intervention within their clinic.

References. Include references to prior human or animal research and references that are relevant to the design and conduct of the study.

Bentzley, B. S., Han, S. S., Neuner, S., Humphreys, K., Kampman, K. M., & Halpern, C. H. (2021). Comparison of treatments for cocaine use disorder among adults: A systematic review and meta-analysis. *JAMA Network Open*, *4*(5), e218049-e218049.

Bolívar, H. A., Klemperer, E. M., Coleman, S. R., DeSarno, M., Skelly, J. M., & Higgins, S. T. (2021). Contingency management for patients receiving medication for opioid use disorder: a systematic review and meta-analysis. *JAMA psychiatry*, *78*(10), 1092-1102. https://doi.org/10.1001/jamapsychiatry.2021.1969

Brandt, L., Chao, T., Comer, S. D., & Levin, F. R. (2021). Pharmacotherapeutic strategies for treating cocaine use disorder—what do we have to offer?. *Addiction*, *116*(4), 694-710. https://doi.org/10.1111/add.15242

De Crescenzo, F., Ciabattini, M., D'Alò, G. L., De Giorgi, R., Del Giovane, C., Cassar, C., ... & Cipriani, A. (2018). Comparative efficacy and acceptability of psychosocial interventions for individuals with cocaine and amphetamine addiction: A systematic review and network meta-analysis. *PLoS medicine*, *15*(12), e1002715. https://doi.org/10.1371/journal.pmed.1002715

Dutra, L., Stathopoulou, G., Basden, S. L., Leyro, T. M., Powers, M. B., & Otto, M. W. (2008). A meta-analytic review of psychosocial interventions for substance use disorders. *The American Journal of Psychiatry*, 165(2), 179–187. https://doi.org/10.1176/appi.ajp.2007.06111851

Han, B., Compton, W. M., Jones, C. M., Einstein, E. B., & Volkow, N. D. (2021). Methamphetamine use, methamphetamine use disorder, and associated overdose deaths among US adults. *JAMA Psychiatry*, *78*(12), 1329-1342. https://doi.org/10.1001/jamapsychiatry.2021.2588

McMahan, V. M., Kingston, S., Newman, A., Stekler, J. D., Glick, S. N., & Banta-Green, C. J. (2020). Interest in reducing methamphetamine and opioid use among syringe services program participants in Washington State. *Drug and Alcohol Dependence*, *216*, 108243. https://doi.org/10.1016/j.drugalcdep.2020.108243

Prendergast, M., Podus, D., Finney, J., Greenwell, L., & Roll, J. (2006). Contingency management for treatment of substance use disorders: A meta-analysis. *Addiction,* 101(11), 1546–1560. https://doi.org/10.1111/j.1360-0443.2006.01581.x

Objectives: Clearly state the primary and secondary objective(s) of the study.

We are proposing to pursue the following three specific aims:

Aim 1: To determine the efficacy and feasibility of a financial incentives intervention for abstinence from stimulants among individuals participating in a low barrier, community-based syringe exchange program.

Aim 2: To examine the acceptability of a financial incentives intervention for abstinence from stimulants among individuals participating in a low barrier, community-based syringe exchange program.

Aim 3: To examine the efficacy and feasibility of intervention implementation by staff within a community-based syringe exchange program, including barriers and facilitators to effective implementation.

METHODS AND PROCEDURES

Study Design: Describe the research design, including a description of any new methodology and its advantage over existing methodologies.

We are proposing a two condition, parallel groups, randomized control pilot study to evaluate the efficacy of a financial incentives intervention among individuals who use stimulants and take part in a community-based syringe exchange program. The study design will include recruiting service recipients who already participate in programs offered by the Safe Recovery at the Howard Center, a syringe exchange program located in Burlington, VT (i.e., a convenience sample).The experimental group will have the opportunity to earn financial incentives contingent on providing a negative urine sample for stimulants using a point-of-care test, which indicates abstinence from stimulant use, in addition to health education on the health risks of stimulant use and substance injection. The control group will receive health education on the health risks of stimulants use and injection. All participants will participate in their syringe exchange services as usual. We chose the health education as the control because participants across both conditions already receive the services provided by the syringe exchange program. Moreover, this control condition will help control for a potential type of between-groups variability. The treatment condition will last for 12 weeks. The primary outcome measure will be point-prevalence stimulant abstinence, which will be determined by percentage of negative urine samples for stimulants using a point-of-care test.

Procedures: Describe all procedures (sequentially) to which human participants will be subjected. Identify all procedures that are considered experimental and/or procedures performed exclusively for research purposes. Describe the types, frequency and duration of tests, study visits, interviews, questionnaires, etc.

Note: A clinical research protocol may involve interventions that are strictly experimental or it may involve some aspect of research (e.g., randomization among standard treatments for collection and analysis of routine clinical data for research purposes). It is important for this section to distinguish between interventions that are experimental and/or carried out for research purposes versus those procedures that are considered standard therapy. In addition, routine procedures performed solely for research purposes (e.g., additional diagnostic/follow-up tests) should be identified.

All study procedures are for research purposes only. This will be an experimental study conducted at Safe Recovery at the Howard Center. All study procedures will take place in a private, designated room at Safe Recovery. Erin O'Keefe, our co-investigator and collaborator on the project, is the program manager at Safe Recovery who has authorized and set aside this room as research space to be used for this study. Individuals receiving services at the Howard Center Safe Recovery will be approached for participation by a center staff member; this particular staff member's primary role at the Howard Center is to assist with research. This staff member is listed as a study team member in UVMClick, has a UVM netid, and has completed CITI training. Potentially eligible participants will be asked when they come in for services if they would like to participate in a research study. The research assistant will complete each step in the consent process documentation form (listed in the additional materials). Prospective participants who consent to participate in the study will move on to the screening procedure next. Participants will also be provided with the "Resources Sheet" at the same time as the informed consent.

Screening

Participants will be recruited primarily from Safe Recovery, a harm reduction facility located at the Howard

Center in Burlington, Vermont. Approximately 225 individuals per month attend Safe Recovery to exchange used syringes for new syringes. Staff at Safe Recovery estimate that approximately 25% of these individuals use cocaine and/or methamphetamine as the primary drug they inject. Individuals receiving services at Safe Recovery will be asked about interest in participation by the center research staff. Potentially eligible participants will be asked when they come in for services if they would like to participate in a research study. If interested, prospective participants will be invited to complete the intake assessment.

Intake Assessment

All prospective participants will complete a formal assessment at intake; participants will receive $25 for completing the assessment. The screening will take no more than 2 hours. Prior to completing the intake assessment, the prospective participant will read through and sign the consent form; the consent form will contain information about the intake assessment and its procedures, along with the study procedures. During the intake, questionnaires will be completed using pen and paper, then will be uploaded onto the computer and into a secure web platform, REDCap. The assessment battery will include questionnaires that assess the following six areas: (1) sociodemographic, (2) substance use history, (3) substance use follow-back, (4) substance craving, (5) demand for substances, and (6) decision making. The first 3 areas will be assessed using the WA state syringe exchange survey and Treatment Effectiveness Assessment. Substance craving will be assessed using the three-item craving scale. Demand for substances will be assessed using the simulated substance purchase task. Decision making will be assessed using the monetary choice questionnaire. For additional detail about each measure, see each respective questionnaire. Participants will receive $25 for their time and participation in completing the intake assessment.

Intervention Conditions

Participants will be randomly assigned to one of two intervention conditions. These sessions will be administered by one of the following study team members: Howard Center research assistants, UVM research assistants helping with the project, or Drs. Erath and Rawson.

Health Education Condition. The Health Education condition is based on a previous intervention used as a control in a number of other studies (Mooney et al, 2013). Sessions consist of an educational program addressing a variety of health, wellness, and lifestyle topics adapted from a previously implemented wellness manual. One education topic will be discussed each day. The 12 daily educational topics will include: (1) stress relief, (2) nutrition, (3) hepatitis prevention, (4) HIV prevention, (5) sleep hygiene, (6) health screening, (7) meditation, (8) home emergencies, (9) healthy relationships, (10) common medical problems of people who use drugs, (11) strategies to reduce anxiety, depression and other negative moods, and (12) self-defense. Participants in this condition will be scheduled for two clinic visits per week for 12 weeks. Thus, the health education on the 12 topics listed above will be provided in addition to the services provided to all individuals in the Howard Center Safe Recovery program. At one session each week, the individual will meet with a study team member listed above who will review a topic handout with the participant. We anticipate these sessions will take approximately 10-15 minutes.

Health Education plus Incentives for Abstinence. Participants in the experimental condition will have the opportunity to earn financial incentives for abstaining from stimulant use, in addition to receiving the same health education as the control condition. Monitoring of stimulant use will occur through twice-weekly urinalysis during the 12 weeks of the intervention. Specimens will be screened for stimulant use using a 10-panel point-of-care test taken at the center. The financial incentives will be contingent on negative samples for stimulants which include cocaine, methamphetamine, and amphetamine. The incentive amount will start at $25 and increase for each subsequent stimulant-negative urine sample, up to $65 per sample. Only tests where the display indicates negative samples will result in participants earning reinforcement. The incentive amount

for the first stimulant-negative sample will be $25. Every subsequent negative sample will increase by $2.50, with a maximum amount of $65. Thus, the maximum amount a participant could earn if they provide a stimulant-negative sample for the entire 12 weeks is $1,220. A reset will occur if a participant submits a stimulant-positive sample or has an un-excused absence. The next time the participant submits a stimulant-negative sample, the incentive amount will reset to the initial voucher value (i.e., $25). A recovery of the pre-reset value will occur after the participant provides two consecutive stimulant-negative samples; that is, the participant will recover back to their previously earned incentive level instead of restarting the incentive escalation process. The implementation of the financial incentives will be completed by the study team member overseeing the session (e.g., Safe Recovery staff, UVM RA staff). Based on similar studies using financial incentives, we expect participants will earn approximately 40% to 50% of the maximum possible earnings (Heil et al. 2008; Higgins et al., 1996, 2020).

Data Collection

The primary dependent variable is stimulant-free urine samples; all samples will be assessed using point-of-care test conducted at the center. Urine specimens will be collected for all participants at least once weekly throughout the study. Urine specimens are disposed of following recording of the result, thus, no samples are stored. Participants in the health education condition will receive $10 for providing each urine sample (2x per week). Urine samples will be collected for participants in the financial incentives condition twice weekly for all 12 weeks of the intervention for which they can earn the incentives stated above by providing a negative urine sample. Participants in both conditions will also complete the questionnaires for decision making, demand for substances, craving, and treatment effectiveness at three additional times after baseline, at weeks 4, 8, and 12. Data for the questionnaires will be completed using pen and paper, then will be uploaded onto the computer and into REDCap. All participants will be compensated $10 per assessment independent of substance use status to ensure high compliance.

Delivery of Financial Incentives

All earned incentives will be provided to participants using a gift card or a PEX debit card, a reloadable debit card. The gift cards and PEX debit cards do not require a credit history check, and participants will pay no monthly fees for carrying the card. There are no costs for using the gift cards or PEX Debit Cards for instore or online shopping. Research staff or Safe Recovery staff will load money onto the participants gift or debit card after completion of an activity in which an incentive has been earned (i.e., completion of a urinalysis screening; negative urinalysis sample). We are choosing to use gift cards or PEX debit cards because they are easy to implement and money can be immediately loaded to the cards, thereby reducing the delay between the target behavior and delivery of the incentive, an important variable to maximizing the efficacy of the incentive.

Examining Intervention Acceptability

At the 12-week assessment or shortly thereafter, participants in both the incentives for abstinence condition and psychoeducation plus usual care condition will complete a Study Acceptability Questionnaire (SAQ). This measure will be administered via pen and paper and will then be uploaded onto the computer into REDCap. The questionnaire will ask participants about the ease of use, helpfulness, and convenience of the intervention, as well as whether the intervention was fair, fun, and whether they would recommend it. Participants in the psychoeducation plus incentives condition will receive additional SAQ questions inquiring about whether they liked the incentives for abstinence and whether the incentives were helpful in terms of promoting stimulant abstinence.

As noted above, participants will be recruited primarily from Safe Recovery, a harm reduction facility located at the Howard Center in Burlington, Vermont. Individuals receiving services at Safe Recovery will be approached about participation by the Safe Recovery research staff. Potentially eligible participants will be asked when they come in for services if they would like to participate in a research study. If interested, prospective participants will be invited to complete the intake assessment.

For research involving survey, questionnaires, etc.: Describe the setting and the mode of administering the instrument and the provisions for maintaining privacy and confidentiality. Include the duration, intervals of administration, and overall length of participation.

☐ **Not applicable**

All efforts will be made to maintain confidentiality. Assessments will be completed in a private room at Safe Recovery. Prospective participants who are eligible (i.e., participate in the Howard Center's syringe exchange program) will be approached by a study team member and asked about their potential interest in participating in the study. If interested, participants will then be provided with information about the study (via informed consent) and the study team member will review all steps on the consent process documentation sheet and answer any potential questions. If the participant consents to participate, then they will be asked to complete the following questionnaires. At intake, the Washington State syringe exchange health survey will be used to assess sociodemographic, substance use history, and substance use follow-back (McMahan et al., 2020). Demand for substances will be assessed using the simulated substance purchase task (Murphy et al., 2011). Decision making will be assessed using the Monetary Choice Questionnaire (Kirby et al., 1999). Substance craving will be assessed using the three-item craving scale (McHugh et al., 2021). The intake assessment will take no longer than 120 minutes and will occur once at the intake.

At weeks 4, 8 and 12 of the intervention, all participants will complete the Monetary Choice Questionnaire, three-item craving scale, and demand for substances using the simulated purchase task. Data for the questionnaires will be completed using pen and paper, then will be uploaded onto the computer and into REDCap. Each assessment will take no longer than 20 minutes.

All data will be coded by an assigned identification number, with the codes known only by the investigators on this project. Names will not be connected with any results. The security of the records will be maintained by keeping paper files in a locked file cabinet and by keeping REDcap computer files in password protected files. The master copy will be kept in a different locked file cabinet from the coded data. The results of this study will eventually be published, but patient confidentiality will be maintained.

TYPES OF PROCEDURES (Please do not use the "other" option unless the procedure is not listed.)
Check all that apply.

x	Survey (mail, telephone, in-person, on-line)	☐	Blood drawing: Vol. ☐ Over days, weeks? ☐		
x	Medical exams/history				Type & Amt. ☐
☐	Deception ***see below**	☐	Surgery	x	Collection of Urine and/or Feces
x	Observation	☐	Drug Administration	☐	HIV Testing
☐	Photographs	☐	Device Use	☐	Ultrasound (e.g. echocardiogram)
☐	Audio Recording	☐	Exercise	☐	Imaging (e.g. CT scan, DEXA, mammogram, PET scans, SPECT)
☐	Video Recording	☐	Diet	☐	Use of Radiation treatment
☐	Interviews in person or by phone	☐	Pathology Specimens (retrospective)	☐	Use of Radioactive substances (e.g. radiolabeled antibodies, drugs or contrasts)
☐	Focus Groups	☐	Genetic Materials (DNA)** **see below**	☐	MRI (for treatment studies)
☐	Review of prospective data	x	Questionnaires	☐	MRI (not for treatment studies)
☐	Review of retrospective data	☐	Diaries	☐	Tissue (obtained for clinical purposes)

☐	Recording of Identifiable Data	☐	Pregnancy Tests	☐	Tissue (obtained solely for research)
☐	Electrocardiograms				
x	Sensitive Data (criminal or sexual conduct, drug or alcohol conduct or use)	(specify):			

****If genetic information is being collected, GINA language must be added to the consent form.**
*****Deception typically involves withholding information from the potential subject and would require an alteration to the consent process.

Statistical Considerations: Delineate the precise outcomes to be measured and analyzed. Describe how these results will be measured and statistically analyzed. Delineate methods used to estimate the required number of subjects. Describe power calculations if the study involves comparisons. Perform this analysis on each of the primary and secondary objectives, if possible.

Participant baseline demographics and characteristics will be compared between treatment conditions (Health Education vs. health Education plus Incentives for Abstinence) using Chi Square Tests of Independence or Fisher's Exact Tests for categorical variables and Wilcoxon Rank Sum Tests or Two-Sample T-tests for continuous variables, depending on the distributions of the variables. If a specific characteristic differs significantly between treatment conditions and is predictive of the outcome, it will be considered as a potential covariate in subsequent analyses. The primary outcome to be analyzed will be point-prevalence stimulant abstinence, which will be determined by percentage of negative urine samples for stimulants using a point-of-care test. Analyses of treatment condition effect on point-prevalence stimulant abstinence will adhere to an intent-to-treat approach whereby all participants randomized to each treatment condition will be included in the analyses independent of early dropout, noncompliance, etc. Point-prevalence abstinence rates will be compared between treatment conditions at individual timepoints using Chi Square Tests of Independence. Comparisons of point-prevalence abstinence rates between treatment conditions across all assessments will be analyzed using mixed model repeated measures for categorical data based on generalized estimating equations (GEE) using a logistic link function. Comparisons of predictors of abstinence that are continuous outcomes and continuous outcomes based on survey responses between treatment conditions across all assessments will be analyzed using mixed model repeated measures analyses of variance. Comparisons of predictors of abstinence that are categorical outcomes and categorical outcomes based on survey responses between treatment conditions across all assessments will be analyzed using mixed model repeated measures for categorical data based on generalized estimating equations (GEE) using a logistic link function.

Because this is an exploratory pilot study evaluating the potential efficacy, feasibility, and acceptability of a contingency management intervention for stimulant use within a syringe exchange program, we are proposing a small, initial pilot study of 40 participants. Data from a previous meta-analysis study (Bolívar et al., 2021), which examined the CM treatment effects on abstinence from psychomotor stimulant use found a mean effect size for treatment effect on abstinence from psychomotor stimulant of Cohen's d = 0.70. However, among studies included in this analysis, the minimum effect size which was for the outcome of point-prevalence stimulant abstinence was Cohen's d = 0.51 (Rawson et al., 2002; doi:10.1001/archpsyc.59.9.817). Using this "medium" effect size for sample size calculation, in order to detect a statistically significant difference in point-prevalence stimulant abstinence between treatment conditions with 80% power, with 2-sided significance level alpha of 0.05, a total sample size of 88 participants would be required. However, because this is an initial pilot study looking to assess feasibility and potential efficacy, we expect to observe discernable differences between the two conditions with a sample size of 40. The goal is to conduct a pilot study where the data could then be used to inform a larger, fully powered randomized control trial.

Risks/Benefits: Describe any potential or known risks. This includes physical, psychological, social, legal or other risks. Estimate the probability that given risk may occur, its severity and potential reversibility. If the study involves a placebo or washout period, the risks related to these must be addressed in both the protocol and consent. Describe the planned procedures for protecting against or minimizing potential risks and assess their likely effectiveness. Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. Discuss the potential benefits of the research to the subjects and others. Discuss why the risks to the subjects are reasonable in relation to the anticipated benefits to subjects and others. Discuss the importance of the knowledge gained or to be gained as a result of the proposed research and why the risks are reasonable in relation to the knowledge that reasonably may result. If there are no benefits state so.

Risks

- Prospective participants who consent to participate in the study will be asked questions about their substance use, which may be uncomfortable. This research is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify participants in any action or suit unless they say it is okay. They also cannot provide them as evidence unless the participant has agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena. The CoC is automatic with NIH funding.
- Although unlikely, a breach of confidentiality could occur. Signed informed consent forms will be stored separately from all collected data in a different locked cabinet in a locked office at the Vermont Center on Behavior and Health, which is located in the University of Vermont Medical Center, UHC campus.
- Participants in this study may experience withdrawal. These symptoms can include anger, irritability, frustration, anxiousness, depressed mood, substance cravings, difficulty concentrating, sleep problems, restlessness, impatience, constipation, dizziness, nightmares, and nausea. If these mood changes appear to put a participant's health at risk, they will be asked to stop participating in the study. We will be providing a resources sheet about withdrawal services available to each participant (and other services available) when they complete the informed consent. Additional copies will also be available for participants throughout the study.

Benefits

- The primary benefit is that participation could result in abstinence or reduced use of psychomotor stimulants. This would have numerous positive health benefits for the participant. This study may also teach us how to more effectively help others stop using stimulants. The other information that participants provide may increase knowledge about factors that influence the ability to quit using stimulants.

Therapeutic Alternatives: List the therapeutic alternatives that are reasonably available that may be of benefit to the potential subject and include in the consent form as well.

☐ **Not Applicable**

Participants could attempt to stop or reduce their stimulant use on their own, without support offered by participation in the study.

Data Safety and Monitoring: The specific design of a Data and Safety Monitoring Plan (DSMP) for a protocol may vary extensively depending on the potential risks, size, and complexity of the research study. For a minimal risk study, a DSMP could be as simple as a description of the Principal Investigator's plan for monitoring the data and performance of safety reviews or it could be as complex as the initiation of an external, independent Data Safety and Monitoring Board (DSMB). The UVM/UVM Medical Center process for review of adverse events should be included in the DSMP.

All efforts will be made to maintain confidentiality. The IRB at UVM will review this protocol. Oversight of the project and monitoring will be conducted by the primary investigators (Dr. Erath and Dr. Higgins). All procedures will be monitored to ensure adherence with the protocol. All assessments will be conducted privately. All questionnaires will be administered on paper. A hard copy of the collected data will be stored in a locked office within a locked file cabinet. All hard copy questionnaire data does not contain any directly identifiable information. Hard copy data will be inputted into, and directly stored on, a secure web platform, REDCap. All data will be coded by identification number, with the codes known only by the investigators on this project. Names will not be connected with any results. The monitoring plan will consist of ongoing, close monitoring of data and safety issues by the PI and other project staff and prompt reporting of any adverse events (AEs) or serious adverse events (SAEs) to the institutional review board and/or NIGMS. The security of these records will be maintained by keeping paper files in a locked file cabinet and by keeping computer files in a password protected file on REDcap. The results of this study

will eventually be published, but patient confidentiality will be maintained.

Define criteria to be used for decision making regarding continuation, modification, or termination of the entire study (not individual participation) (i.e. "stopping rules).

We plan to continue this study until the sample size has been met, after which the study will be terminated.

What will be the frequency of the review? Please note that the frequency of reviews should be commensurate with the risk of the study. At a minimum, a review of the data should be conducted annually at time of continuing review. **Forward copies of the data and safety monitoring reports to the 1) IRB, 2) CRC (if applicable), and/or 3) UVMCC (if applicable).**

- [ ] Monthly
- [ ] Quarterly
- [ ] Bi-annually
- [x] Annually
- [ ] Other (e.g. by dosing level, no. of subjects enrolled):

Will the sponsor be conducting data monitoring visits for this study?

- [ ] Yes
- [x] No
- [ ] NA

If yes, how often?

Adverse Event, Unanticipated Problem (UAP), Reportable New Information (RNI): Describe how events and UAPs will be evaluated and reported to the IRB. All protocols should specify that, in the absence of more stringent reporting requirements, the guidelines established in the "Adverse Event and Unanticipated Problems Reporting Policy" will be followed. The UVM/UVM Medical Center process for review of adverse events and UAPs to subjects or others should be included in the DSMP.

The primary investigators will evaluate all AEs, UAPs, and RNIs. We will follow the guidelines established by the Committees on Human Research "Adverse Event and Unanticipated Problems Reporting Policy". Any SAE will be brought to the attention of the PIs as soon as possible and no longer than 24 hours. Any AE or SAE that is both unexpected and related to study participation will be reported to the IRB within 7 days of the event. The IRB will make a determination as to whether additional reporting requirements are needed. IRB actions will be reported to the funding agency by the PIs no less than annually and more frequently as recommended by the local IRB. Any SAEs will be summarized in the yearly Progress Reports to the funding agency, including a review of frequency and severity. All SAEs will be followed through ongoing consultation with the physician caring for the patient until they resolve, result in death, or stabilize and are not expected to improve. The study staff will be in close contact with participants and health care providers throughout the study to monitor for potential unanticipated problems. Any unanticipated problems will be discussed at the weekly research staff meetings and reported as required to the CHRBSS using the Report of Protocol-Related Problems & Deviations Form.

Withdrawal Procedures: Define the precise criteria for withdrawing subjects from the study. Include a description of study requirements for when a subject withdraws him or herself from the study (if applicable).

Participants are free to withdraw from the study at any time and for any reason while they are completing the study. Participants may be withdrawn if the PIs determine it is not advisable that they continue on in the study. Regarding data analysis, we will adhere to an intent-to-treat approach (Armitage, 1983) wherein all participants randomized to the study conditions will be included in the analyses independent of early dropout, or noncompliance.

Sources of Materials: Identify sources of research material obtained from individually identifiable human subjects in the form of specimens, records or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records or data.

All data collected will be for research purposes only. This study will include individuals 18 years and older who participate in services provided by Safe Recovery at the Howard Center in Burlington, VT. The data collected will include both answers to the questionnaires described above and urine specimens which will be tested for psychomotor stimulants. Thus, the sources of materials include:

- Questions on sociodemographic, substance use history, and substance use follow-back
- Questions on demand for substances, decision making, and substance craving
- Urine samples to be tested for recent stimulant use

DRUG INFORMATION

Investigators are encouraged to consult the UVM Medical Center Investigational Pharmacy Drug Service (847-4863) prior to finalizing study drug/substance procedures.

Drug (s) [x] **Not applicable**

Drug name – generic followed by brand name and common abbreviations. Availability – Source and pharmacology; vial or product sizes and supplier. If a placebo will be used, identify its contents and source.

Preparation: Reconstitution instructions; preparation of a sterile product, compounded dosage form; mixing guidelines, including fluid and volume required. Identify who will prepare.

Storage and stability – for both intact and mixed products.

Administration – Describe acceptable routes and methods of administration and any associated risks of administration.

Toxicity – Accurate but concise listings of major toxicities. Rare toxicities, which may be severe, should be included by indicated incidence. Also, adverse interactions with other drugs used in the protocol regimen as well as specific foods should be noted. Address significant drug or drug/food interactions in the consent form as well. List all with above details.

Is it FDA approved: (include FDA IND Number)

1. in the dosage form specified? If no, provide justification for proposed use and source of the study drug in that form.
2. for the route of administration specified? If no, provide justification for route and describe the method to accomplish.
3. for the intended action?

SUBJECT CHARACTERISTICS, IDENTIFICATION AND RECRUITMENT

Subject Selection: Provide rationale for subject selection in terms of the scientific objectives and proposed study design.

This study will be comprised of individuals 18 years and older who participate in services provided by Safe Recovery at the Howard Center in Burlington, VT. This convenience sample was chosen based on interest from the organization to query information about current substance use behavior and potential interest in participating in an evidence-based intervention to reduce substance use.

Vulnerable Populations: Explain the rationale for involvement of subjects (e.g., cognitively impaired, Non-English speaking, prisoners, students). Discuss what procedures or practices will be used in the protocol to minimize their susceptibility to undue influences and unnecessary risk (physical, psychological, etc.).

[ ] **Not applicable**

Individuals who use stimulants and participate in a syringe exchange program, in order to develop more effective interventions to help them stop or reduce their stimulant use.

Inclusion/Exclusion Criteria: Eligibility and ineligibility criteria should be specific. Describe how eligibility will be determined and by whom. Changes to the eligibility criteria at a later phase of the research have the potential to invalidate the research.

Study participants will be individuals who participate in the syringe exchange. Participants will be recruited from the safe recovery syringe exchange program at the Howard Center – a local, community-based care center – in which they already participate.

To be included in the study, prospective participants must meet the following criteria: (a) be 18 years or older, (b) report using stimulants in the past 30 days, and (c) meet the DSM-5 diagnosis for stimulant use disorder at a moderate or severe level (i.e., 6 or more of the 11 DSM criteria), and (d) participation in services offered by Howard Center Safe Recovery

Exclusionary criteria: (a) failure to meet one or more inclusionary criteria above, (b) individuals who are cognitively impaired by their drug use or psychiatric conditions that could preclude informed consent. Specifically pertaining to criterion b: individuals who are intoxicated and/or acutely psychotic will be precluded from the study. The Howard Center staff will make this assessment based on their training and clinical judgement.

Individuals will be formally enrolled in the study if they meet all inclusionary criteria, complete the initial intake assessment, and complete the informed consent process.

Inclusion of Minorities and Women: Describe efforts to include minorities and women. If either minorities or women are excluded, include a justification for the exclusion.

This study will include all individuals who receive services from Safe Recovery at the Howard Center, including women and minorities.

Inclusion of Children: Describe efforts to include children. Inclusion is required unless a clear and compelling rationale shows that inclusion is inappropriate with respect to the health of the subjects or that inclusion is inappropriate for the purpose of the study. If children are included, the description of the plan should include a rationale for selecting or excluding a specific age range of children. When included, the plan must also describe the expertise of the investigative team in working with children, the appropriateness of the available facilities to accommodate children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study. Provide target accrual for this population. Identify whether children are wards of the state. **If children are excluded** then provide appropriate justification.

The Safe Recovery Program primarily targets adults. Children are excluded.

For protocols including the use of an investigational drug, indicate whether women of childbearing potential have been included and, if not, include appropriate justification.

There will be no use of an investigational drug.

If HIV testing is included specifically for research purposes explain how the test results will be protected against unauthorized disclosure. Include if the subjects are to be informed of the test results. If yes, include the process and provision for counseling. If no, a rationale for not informing the subjects should be included.

x **Not applicable**

Will the SONA Psychology Pool be utilized? *Include documentation indicating permission to use this recruiting tool* Yes ☐ No ☐

FINANCIAL CONSIDERATIONS

Describe all potential research related expenses to subjects:

There are no expenses for participants.

Compensation for participation: Describe all plans to pay subjects, either in cash, a gift or gift certificate. Please note that all payments must be prorated throughout the life of the study. The IRB will not approve a study where there is only a lump sum payment at the end of the study because this can be considered coercive. The amount of payment must be justified. Clarify if subjects will be reimbursed for travel or other expenses.

☐ **Not applicable**

All prospective participants will complete a formal assessment at intake for which they will receive $25 for completing the assessment. All participants will complete the questionnaires for decision making task and demand for substances three additional times after baseline, at weeks 4, 8, and 12, and will be compensated $10 per assessment independent of substance use status to ensure high compliance. If randomized to Intervention A, participants can earn $10 for providing each urine sample twice per week (total up to $240); the incentive is not contingent on a stimulant negative urine sample (i.e., is only contingent on providing the sample). Thus, the maximum amount a participant can earn in Intervention A is $295. If randomized to Intervention B, urine samples will be collected for participants twice weekly for 12 weeks where participants can earn incentives by providing a negative urine sample (i.e., the incentive is contingent on providing a stimulant negative urine sample). Incentives for these samples start at $25 and max out at $65 (max total - $1,220). Thus, the maximum amount a participant can earn is $1,275. All compensation will be delivered on a gift card or a reloadable debit card.

Research Data Management Plan: The Research Data Management and Security Plan form must be completed. The form, along with guidance, can be found in our forms library and must be submitted with your initial application.