

Brief acceptance and commitment therapy for HIV-infected at-risk drinkers

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(Syracuse University Institutional Review Board)

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Protocol Adapted from IRB-approved Full Board Application that was in use at the time the study was officially closed (January 20th, 2023).

1. Study Rationale

1.1. Using non-technical language, describe the objective of this proposed research including purpose, research question, hypothesis, etc. From your description, the IRB should be able to determine how this proposed study adds to the knowledge on the research topic in order to judge the risks and benefits to the research participants. NOTE: A reference list citing relevant background information must be provided as an appendix with this application.

Alcohol use is a major problem in HIV care. Sixty-six percent of people living with HIV (PLWH) report using alcohol in the previous year (Blair et al., 2014), 8-20% report drinking at hazardous or heavy levels (Chander, Lau, & Moore, 2006; Kelly et al., 2016; Marshall et al., 2015; Sullivan, Goulet, Justice, & Fiellin, 2011), and 30% report current binge drinking (>5 drinks in an occasion in the past 30 days) (Kelly et al., 2016). PLWH who are hazardous drinkers, compared to those who abstain, experience a significant increase in risk for: mortality (Justice et al., 2016), lack of viral suppression (Chander et al., 2006), less ART utilization (Chander et al., 2006), taking ART medications off schedule (Cook et al., 2001), sub-optimal adherence to ART (Hendershot, Stoner, Pantalone, & Simoni, 2009), and engagement in sexual risk behavior (Shuper, Joharchi, Irving, & Rehm, 2009). Hazardous alcohol consumption has been found to affect nearly every stage of the HIV care continuum (Vagenas et al., 2015), making it a critical factor in HIV treatment that, if unaddressed, may significantly contribute to onward transmission (Bryant, 2006).

Behavioral interventions for HIV-infected drinkers have provided limited evidence of benefit. HIV-prevention interventions do not typically address alcohol use (Vagenas et al., 2015), and it is often overlooked in HIV care (Williams et al., 2016). While there have been several clinical trials of alcohol interventions for PLWH in the US, these trials have shown mixed results for reducing alcohol use and improving HIV-related outcomes (Brown, DeMartini, Sales, Swartzendruber, & DiClemente, 2013; Samet & Walley, 2010; Williams et al., 2016). No alcohol intervention for PLWH has shown long-term reductions in heavy drinking or a significant impact on HIV-related outcomes (Williams et al., 2016). One hypothesized reason for this limited success is that PLWH who are hazardous drinkers are also likely to have multiple overlapping problems (Brown et al., 2013; Samet & Walley, 2010). It is estimated that 38% of PLWH meet criteria for both a substance use and another psychiatric disorder (Tegger et al., 2008) and also have a myriad of behavioral health needs (e.g., treatment adherence, condom use), any one of which would benefit from intervention. In order to adequately address these issues, PLWH require innovative alcohol intervention strategies that can also have an impact on other behavioral and mental health needs, in a format that can be feasibly delivered in the context of HIV care.

Brief acceptance and commitment therapy (ACT) is a promising intervention for HIV-infected drinkers.

ACT is a transdiagnostic treatment that targets experiential avoidance (i.e., repeated attempts to eliminate or avoid difficult thoughts/feelings) as an underlying factor common to mental and behavioral health problems. Mindfulness skills and values-guided behavioral action plans are used to decrease experiential avoidance and impact a broad array of psychological symptoms. ACT has shown efficacy for treatment of anxiety (Arch et al., 2012; Landy, Schneider, & Arch, 2015), depression (Zettle, 2015), and chronic pain (Veehof, Trompetter, Bohlmeijer, & Schreurs, 2016), making it a promising approach for HIV-infected hazardous drinkers. A recently published meta-analysis also indicates that ACT is efficacious for smoking, opiate use, methamphetamine use, and polydrug abuse (Lee, An, Levin, & Twohig, 2015), showing a small to medium effect size compared to active treatment controls (e.g., Cognitive Behavioral Therapy (CBT)). ACT's focus on skills that increase the ability to experience and accept, rather than change and control, urges and cravings related to substance use is different from more traditional forms of addiction treatment such as CBT (Bricker, Bush, Zbikowski, Mercer, & Heffner, 2014). Indeed, a pilot RCT of a brief, telephone-delivered ACT intervention for smoking cessation had quit rates more than double that of traditional CBT for smokers with comorbid depression (Bricker et al., 2014). However, ACT has not been studied for hazardous drinkers.

The overall objective of this application is therefore to adapt an existing brief ACT intervention (Bricker et al., 2014) and pilot test its feasibility, acceptability, and preliminary efficacy for PLWH who are hazardous drinkers. **We hypothesize that** the resulting intervention will have a significant effect on biological and self-reported measures of alcohol use and ART adherence. Secondary analyses will also examine changes in acceptance—a known mechanism of change in ACT (Bricker et al., 2014; Cederberg, Cernvall, Dahl, von Essen, & Ljungman, 2016; Hesser, Westin, & Andersson, 2014)—, symptoms of depression and anxiety, and drug use, which we expect to differ by treatment group. The specific aims are as follows:

Aim 1: Adapt an existing brief ACT intervention for HIV-infected hazardous drinkers (ACCEPT). We will accomplish this aim by: Modifying an existing 5-session, telephone-delivered ACT intervention for smoking cessation (Bricker et al., 2014) (The **TALK** Intervention) using a theoretical framework that has been previously used to systematically adapt evidence-based HIV interventions (Wingood & DiClemente, 2008). We will conduct iterative multidisciplinary team meetings, focus group discussions with HIV clinic patients (N = 15-20), and qualitative interviews with HIV clinic providers (N = 5-10) to inform the adaptation process, get feedback on intervention content, and develop a new treatment manual.

Aim 2: Conduct a pilot superiority trial of ACCEPT compared to a brief alcohol intervention. We will accomplish this aim by: Randomly assigning N = 74 HIV-infected hazardous drinkers (50% women) to the intervention developed in Aim 1, or a brief alcohol intervention previously developed for PLWH (Chander, Hutton, Lau, Xu, & McCaul, 2015) that is nearly equivalent in number and length of sessions. We will assess feasibility, acceptability, and primary trial outcomes of alcohol use and ART adherence immediately post-treatment and again at 3 and 6-months post-randomization. Secondary outcomes of changes in acceptance, symptoms of depression, symptoms of anxiety, and drug use will also be assessed at all time points. Tertiary outcomes of chronic pain, HIV medication adherence self-efficacy, alcohol-related problems, quality of life, food insecurity, reasons for drinking, and HIV-related stigma will also be assessed at all time points.

The proposed research will provide essential pilot data for an R01 application to conduct a full-scale RCT to determine the efficacy of the ACCEPT intervention compared to an active treatment control. If successful, this intervention will have broad implications for implementation in HIV care settings.

2. Methods

2.1. Provide a detailed description of what participants will be required to do; including any technical terms or procedures.

Aim 1: Adapt an existing brief ACT intervention for HIV-infected hazardous drinkers (ACCEPT)

Prior to beginning study activities with human subjects, the research team (the Co-Principal Investigators, Drs. Maisto and Woolf-King, and the Co-Investigators, Drs. Hahn and Bricker) will meet to make a preliminary adaptation of the **TALK** Manual (see Appendix IV), an existing 5-session, telephone-delivered ACT intervention for smoking cessation which we propose to adapt. We will modify all content related to smoking cessation to be relevant for alcohol use, and add content related to managing HIV infection. Once we have an initial draft of the adapted manual (hereafter referred to as the **ACCEPT** intervention/manual), we will proceed to the activities in Aim 1 that involve human subjects.

A1a. Recruitment. Sample sizes described below were chosen for feasibility and for adequate variability in participant responses. Should we not achieve adequate variability (i.e., not reach qualitative data saturation), we will submit an amendment to request to conduct additional interviews/focus groups. As we are currently doing in our other (SU IRB-approved) NIH-funded study with HIV-positive men (the IN-VOICE study; IRB#16-143), we will recruit HIV-infected hazardous drinkers directly from the Immune Health Services (IHS) Clinic at SUNY Upstate in conjunction with their HIV clinic appointment. IHS clinic staff will inform the patient about the study during their routine HIV clinic appointment using a standard recruitment script (**see Appendix II**). If interested, the participant will be referred directly to one of the research assistant (RAs) for the project and/or given contact information. The participant will subsequently be pre-screened for eligibility either in person or via telephone and, if eligible, will be scheduled for an in-person appointment at our research offices. We will also contact participants who have participated in and/or were screened for the IN-VOICE study and indicated interest in being contacted for future research (which we documented in our secure tracking database in REDCap). HIV clinic providers will be recruited via presentations from study staff at ongoing HIV clinic meetings, listservs to HIV clinic providers, and word-of-mouth via former participants in the study. A full description of all recruitment procedures may be found in **section 8** of this application.

A1b. Qualitative Interviews with HIV Clinic Providers We will conduct individual semi-structured interviews with 5-10 HIV clinic providers from the IHS Clinic at SUNY Upstate. We will present the interviewee with a draft of the adapted **TALK** manual (**see Appendix V**) and use a qualitative interview guide (**see Appendix III**) to elicit feedback

on the first session represented in the manual. We will go through the manual page-by-page, demonstrating the activities in the manual, and requesting comments/feedback. All interviews will take place in a private interview room in Dr. Woolf-King or Dr. Maisto's lab space on the basement or 2nd floor of 804 University Avenue respectively or in a private office at the IHS Clinic at SUNY Upstate. All participants will receive a detailed informed consent (see **Appendix VI**), after which the interview will commence. Interviews will be audio recorded with permission, and are expected to take 90-120 minutes to complete. Participants will be paid \$40 for their time. Recorded interviews will be uploaded to a secure, Syracuse University server immediately upon completion and subsequently deleted from the recording device. Written debriefings will be generated after each interview and all de-identified interviews will be transcribed by a professional transcriptionist, Sally Black, with whom we are currently working with in our SU-IRB approved study with HIV-infected men (IN-VOICE Study).

A1c. Focus groups discussions (FGD) with HIV-infected hazardous drinkers. We will conduct 2-3 focus group discussions (FGDs) with HIV-infected hazardous drinkers (total N = 15-20). As with the individual interviews, FGD participants will be presented with a copy of the adapted first session of the TALK manual, which the group will review with the facilitator. For each section, participants will be asked open-ended questions related to the appropriateness and relevance of the elements in the session to the target population, further adaptation of the content and materials, and suggestions for any areas for improvement. All participants will receive a detailed informed consent (see **Appendix VI**) and be reminded about the importance of keeping confidential other group members' identities and information shared in the FGD. FGDs will be audio recorded with written permission of ALL FGD participants. FGDs are expected to take 90-120 minutes to complete and participants will be paid \$40 each for their time. Recorded interviews will be uploaded to a secure, Syracuse University server dedicated to our lab immediately upon completion and subsequently deleted from the recording device. Written debriefings will be generated after each FGD and all de-identified FGDs will be transcribed by a professional transcriptionist (Sally Black), with whom we are currently working with for the IN-VOICE Study.

After the Interviews and FGDs have been transcribed, all de-identified interview transcripts will be uploaded into Dedoose—a secure, password-protected, cloud-based qualitative data analysis software program. Dr. Woolf-King and two graduate RAs affiliated with the project will independently read the transcripts and meet weekly to discuss emerging themes. At the descriptive level, analyses will involve identifying and summarizing themes related to acceptability, relevance, and improvement of the adapted intervention. We will develop a list of thematic content codes, and once we have a working codebook, we will build consensus in coding (90% coder agreement) and then code the data in Dedoose. Once qualitative data analysis is complete, we will complete adaptation of the TALK Manual, which will then become the ACCEPT Manual and will be used in the pilot RCT described in Aim 2. We will submit an amendment to the SU IRB with the ACCEPT manual prior to initiation of the human subjects activities described in Aim 2.

Aim 2. Conduct a pilot superiority trial of ACCEPT compared to a brief alcohol intervention

We will conduct a pilot superiority RCT with N = 74 hazardous drinking PLWH in order to determine the feasibility, acceptability, and preliminary efficacy of the brief ACT intervention developed in Aim 1 (ACCEPT) compared to an active treatment control. Two trials have demonstrated that a brief alcohol intervention can reduce the alcohol use of PLWH in the short-term^[1, 48]. One of these trials, Chander et al. (2015), is similar in dose to the intervention proposed in this application (4 brief sessions), offering an active treatment comparator that is also closely matched for attention. We will thus randomize 74 PLWH who are hazardous drinkers to either the brief ACT intervention developed in Aim 1 (ACT, or an active treatment control – the Chander et al. (2015) brief alcohol intervention (BI; see **Appendix V**). The sample size for the trial was chosen to be logistically practical and feasible given the proposed timeframe and budget constraints of the study, patient flow in the IHS clinic, anticipated rate of recruitment and retention, and the size of study staff—all of which will inform the full RCT for which this pilot trial is designed to inform.

A2a. Recruitment. Recruitment procedures will be identical to those described in Aim 1 and will include only HIV-infected hazardous drinkers (no HIV clinic providers will be recruited for Aim 2). Recruitment will occur through remote recruitment from HIV clinics and organizations that service PLWH in the continental U.S., online recruitment from online venues that target PLWH, smartphone applications (e.g., Grindr, OKCupid, etc.), and recruitment from community-based organizations and bars. To aid in reaching recruitment goals, study methods were revised to include the use of TrialFacts, an online digital advertising company that recruits research study participants (<https://trialfacts.com/>). As part of our contract with TrialFacts, they developed recruitment materials (i.e., study

flyers, recruitment videos, study advertisements, stock images, recruitment scripts, and email templates), as well as a web-based study landing page that facilitated screening and scheduling. The RA will use recruitment scripts and flyers when engaging with recruitment sources (see **Appendix II**).

A2b. Baseline (BL) visit. Prior to scheduling, potential participants will be screened for age (18+), HIV-status, current prescription for HIV medication, the ability/willingness to provide a physical address for mailing study materials, and alcohol use via the Alcohol Use Disorders Identification Test-Consumption (AUDIT-C; score of ≥ 4 for men; ≥ 3 women to be eligible for participation) via telephone or Zoom-based video. Eligible participants will be scheduled for remote baseline study appointment via telephone or Zoom-based video. If the participant is deemed eligible to participate in the study, they will be mailed a baseline package containing an informed consent document (hard copy), a dried blood spot (DBS), nail sample, and hair sample collection kits with instructions for self-collection, a copy of the REALM-R list of words, an incentive accrual handout, a mental health resources list, and an envelope with pre-paid postage for mailing the biological specimen kit back to the lab P.O. Box. If a participant does not have access to a smartphone, tablet, or computer, they will also be mailed a lab study phone containing a pre-paid data plan.

At the beginning of the baseline visit, the RA will contact the participant and re-screen for eligibility including the addition of a health literacy screener (i.e., Rapid Estimate of Adult Literacy in Medicine, revised; participants deemed ineligible after the re-screen will be paid **\$10.00**). The RA will electronically send the eligible participant the informed consent generated link from REDCap. The RA will then review the informed consent with the participant and administer the informed consent understanding check (see **Appendix VI**). Participants will have the ability to confirm their consent by clicking “yes” or “no” on the survey. This will automatically generate a notification in REDCap that the participant completed the informed consent. If the participant consents to participate, the RA will inform them that they are enrolled in the study at this point and continue with the baseline appointment. Participants will be compensated **\$50.00** for completing the baseline study visit, which includes the following procedures:

- **Collection of self-report data.** All self-report questionnaires (see **Appendix IV**) will be administered and stored via Research Electronic Data Capture (REDCap), a web-based, data collection system that allows for secure computerized collection and storage of data as well as stratified randomization algorithms (<https://projectredcap.org/>). REDCap is managed by Syracuse University’s Information Technology Services (ITS) and we have previously used it for data collection in our lab (IN-VOICE study).
- **Randomization.** The participant will be randomized (stratified by gender and interventionist) to the treatment condition (ACT or BI) and randomized to a Masters-level graduate student RA within that condition. Participants will be randomized equally between the ACCEPT and the BI conditions, and equally between the three graduate RA interventionists. We will use the randomization module within REDCap to implement a pre-defined stratified (by gender and interventionist) blocked randomization model, which will be securely stored in the REDCap database.
- **Collection of dried blood spots (DBS).** The RA will remotely instruct the participant on how to self-conduct Fingerstick Blood Sampling (FSBS) to collect DBS via the standardized operating procedures (SOPs) described in **Appendix VII**. We developed this SOP in consultation with the Biosafety office at Syracuse University and have previously used it to collect DBS for the IN-VOICE study. The participant will use a provided microlancet to puncture the skin on one of their fingers and then places five drops of blood on a pre-labeled DBS card (containing only the participant’s ID number, date of the appointment, type of visit (i.e., baseline, post-treatment, 6-month follow-up), and the research assistant’s initials. Participants will cover their pricked finger location with provided gauze and a bandage, wash their hands and disinfect all work surfaces, and then place the collection card in the pre-labeled white box inside the pre-paid envelope. After participants collect and package their DBS, they will be instructed to mail them to the lab P.O. Box using the pre-paid envelope they received. DBS samples will be mailed to the lab P.O. Box and upon receipt will be stored in our -80-freezer located at 426 Ostrom Ave. Room #109 prior to shipment to the United States Drug Testing Laboratory (USDTL) at 1700 South Mount Prospect Road, Des Plaines, IL 60018. USDTL uses liquid chromatography–tandem mass spectrometry (LC-MS-MS) to detect phosphatidylethanol (PEth), a biomarker of recent alcohol use, and sends the de-identified results via an emailed pdf file that contains the subject ID, the date of collection, the date of processing, and the result (e.g., PEth positive, 54ng/mL).
- **Collection of hair samples.** The participant will self-collect several strands of hair for analysis of levels of antiretroviral (ARV) medication. Hair collection is noninvasive and does not require specialized skills, sterile equipment, specific storage conditions, or shipment with precautions for biohazardous materials. The SOP for

collection of hair can be found in **Appendix VII**. Briefly, the RA will instruct the participant to do the following: 1. Clean the blades of a pair of scissors with an alcohol pad and allow blades to dry; 2. Lift up the top layer of hair from the occipital region of the scalp. Isolate a small thatch (50-100 strands) from underneath this layer; 3. Cut the small hair sample as close to the scalp as possible; 4. Place the thatch inside an unfolded piece of foil; 5. Place a narrow label over the distal end (the side furthest from the scalp) to denote directionality if strands long enough; 6. Refold the foil to enclose the sample; 7. Place a study ID label on the folded piece of foil; 8. Place the foil inside the plastic (e.g. Ziploc) bag, each containing a desiccant pellet, and seal. Samples will be mailed in a pre-paid mailer from the participant to the Lab P.O. Box and kept at room temperature in a locked cabinet in our lab in Room 001 in 804 University Ave and subsequently shipped via USPS in batches to the Hair Analysis Lab (HAL; <http://hairlab.ucsf.edu>) at the University of California, San Francisco (UCSF) at 505 Parnassus Ave, San Francisco, CA 94143. Dr. Monica Gandhi, Professor of Medicine in the Division of HIV at the University of California San Francisco (UCSF) and Director of the HAL at UCSF, has helped to pioneer the use of small hair samples to monitor ARV adherence and exposure for patients on antiretroviral therapy and has agreed to analyze ARV levels in hair for our study. She and her team have developed methods to extract and analyze prevalent-use ARVs from hair (Huang et al., 2008; Huang et al., 2011) and have demonstrated that hair concentrations of ARVs are the strongest independent predictor of virologic success in prospective cohorts of HIV-infected patients (Baxi, Greenblatt, et al., 2015; Gandhi et al., 2011; Gandhi et al., 2009; Koss et al., 2015; Prasitsuebsai et al., 2015; van Zyl et al., 2011). Furthermore, her studies have shown high levels of acceptability and feasibility (>95%) for collection of hair samples for ARV monitoring in multiple populations and settings (Baxi, Liu, et al., 2015; Hickey et al., 2014; Prasitsuebsai et al., 2015). Dr. Gandhi, who is a Consultant on this project, has also agreed to provide guidance on the appropriate collection methods and interpretation of the hair ARV concentration data in the analytic phase of the study (see letter of support in **Appendix VIII**). Once shipped to the HAL, the hair sample is cut down and chopped to 1-2 mm length segments and 5 mg is weighed and processed. ARVs in the cut hair sample are extracted with 50% methanol/water containing 1% trifluoroacetic acid, 0.5% hydrazine dihydrochloride, and internal standard in a 37°C shaking water bath overnight (>12 hours) and then analyzed via LC-MS/MS. De-identified results are communicated via email in an excel spreadsheet.

- **Collection of nail samples.** The participant will self-collect either 10 fingernails or 10 toenails for analysis of levels of stress cortisol. Nail collection is noninvasive and does not require specialized skills, sterile equipment, specific storage conditions, or shipment with precautions for biohazardous materials. The SOP for collection of nails and the nail collection survey can be found in **Appendix VII**. Briefly, the RA will instruct the participant to do the following: remove any nail polish 24 hours prior to sample collection. On the day of sample collection, the RA will instruct the participant 1) to wash their hands or feet with soap and water prior to clipping to remove any dirt from the nails, 2) wipe the nail clippers with an alcohol pad and allow it to dry for 1 minute, 3) place a piece of clean white paper on the table to catch any nail clippings, 4) clip all finger nails using nail clippers, and 5) carefully place all clippings into the plastic bag and label the bag with the date of collection, noting any lost nails. As part of each study visit, the RA will have the participant complete a nail collection survey. As part of the administrative supplement, we are also requesting to collect feasibility and acceptability data for the nail collection. The RA will ask the participant open-ended questions about the perceived difficulty of nail sample collection, suggestions for improved protocols for sample collection/shipment, and perceived relevance of the interventions to coping with COVID-related stress. Samples will be mailed in a pre-paid mailer from the participant to the Lab P.O. Box and kept at room temperature in a locked cabinet in our lab in Room 001 in 804 University Ave and subsequently shipped via USPS in batches to CO-Investigator Kestutis G Bendinskas at SUNY Oswego for analysis via either PirateShip.com mailed packages or in-person delivery via lab personnel. Nail cortisol is an emerging and viable biomarker of stress cortisol (for a review see Phillips, Kraeuter, McDermott, Lupien, & Sarnyai, 2021). Nail samples, when compared to other measures of stress cortisol such as saliva or hair, are easier to obtain across a variety of populations (Liu & Doan, 2019). The ease of clipping nails produces fewer constraints on participants who are already collecting hair and blood samples. Results of the biomarker analysis will be delivered to the PIs via a password-protected Excel spreadsheet with only study ID for identification of nail samples.
- **Scheduling of intervention sessions.** Post-randomization, the participant will be instructed on what to expect over the 6-week intervention period, select a time/day during which he/she would like to receive his/her first

treatment session, and provide information (e.g., phone numbers, email, addresses) for tracking purposes (to be stored in REDCap). The participant will receive a certified mailed money order of **\$50** for his/her time.

A2c. Intervention sessions. Participants will also accrue **\$5** for each successfully completed telephone-based treatment contact (max = \$30) during the treatment period.

- **ACT intervention.** Participants randomized to the ACT group will receive the manualized brief telephone-delivered ACT intervention adapted in Aim 1. The finalized ACT manual has been submitted as an amendment to the IRB (IRB Amendment Approval #6, 7/3/19). All intervention content will be delivered via telephone, at a time pre-determined by the participant, on a weekly basis for 6 consecutive weeks. The first session is expected to take approximately 45-60 minutes to complete and subsequent sessions are expected to take approximately 30-45 minutes to complete. All sessions will be audio recorded for subsequent fidelity monitoring. The graduate student interventionist will conduct the session in a private space. If a participant does not answer the phone at the regularly scheduled session time, the interventionist will call back every 15 minutes for 1 hour. All recorded interviews will be uploaded to the laboratory server and deleted from the recording device immediately after completion. Audio recordings will be reviewed by the PIs (Drs. Woolf-King and Maisto) for treatment fidelity. The ACT Adherence Raters Manual (Gifford et al., 2011), will be used to rate a random selection of 20% of the audio recorded ACT treatment sessions (to ensure no cross-contamination). Fidelity monitoring will be conducted by Drs. Woolf-King and Maisto (each will rate 10%).
- **BI intervention.** Participants randomized to the BI group will receive a 2 session + 2 booster call + 2 reminder calls BI previously shown to reduce drinking days among HIV-infected women. All intervention content will be delivered via telephone, at a time pre-determined by the participant, on a weekly basis for 6 consecutive weeks. Sessions are expected to take approximately 30-45 minutes to complete, booster calls are expected to take 5-10 minutes to complete, and reminder phone calls are expected to take less than 5 minutes to complete. All calls will be audio recorded for subsequent fidelity monitoring. The BI has been adapted and manualized (see **Appendix V**) and will be telephone-delivered. We modified the intervention slightly to be consistent with the participants in our study (e.g., revised content to be relevant to men *and* women, removed content related to Baltimore – the location of the original intervention). We submitted the finalized manual that we will use in this study to the IRB (IRB Amendment Approval #22, 5/3/22). Content includes: the creation of a drinking agreement, self-monitoring via drinking diary cards, and discussion of barriers/facilitators to change. The participant will receive the telephone-delivered BI in week 1, a booster call in week 2, a reminder phone call for the next session in week 3, a second BI in week 4, a booster call in week 5, and a reminder call for the follow-up appointment in week 6. The sessions are expected to be 30-45 minutes in length, and the booster calls will be 5-10 minutes, focused on the participant's progress towards his or her drinking goal(s). All other procedures are the same as described in the ACT condition.

A2d. Follow-up (FU) visits

Procedures for the FU visits will be identical to the BL session except that consent, collection of tracking information, and randomization will not occur. Collection of DBS and hair samples will occur remotely for all follow up sessions.

- **Post-treatment FU.** The post-treatment FU will occur remotely via telephone or Zoom-based video within one week of completing the final intervention session and will be approximately 1.5 hours long. The same REDcap questionnaires administered at the baseline will be administered at the FU and will include additional questionnaires related to treatment satisfaction and acceptability (see **Appendix IV**). Participants will be paid **\$50** for the post-treatment FU appointment and will also receive their compensation for the intervention sessions (max = **\$30.00**) via a certified mailed money order that is mailed to the participant after the post-treatment FU.
- **3-month FU.** Three months post-randomization, we will schedule a telephone or Zoom-based video assessment with the participants to administer the same REDCap questionnaires as the post-treatment FU. We expect this phone call to take ~60 minutes. Participants will be compensated **\$50.00** for the 3-month follow-up and it will be mailed via a certified money order.
- **6-month FU:** The 6-month FU appointment will be identical to the post-treatment FU appointment. Participants will be paid **\$50.00** for the 6-month FU and it will be mailed via a certified money order.

- **12-month FU:** The 12-month FU appointment will be identical to the post-treatment FU appointment. Participants will be paid **\$50.00** for the 12-month FU. If participants complete all follow-up appointments, they will receive a \$50 bonus compensation via certified mailed money order. Participants will also be provided with a small token of appreciation (i.e., water bottle with candy). The compensation and small token of appreciation will be mailed via certified mail to the participant after the 12-month FU.

A2.e. Retention procedures. Consistent with the literature on strategies for successfully retaining research participants in behavioral intervention trials (Coday et al., 2005; Little et al., 2012; Olem, Sharp, & Johnson, 2009), we will: (1) maintain a high degree of flexibility in scheduling, rescheduling visits multiple times and allowing participants to guide the time/day of study-related phone calls, (2) minimize breaks in contact and reinforce our appreciation for participation by asking permission to contact participants mid-way between their sessions, and bi-weekly during the follow-up period, and (3) explore and problem solve barriers to participation at baseline (e.g., “is there anything that could make it hard for you to make your telephone-based appointments?”) and continue to re-assess throughout the study follow-up period. In order to increase the likelihood that participants will receive all sessions of intervention content for both treatments, we will ensure that: (1) sessions occur weekly at a time and day chosen by the participant, (2) after a missed session we will call the participant up to 5 times within a two-week period, and (3) we will send up to 5 text messages if calls go unanswered. In summary, we will train the RAs to have a friendly relationship with our participants that is characterized by flexibility and accommodation.

Study measures (see Appendix IV)

- **AUDIT-C.** The Alcohol Use Disorders Identification Test – Consumption (AUDIT-C), a brief (3 item), standardized screener for past year hazardous drinking, will be administered by the RA prior to study entry and, for eligible participants, used to characterize baseline levels of alcohol consumption. Scores range from 0-12 with a score of ≥ 4 (men) or ≥ 3 (women) indicative of hazardous drinking (Bush, Kivlahan, McDonell, Fihn, & Bradley, 1998).
- **Brief Symptom Inventory.** The BSI is a standardized measure of general mental health symptoms and in addition to characterized basic mental health functioning, will be used to screen for psychosis (as we are currently doing in the IN-VOICE study)(Derogatis & Melisaratos, 1983).
- **Demographics.** We will collect demographic data on age, race, ethnicity, education, socioeconomic status (SES), time since HIV diagnosis, and time since ART initiation.
- **The Timeline Follow-Back (TLFB).** The TLFB (Sobell & Sobell, 1992) is a calendar-prompted method used to collect data on daily alcohol and other drug use in the previous 42 days. The TLFB will also be used to collected data on HIV medication adherence in the previous 14 days. We have a computerized version of the TLFB available in REDCap.
- **PHQ-9.** The Patient Health Questionnaire (PHQ)-9, a brief, standardized, measure of depression severity, will be used to assess depression symptoms (Kroenke, Spitzer, & Williams, 2001). Participants scoring ≥ 20 will be screened out and offered referrals for more intensive mental health treatment.
- **GAD-7.** The Generalized Anxiety Disorder 7-item (GAD-7) Scale will be used to assess symptoms of anxiety and any participant who scores ≥ 15 (indicative of severe anxiety) will be screened out and offered referrals for more intensive mental health treatment (Spitzer, Kroenke, Williams, & Löwe, 2006).
- **HIV Medication adherence via the visual analogue scale (VAS).** We will measure self-reported adherence to ART via the validated visual analog scale (VAS). The VAS asks participants to point to the place on a line ranging from 0-100% that best represents how much of their ART medication that they have taken in the last month (Amico et al., 2006).
- **Brief Experiential Avoidance Questionnaire (BEAQ).** Self-reported acceptance will be measured with the Brief Experiential Avoidance Questionnaire (BEAQ), a 15-item measure that assesses six domains of experiential avoidance: behavioral avoidance, distress aversion, procrastination, distraction, repression/denial and distress endurance (Gamez et al., 2014; Wolgast, 2014).
- **Graded Chronic Pain Scale (GCPS).** We will measure chronic pain using the GCPS, a 4-item measure that assesses two dimensions of overall chronic pain severity: pain intensity and pain-related disability (Von Korff, Ormel, Keefe, & Dworkin, 1992).
- **Short Inventory of Problems (SIP-2L).** Alcohol-related problems will be measured using the Short Inventory of Problems (SIP-2L), a 15-item measure that assesses negative consequences of alcohol use (Miller, Tonigan, & Longabaugh, 1995).

- **An adapted version of the Contemplation Ladder.** Readiness to change alcohol use will be assessed using an adapted version of the Contemplation Ladder. Contemplation ladders are single-choice, visual analogue scales that depict a ladder whose higher rungs represent greater levels of readiness to change (Biener & Abrams, 1991; Slavet et al., 2006).
 - **HIV Treatment Adherence Self-Efficacy Scale (HIV-ASES).** The HIV Adherence Self-Efficacy Scale (HIV-ASES) is a 12-item scale that assesses patients' confidence to carry out important treatment-related behaviors related to adhering to treatment plans, including medication regimen adherence and following plans for nutrition, exercise, etc. in the face of barriers (Johnson et al., 2008).
 - **Interactive Toxicity Beliefs Scale (ITB).** The 5-item ITB scale assesses participants' perceived adverse outcomes of mixing alcohol and ART (Kalichman et al., 2009).
 - **Alcohol Expectancies on ART Adherence.** To assess participants' perceptions of the effect of alcohol on ART adherence, a single-item alcohol expectancies measure will be utilized (Fromme, Stroot, & Kaplan, 1993).
 - **Six-item Short Form of the Food Security Survey Module.** The six-item Food Security Survey will be used to assess participants' ability to acquire nutritionally adequate foods (Palar, Laraia, Tsai, Johnson, & Weiser, 2016).
 - **Reasons for Drinking Scale (RFD).** We will assess participants' reasons for drinking using the 23-item Reasons for Drinking Scale (Carpenter, Kenneth, & Hasin, 1998).
 - **HIV-Stigma Mechanism Measure.** The HIV-Stigma Mechanism Measure assesses participants' internalized, enacted, and anticipated associated with their HIV status (Earnshaw, Smith, Chaudoir, Amico, & Copenhaver, 2013).
- SF-8 Health Survey.** The SF-8 Health Survey measures health-related quality of life and consists of eight items, each representing one health profile dimension: general health perception (GH), physical functioning (PF), role functioning-physical (RP), bodily pain (BP), vitality (V T), social functioning (SF), mental health (MH), and role functioning-emotional (RE; Yiengprugsawan, Kelly, & Tawatsupa, 2014).
- **The Pandemic Stress Index (PSI).** The PSI assesses participants' experiences with social distancing and quarantining (Harkness, 2020).
 - **General Assessment of Health-Behaviors During COVID-19:** The survey measures change in participants' alcohol use, sexual behaviors, and stress and anxiety levels during the pandemic.
 - **Perceived Stress Scale (PSS).** The PSS is a 10-item scale that assesses the extent to which the circumstances of one's life are appraised as stressful and/or out of control during the last month (Cohen, Kamarck, & Mermelstein, 1983). Questions are answered with a 5-point Likert-type scale ranging from 0 = never to 4 = very often. The PSS has shown good internal consistency ($\alpha = .85$) in a sample of 358 PLWH on ART recruited from three U.S. cities (Royal et al., 2009).
 - **Lubben Social Network Scale Revised (LSNS).** The LSNS-6 (Lubben et al., 2006) measures perceived social support from family and friends. The original 10-item scale is available in a 6-item version that has three questions that assess social ties to family, and three questions that assess social ties to friends (e.g., How many relatives/friends do you see or hear from at least once a month). A Likert-type scale of 0 to 5 is used to respond, with scores ranging from 0-30. A score of >12 is indicative of "at-risk" for social isolation. The LSNS has been used with samples of people living with HIV (Emlet, 2006; Greene et al., 2018), with good internal consistency of the abbreviated scale with this population ($\alpha = .84$) (Webel et al., 2016).

2.2. Describe how you will have sufficient time to conduct and complete the research?

One postdoctoral fellow employed 40 hours/week, one graduate research assistant employed 10 hours/week, and four Masters-level interventionists work on the project. We also have a team of two undergraduate research assistants and an additional graduate research assistant in the Master's of Marriage and Family therapy program to assist with lab-related activities. The R34 award gives both Dr. Woolf-King and Dr. Maisto a teaching reduction to allow them to complete the proposed research successfully. Dr. Woolf-King's K01 study completed data collection in the Summer of 2019 and Dr. Woolf-King took her 1 semester research leave during the launch of the pilot RCT. We thus believe we have the time and resources to successfully execute the project.

2.3. Surveys, interviews, questionnaires will be conducted:

☐ No (Skip to 4.4)

☒ Yes Include all research instruments including surveys, questionnaires, sample interview questions, etc. as separate appendices. If the survey instrument is commonly used in your discipline, only

provide a citation to the instrument.

All research instruments are included in the appendices.

2.4. Community Based Participatory Research (CBPR) is described as research that is conducted as an equal partnership between traditionally trained "experts" and members of a community. Is this research categorized as CBPR?

☒ No. (Skip to 4.5)

☐ Yes. Please explain:

2.4.1. In CBPR research studies, the community participates fully in all aspects of the research process including conception, design, and analysis.

With this in mind, describe how you plan to engage community members in your research study:

2.4.2. Describe how you plan to provide community members with appropriate training for human subjects research? Include in your description what training will be provided.

2.4.3. Describe your plan to disseminate research findings with members of the community throughout the course of your study.

2.5. Will this research be conducted by SU investigators in foreign countries?

☒ No. (Skip to 4.6)

☐ Yes. An International Research Form must be completed and submitted with this application.

<http://researchintegrity.syr.edu/wp-content/uploads/2016/10/International-Research-Form-2013.doc>

2.6. Will this research involve genetic testing?

☒ No. (Skip to Section 5)

☐ Yes. A Genetic Research Form must be completed and submitted with this application.

<http://researchintegrity.syr.edu/wp-content/uploads/2016/10/Genetics.doc>

3. Performance Site Information

3.1. Describe how you will have adequate facilities to conduct your study.

Study activities will occur remotely in private spaces chosen by research staff or participants. In addition, research staff, as permitted by Syracuse University, will utilize Dr. Woolf-King's and Dr. Maisto's lab spaces which are adjacent to the Department of Psychology. The two laboratory spaces combined occupy eight private rooms on the basement and 2nd floor of 804 University Avenue. In addition to the computing resources supplied in the lab space (10 desktops, 4 laptops), there is a small kitchen, two large rooms for research team meetings, private interview rooms, and a pre-approved space (by the Biosafety Office at Syracuse University) for fingerstick blood sampling and storage of biospecimens. All research staff have been provided with lab phones for study use to conduct study responsibilities.

3.2. List all Performance Sites Other than SU (insert additional rows if needed).

(This may apply when a SU investigator collaborates with a non-SU investigator or institution. Please check all that apply and add additional sites. Each will require a letter of cooperation and/or IRB approval.)

Check all that apply	Name of Performance Site (list all participating sites below)	IRB Approval and/or Letter of Cooperation
<input type="checkbox"/>	SUNY Upstate Medical University	<input type="checkbox"/> Attached <input type="checkbox"/> Pending
<input type="checkbox"/>	*Syracuse City Schools	<input type="checkbox"/> Attached <input type="checkbox"/> Pending
<input type="checkbox"/>	*Other, specify site:	<input type="checkbox"/> Attached <input type="checkbox"/> Pending

**The following additional information is required: contact information for the site, if the site has an IRB, and whether the IRB has approved the research, or plans to defer review to SU's IRB:*

Human subjects activities will only take place at Syracuse University.

3.3. Will this research be conducted in a school or is it funded by the US Department of Education?

☒ No (Skip to 5.4)

☐ Yes. If yes, complete the form found at:

<http://researchintegrity.syr.edu/wp-content/uploads/2016/10/Department-of-Education-Schools-Form.doc>

3.4. Is this a multi-center research project in which Syracuse University will function as the coordinating center/lead institution? (*A multi-center study is one where different PIs at different institutions are conducting the same study.*)

☒ No

☐ Yes. If yes, describe the plans to manage information obtained in multi-site research that may be relevant to the protection of research participants such as: unanticipated problems involving risks to participants or others, interim results, and protocol modifications:

4. Research Qualifications

CITI training is required for the faculty member listed below and all researchers and research staff who have direct contact with participants and/or identifiable human participant data. **NOTE:** If training is not completed at the time of submission, approval of your application will be delayed.

4.1. List the names and research qualifications of the primary investigator/faculty advisor listed in Section 1 of this application.

This is a Multiple-PI project.

Dr. Sarah E. Woolf-King, PhD, MPH, Co-Principal Investigator (contact PI) is a licensed clinical psychologist with a MPH in Epidemiology who is an assistant professor in the Department of Psychology. Dr. Woolf-King has conducted studies on HIV and alcohol use over the last 14 years and has experience managing and implementing NIH-funded studies a PI (F31, K01, R34), Co-I (R01, U01), and graduate research assistant (R01). Her laboratory in the Department of Psychology (The Psychology and Health Lab) currently completed enrolling participants for an NIH (K01)-funded study on alcohol use and sexual risk behavior among HIV-positive men who have sex with men (MSM). She thus already has an ongoing and successful partnership with the IHS clinic at SUNY Upstate, and has implemented many of the procedures described in this application (e.g., DBS collection, self-report questionnaire administration in REDCap, telephone-based assessments of alcohol use). Dr. Woolf-King received her graduate training at Syracuse University and is thus well acquainted with both the University and the surrounding community having been an active member of the SU and Syracuse community for 6 years prior to moving back in August 2016. Dr. Woolf-King's status as a licensed clinical psychologist means that she has completed the necessary clinical training and examinations (i.e., Examination for Professional Practice in Psychology (EPPP), state law and ethics exam) to practice psychology including the diagnosis and treatment of mental disorders. She is also currently a clinical supervisor in the Psychological Services Center (PSC) at Syracuse University. This, combined with her years of experience conducting clinical research with populations at increased risk for mental disorders, makes her well qualified to supervise students on the proper assessment and treatment of alcohol use, anxiety, and depression, and the assessment and treatment of symptoms of mental disorders that may preclude participation in a research study (i.e., acute psychosis).

Dr. Stephen A. Maisto, PhD, Co-Principal Investigator, is a Professor in the Department of Psychology at Syracuse University and a licensed clinical psychologist who has been conducted alcohol-related research for the past 30 years. He has been the PI and Co-PI for numerous NIAAA-funded projects and currently has a K05 from NIAAA to support his mentoring of junior investigators. Dr. Woolf-King has been working with Dr. Maisto since her time as a graduate student (2003-2010) in his NIAAA-funded alcohol research laboratory and Dr. Maisto is a primary mentor on Dr. Woolf-King's K01 Career Development Award. Dr. Maisto's status as a licensed clinical psychologist means that he has completed the necessary clinical training and examinations (i.e., Examination for Professional Practice in Psychology (EPPP), state law and ethics exam) to practice psychology, including the diagnosis and treatment of mental disorders. He is also currently a clinical supervisor in the

Psychological Services Center (PSC) at Syracuse University. This, combined with his years of experience conducting clinical research with populations at increased risk for mental disorders, makes him well qualified to supervise students on the proper assessment and treatment of alcohol use, anxiety, and depression, and the assessment and treatment of symptoms of mental disorders that may preclude participation in a research study (i.e., acute psychosis).

4.2. List the names and research qualifications of the student/research staff listed in Section 1 of this application.

Redacted to protect privacy of research staff and students

4.3. List the name(s) and research qualifications of all other individuals who will be involved in this research and will have direct contact with participants and/or identifiable human participant data

Redacted to protect privacy of research staff and students.

4.4. How will you ensure that all persons listed above are adequately informed about the protocol and their research related duties and functions?

Dr. Woolf-King and Dr. Maisto will provide close supervision to all staff members involved with data collection via weekly team meetings and ongoing, as-needed supervision for all study-related activities via phone and email. Prior to having any direct contact with research participants, all study staff received extensive training on study protocols and clinical sensitivity in working with people living with HIV. Mock recruitment and study sessions were used to assess competency prior to interacting with research participants. All students in Dr. Woolf-King's lab are required to take the Blood borne Pathogen and Hazard Communication trainings offered by Syracuse University, and an online course on the basics of HIV.

The graduate student interventionists have received a formal, multi-day training on the implementation of the BI intervention (training conducted by Dr. Maisto) and the implementation of the ACT intervention (training conducted by Dr. Woolf-King), which included a review of intervention-specific readings, familiarity with the treatment manual, and mock intervention sessions. All graduate student interventionists are required to use the treatment manuals included in **Appendix V** while conducting intervention sessions. Drs. Woolf-King and Maisto have been providing weekly group supervision of treatment sessions during the pilot RCT to ensure fidelity to the treatment manuals and to discuss any issues that arise on an ongoing basis. Audio recordings of the treatment sessions are reviewed in these supervision meetings, with suggestions for improvement as needed.

4.5. Explain how you will have adequate numbers of qualified staff to conduct your study.

We believe that one postdoctoral research assistant at 40 hours/week, one research assistant at 10hours/week, supported by an additional graduate RA, two undergraduate RAs, four Masters-level interventions, and the Co-PIs should be able to successfully execute the proposed research. If the team determines that this number of staff is insufficient, Drs. Woolf-King and Maisto will discuss hiring a part-time (20 hours/week) project coordinator. The R34 award gives both Dr. Woolf-King and Dr. Maisto ample teaching reduction time to allow them to complete the proposed research successfully. Further, as mentioned previously, Dr. Woolf-King has taken her one-semester research leave during the semester in which the pilot RCT launched.

All research team members have been recruited after an extensive application interview process and additional information about the qualifications of the team members is available upon request.

5. Characteristics of Participants

5.1. Approximate Number of Participants to be recruited:

Aim 1: We enrolled total N = 13 HIV-infected hazardous drinkers and N = 10 HIV clinic providers.

Aim 2: We expect to enroll N = 74 HIV-infected hazardous drinkers (50% women).

The total N for HIV-infected drinkers is: 87

The total N for HIV clinic providers is: 10

5.2. Sex: M ☐ F ☐ Both ☒

5.3. Age Range-Check all that apply:

- ☐ 0-6 (Include parental consent form)
☐ 7-17 (Include parental consent form and child assent form)
☒ 18-64
☒ 65 and older

Exact ages to be included:

5.4. When the age range indicates an upper limit, provide justification:

5.5. Does this study target one gender or specific social/ethnic group(s)?

- ☒ No. (Skip to 7.6)
☐ Yes. If yes, answer 7.5.1. and 7.5.2. below.

5.5.1. If yes, check all that are targeted/vulnerable populations (Code of Federal Regulations: http://www.access.gpo.gov/nara/cfr/waisidx_00/45cfr46_00.html).

*These additional forms can be found on the IRB Website under Special Populations:

<http://researchintegrity.syr.edu/human-research/forms/>

- ☐ Children/minors - *Requires additional form*
☐ Cognitively impaired - *Requires additional form*
☐ Prisoners - * Requires additional form*
☐ Pregnant women - *Requires additional form*
☐ Legally restricted, non-prisoner
☐ Educationally disadvantaged
☐ Economically disadvantaged
☐ Elderly/aged
☐ Other, specify:

***NOTE*:** These additional forms can be found on the IRB Website (under Special Populations):
<http://researchintegrity.syr.edu/human-research/forms/>

5.5.2. Explain the rationale for using this particular group(s):

5.6. List the inclusion criteria:

- Inclusion criteria for PLWH will match criteria for the pilot RCT (Aims 1 and 2):
 - ≥ 18 years of age,
 - HIV-positive,
 - score of ≥ 4 (men) or ≥ 3 (women) on the AUDIT-C,
 - Currently prescribed ART medication,
 - Owns a cellphone,
 - Able to provide informed consent,
 - Understands written and spoken English,
 - Able to provide a physical home address
- Inclusion criteria for HIV clinic providers:
 - (1) ≥ 18 years of age and
 - (2) employed by IHS as an HIV care provider with direct patient contact
 - (3) able to understand spoken English
 - (4) able to provide informed consent.

5.7. List the exclusion criteria:

- Exclusion criteria include for PLWH:

- (1) experiencing acute illness or declining health status when it is determined by a treatment provider that research participation is contraindicated,
- (2) unable to understand spoken English,
- (3) does not own a cell phone,
- (4) a score of 12 on the AUDIT-C, indicating high risk for a severe alcohol use disorder,
- (5) a score of ≥ 20 on the PHQ-9 indicating severe depressive symptoms,
- (6) a score of ≥ 15 on the GAD-7, indicating severe symptoms of anxiety,
- (7) Has active psychosis as judged by research staff via scores on the BSI. A score of 3 or greater on any item on the BSI, prompts the facilitator to ask the participant to elaborate and provide examples of the specific symptom. The facilitator will then determine whether the participant is eligible to continue participation in the study. If a participant selects a 4 on any critical item (3, 9, 13, 35, 39, 40, 41, 53) he/she is ineligible to participate in the study. If a participant endorses a 3 on any of the critical items, the facilitator will probe and then discuss the replies with Dr. Woolf-King,
- (8) a score of ≤ 6 on the REALM-r, indicating poor health literacy skills.
- (9) inability to provide a physical home address

- Exclusion criteria for HIV clinic providers

- (1) <18 years of age
- (2) Not a provider in the IHS clinic.

5.8. Does this research involve participants likely to be vulnerable to coercion or undue influence?

☒ **No. (Skip to 7.9)**

☐ **Yes. If yes, describe the additional protections included in the protocol to protect their rights and welfare.**

5.9. General state of Health: ("Unknown"- *unless you will obtain health data on participants prior to beginning the study.*)

HIV-positive; Unknown for HIV clinic providers

6. Recruitment of Participants

6.1. Describe in detail how participants will be identified and recruited. Include in your description how you will have access to a population that will allow recruitment for the number of participants required for your research. Do not merely state "Volunteers".

- a) **Remotely recruit participants from HIV-clinics and organizations that service PLWH in the continental US:** The new recruitment protocol will be as follows: the research assistant will contact the respective clinic or program using an email template (**Appendix II**) in which we introduce the research team and purpose of the study. Whether contacting by email or phone, the RA will follow the applicable script and notate the name of the individual they contacted (and a second point of contact if possible), as well as if the organization is willing to assist in the study recruitment, and any referrals to other organizations they might be able to offer. The research assistant will also attach the recruitment flyer to an email that can be displayed in common areas or provided to participants (e.g., waiting rooms; **Appendix II**). The research assistant will respond to any questions and/or concerns presented by the clinics.
- b) **Online recruitment:** We will advertise the study via Facebook and other online venues that target and/or have the capability to target local HIV-positive adults (e.g., website for AIDS Community Resources a local non-profit supportive people living with HIV in CNY). See **Appendix II** for advertising content.
- c) **Smartphone applications:** We will use smartphone applications (e.g., Grindr, OKCupid, etc.) to recruit

potential participants. The RA will download the smartphone application and create a profile using the copy scripted About-Me text into appropriate profile section. Potential participants will message the profile and RA will respond using one of the scripted responses (see **Appendix II** for content).

- d) **Recruitment in community-based organizations and bars:** We will place flyers (see **Appendix II**) in local community service organizations (e.g., AIDS Community Resources) and LGBT-friendly bars (e.g., Rain lounge, Trexx). We will also attend community events (e.g., the AIDS Walk, PRIDE) and have a table with recruitment materials.

Procedures for recruitment when potential participant contacts the study via phone or email: Participants who contact the study via phone or email (having seen a recruitment flyer) will be told about the study and screened for eligibility using a standardized phone recruitment script.

6.2. Describe who will recruit participants.

The postgraduate and undergraduate research assistants described in Section 6 will be responsible for recruitment. The project coordinator will oversee recruitment.

6.3. Identify all applicable recruitment methods that apply: NOTE: Copies of all advertising materials including flyers, posters, ads, letters, scripts or detailed descriptions; including graphics **MUST** be provided with your application. ([See SOP 036 for Recruitment/Advertising](#)).

- | | | |
|--|---|--|
| <input checked="" type="checkbox"/> Flyers | <input type="checkbox"/> Mass E-mail Solicitation | <input type="checkbox"/> SU Today News Service |
| <input checked="" type="checkbox"/> Internet | <input checked="" type="checkbox"/> Posters | <input type="checkbox"/> Television |
| <input type="checkbox"/> Letter | <input type="checkbox"/> Newspaper | <input checked="" type="checkbox"/> Departmental Research Boards |
| <input checked="" type="checkbox"/> Telephone | <input type="checkbox"/> Radio | <input checked="" type="checkbox"/> Social Media |
| <input checked="" type="checkbox"/> Other (describe): Community-based events; in-person at the Immune Health Services Clinic | | |
| <input type="checkbox"/> Not applicable | | |

6.4. Will participants be compensated?

- ☐ No. (Skip to Section 9)
- ☒ Yes. If yes, answer 8.4.1. and 8.4.2. below.

Note: All information regarding compensation must be included in consent/assent documents.

6.4.1. If Yes, specify the method of compensation (e.g. monetary, course credit, gift card, toy, etc.), the amount of compensation, and how the compensation will be awarded (per task, per session, etc.).

Aim 1

- **Qualitative interviews and focus group discussions.** Participants were paid **\$40** for participation in the qualitative interviews and FGDs. If the participant arrived at the session, and was deemed ineligible, he/she received **\$10** for his/her time.

Aim 2

- **Baseline study visit: \$50** in certified mailed money order, mailed at the end of the session. If the participant arrives at the session, and is deemed ineligible, he/she will receive **\$10** for his/her time.
- **Intervention sessions.** Participants will receive **\$5** in certified mailed money order for each successfully completed intervention phone call (**max = \$30**). If the participant withdraws prematurely, and does not complete all 6 intervention sessions, or misses an intervention session, he/she will be compensated for all completed intervention sessions (e.g., if a participant withdraws after session #1, he/she will receive \$5). All compensation earned during the 6-week intervention period will be mailed via a certified money order after the post-treatment follow-up. If a participant withdraws, he/she will be mailed a money order for the sessions completed.
- **Post-treatment follow-up visit: \$50** in certified mailed money order, mailed at the end of the session. Participants will be mailed one money order that includes the post-treatment follow-up compensation amount and the intervention compensation amount.
- **3-month follow-up phone call:** Participants will receive **\$50** in a certified mailed money that will be mailed after the remote session.

- **6-month follow-up visit. \$50** in certified mailed money order mailed after the session.
- **12-month follow-up visit. \$50** in certified mailed money order mailed after the session.
- **Bonus compensation. \$50** in a certified mailed money order, awarded to participants who complete all follow-up appointments. This compensation will be included in the same money order as the 12-month follow-up.
- **Respondent-driven sampling. \$20** in a certified mailed money order, awarded to participants who refer other participants to the study. If the referred person enrolls in the study, the referring participant will receive a \$20 incentive as compensation.
- **Token of Appreciation.** After completion of the 6-month follow-up, participants will be provided with a water bottle as a token of appreciation for their participation and will be mailed after the 12-month follow-up.

6.4.2. Describe how compensation will be awarded if the participant withdraws after beginning the study. Compensation must be pro-rated in a manner that recognizes the time and effort of the participant prior to withdrawal.

Participants who came to the laboratory for the baseline session or the Interviews/FGDs, but were deemed ineligible after re-screening, were compensated **\$10** for their time.

Participants who do not completed the full 6 weeks of intervention sessions will still be paid for the number of sessions completed. For example, if a participant completed sessions #1 and #2 and then dropped out of the study, he/she would be paid **\$10**.

7. Informed Consent Procedures

Consent is required for all human subject participants. Final copies of **ALL** consent/assent documents (including electronic or oral scripts) must be provided for IRB approval and date stamping. Informed consent/assent documents must be on *official SU departmental letterhead*. For guidance regarding informed consent, consult SOP 017-Documentation of Informed Consent <http://researchintegrity.syr.edu/wp-content/uploads/2016/10/SOP-017-Document-of-Informed-Consent.pdf>. For consent form instructions/sample visit:

<http://researchintegrity.syr.edu/wp-content/uploads/2016/10/Consent-Form-Guidelines.doc>
<http://researchintegrity.syr.edu/wp-content/uploads/2016/10/Consent-Form-Sample.doc>

For assent form instructions/sample visit: <http://researchintegrity.syr.edu/wp-content/uploads/2016/10/How-to-Prepare-a-Child-Assent-Document-and-Assent-Sample.doc>

7.1. How many consent documents are included with this application? 3

7.2. How many assent documents are included with this application? 0

7.3. Is more than one consent/assent document included with this application?

☐ No. (Skip to 9.4.)

☒ Yes. If yes, follow instructions below (9.3.1 and 9.3.2).

7.3.1. Assign form numbers to each individual document and add it to the footer of the document-e.g. Consent form 1, Consent form 2, Assent form 1, etc.

7.3.2. Create a separate log as an appendices identifying each document-e.g. Consent form 1-parental consent, Consent form 2-adult participant consent; Assent form 1-child assent, etc.)

7.4. Indicate the type of consent you will obtain for your study (check all that apply).

7.4.1. Written Consent ☒ (ATTACH COPY)

Provide a brief statement of what will be said when the consent process is initiated:

For both Aim 1 (qualitative interviews and FGDs) and Aim 2 (Pilot RCT), the graduate research assistant will begin the consent process by telling the potential participant: “research studies involve only people who choose to take part after they have been told about what will happen during the study. What I would like to do now is to talk with you about our research study, make sure you understand the risk and benefits of participating, and give you the opportunity to answer any questions that you have. Please feel free to interrupt me at any time.”

7.4.2. Electronic Consent ☒ (ATTACH SCRIPT) *(This is a request to waive the required element of documentation of written consent, e.g. internet studies.)*

Consistent with Amendment #13, informed consent is collected electronically via REDCap and includes documentation from the participant of their consent to participate. A REDCap electronically generated link is sent to the participant that directs the participant to the written consent form (Appendix VI). The RA reviews the consent form with the participant and conducts the informed consent form check (Amendment #11). The participant electronically selects “yes” or “no” to the REDCap survey to indicate their consent to participate. Following participant selection, REDCap generates a confirmation indicating the participant’s decision to consent to the study.

7.4.3. Oral Consent ☐ (ATTACH SCRIPT)

Provide the justification for the waiver of written consent:

7.4.4. N/A ☐ **Data Analysis Only, no consent form required.**

7.5. Who will conduct the consent interview?

The project coordinator

7.6. How will you ensure that prospective participants have sufficient opportunity to consider whether or not to participate in your study?

Informed consent will be guided by an electronic written consent document and will be characterized by an interactive conversation between the RA and the potential study participant. Participants will also be provided a paper copy of the written consent document. The RA will email or text the participant a survey link to the electronic informed consent document that is generated by REDCap. The RA will use the informed consent document as a guide to discuss all content in the form with the potential participant. After each major section and at key points, the RA will pause and check for understanding—for example, by asking the participant to repeat back, in their own words, what “the right to refuse” means. Significant time and attention will be devoted to ensuring that the participant adequately understands and appreciates the risks associated with participation. For example, participants will be asked to repeat back key concepts (e.g., what will happen to them if they choose to participate) of the consent in their own words to ensure understanding. The RA will also administer a consent understanding check, which includes questions such as “What is the purpose of the study?”, after reviewing the informed consent document to ensure comprehension of the informed consent. If the participant is unable to provide a sufficient response in the RA’s judgment, the RA will review the appropriate section of the informed consent again and re-ask the question. If the participant is deemed eligible, participants will indicate their consent by selecting “yes” or “no” on the survey link, which will automatically generate a notification in REDCap that the participant has completed the informed consent form. Once the RA confirms that notification in REDCap has appeared, the RA will inform them that they are enrolled in the study at this point and continue with the baseline appointment. If the participant is deemed ineligible after re-screening for eligibility criteria and reviewing the informed consent, the participant will be informed that they are ineligible to participate in the study.

7.7. What steps will be taken to minimize the possibility of coercion or undue influence?

The voluntary nature of participation will be reiterated and the participant will be encouraged to ask questions until he/she feels an informed decision about participation can be made.

7.8. An ASSENT statement is required for participants who cannot legally give consent themselves. Assent statement:

☒ **No (Skip to 9.9)**

☐ **Yes (ATTACH COPY)**

7.8.1. From whom will consent be obtained and by what means for minors or the individuals considered to be cognitively impaired in their decision making ability? ☐ N/A

7.8.2. If subjects are minors, will they still be involved in the study when they reach the age of majority (18)?

- ☐ No
☐ Yes. If yes, outline your plan to re-consent these participants when they reach the age of majority.

☐ N/A

7.9. Will non-English speaking individuals be participants in the research?

- ☒ No (skip to Section 10)
☐ Yes If yes, indicate how consent will be documented from non-English speaking participants?
☐ A translated written informed consent document in a language understandable to the participant. This should be an accurate translation of the full informed consent. (ATTACH COPY)

Identify the name of the individual or translation service that provided the translation of the consent document.

List the qualifications of the individual or translation service that provided the translation of the consent document.

- ☐ Orally, using a qualified translator to translate the English informed consent document to the participant, and a translated short form in a language understandable to the participant (ATTACH COPY)

Identify the name of the individual or translation service that will provide translation for the consent process and during the conduct of the research.

List the qualifications of the individual or translation service that will provide translation for the consent process and during the conduct of the research.

- ☐ A confidentiality statement from

8. Potential Financial Conflict of Interest

A conflict of interest exists when any investigator or personnel listed in this research protocol's financial interests may reasonably be affected by research, scholarship, educational or other externally funded activity. Or, when the immediate family* of anyone in such a role, have significant financial interests that may compromise, or have the appearance of compromising, an investigator's professional judgment that could directly and significantly affect the design, conduct, or reporting of the research, proposed or funded.

Federal Guidelines emphasize the importance of assuring there are no conflicts of interest in research projects that could affect the welfare of human participants. If this study involves or presents a potential conflict of interest, additional information will need to be provided to the Vice President for Research.

The following significant financial interests must be disclosed if interest is in the sponsor of the research or the product being tested:

Anything of monetary value - aggregated for the Investigator and the Investigator's spouse, domestic partner, and dependent children - including but not limited to the following:

- a. Salary or other payment for services (e.g. consulting fees) of \$10,000 or greater in the past year when aggregated for the immediate family;
- b. Any equity interest (e.g. stocks, stock options or other ownership interests) unless it meets the following three tests:
 - i. less than \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value (e.g. most recent sales price recognized by the company),
 - ii. constitutes less than a 5% ownership interest in any single entity, or

- iii. publicly traded on a national stock exchange,
- iv. no arrangements have been made where the value of the interest will be affected by the outcome of the research.
- c. Intellectual property rights (e.g. patents, copyrights and royalties from such rights).
- d. Services as an officer, director, or in any other executive position in an outside business, whether or not remuneration is received for such service.
- e. Any compensation or equity interests that may be influenced by a particular outcome in sponsor-funded research, even if the identified thresholds are not met.

Syracuse University Policy on Conflict of Interest for Research Investigators:

<http://researchintegrity.syr.edu/wp-content/uploads/2016/10/SOP-032-Institutional-Conflict-of-Interest.pdf>

**Immediate family means a spouse, domestic partner or dependent children.*

8.1. Do any of the investigators or personnel listed in this research protocol, or members of the immediate family of the investigators or personnel, have a financial interest associated with this study that requires disclosure?

- ☒ No (Skip to question 10.3)
- ☐ Yes; If yes, identify the individual(s):

8.2. Has this financial interest been disclosed and managed?

- ☐ Yes. The Office of Research Integrity and Protections will verify that a management plan is in place with the Vice President for Research.
- ☐ No. If the Vice President for Research does not have an approved management plan for this research, complete Parts I and II of the Disclosure of Significant Financial Interest Form (<http://osp.syr.edu/forms%20and%20pages/Forms/COI%20-%20Disclosure%20of%20Financial%20Interests%20Form.PDF>) and submit it to the *Office of the Vice President for Research, 304 Lyman Hall.*

10.3 To your knowledge, did the University, or your School/Department receive a gift or equipment donation, or promises thereof, from commercial sponsors of this research project?

- ☒ No
- ☐ Yes; If yes, identify the sponsor:

Final IRB approval cannot be granted until all potential conflict matters are settled. The IRB requires a recommendation from the Vice President for Research regarding disclosure to participants and management of the conflict.

9. Data Collection, Storage of Data and/or Confidentiality

Confidentiality pertains to the treatment of information that an individual has disclosed in a relationship of trust with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure without permission.

9.1. Specify the individually identifiable data you will obtain, use or disclose to others.

We will collect names, email addresses, phone numbers, addresses, and names of other contacts for tracking purposes. We will also collect audio recordings for the qualitative interviews, FGDs, and interventions sessions. Identifiable data that will be obtained, and ways it will be stored and managed, are described below.

9.2. Describe how data will be maintained (e.g., paper or electronic spreadsheet, desktop computer, laptop or other portable device); how you will maintain the confidentiality and data security, (e.g., password protected computer, encrypted files, locked cabinet and office); and who will have access to the data (e.g., research team, sponsors, consultants).

We will take the following steps to maintain the confidentiality of participant data:

- a) **Use of Study Identification Numbers (IDs).** All participants will be assigned a unique study ID that will be used on all study forms. No identifying information will be recorded on the self-report

questionnaires administered in REDCap or the lab collection forms and labels associated with the DBS and hair collection.

- b) **Use of Research Electronic Data Capture (REDCap).** REDCap is a “mature, secure web application for building and manage online surveys and databases” that is “specifically geared to support data capture for research studies” (project-redcap.org). Syracuse University has a REDCap account that is managed by ITS and that allows SU-affiliated researchers free access. REDCap is secure, and password protected, and allows questionnaires to be filled out directly on the REDCap interface. Only the PI and supervised, designated research staff will have access to the database, and all participant information is stored according to a REDCap-generated study ID. We will create two REDCap databases: one will contain tracking information and the other will contain the self-report questionnaires (i.e., TLFB, SIP-2L, Contemplation Ladder, medication adherence VAS, HIV-ASES, Interactive Toxicity Beliefs, alcohol expectancies on adherence, PHQ-9, GAD-7, BEAQ, GCPS-PCS, SF-8 Health Survey, Six-item Short Form of the Food Security Survey Module, Reasons for Drinking Scale, HIV-Stigma Mechanism Measure, intervention feedback survey, Pandemic Stress Index, and the general assessment of health behaviors during COVID-19). REDCap allows users to customize security/access settings for each project and each database within each project. Thus, only the PIs and designated RAs will have access to the REDCap tracking database. The electronic consent forms will be stored in the REDCap tracking database under the participant number.
- c) **Collection and storage of audio recorded data.** Qualitative interviews, FGDs, and intervention sessions will be recorded with a digital recorder. Immediately after the completion of the interview/FGD/sessions, the recording will be uploaded to a secure, password protected Syracuse University server and stored according to the REDCap ID number. The electronic recorder will be erased immediately after upload. Debriefs and transcriptions of the interviews will be stored according to ID number, not name, and only the PI and designated research staff will have access to these recordings, transcripts, and debriefs.
- d) **Storage of paper consent forms with identifiable data.** Informed consent forms with participant names will be stored in a locked file cabinet in a locked room in our laboratory space in room 001 of 804 University Ave. Only the PI and approved staff members will have access to the file cabinet. The informed consents will be stored separately from other data.
- e) **Storage of DBS cards, hair samples, and nail samples.** DBS cards and labeled (participant’s ID number, date of the appointment, type of visit (i.e., baseline, post-treatment, 6-month follow, 12-month follow-up) will be stored in our locked -80 freezer in Ostrom prior to shipment to USDTL. The ziplock bags with hair and nail samples will be stored in a locked cabinet in our lab space at 804 University Ave. Biospecimen collection forms are stored in the REDCap database. Only the PI and approved staff members will have access to the file cabinet.
- f) **Use of laptops for data collection.** All laptops used to access the REDCap databases will be password protected and stored in Dr. Woolf-King’s lab space at 804 University Ave. Participant data will not be shared with IHS clinic providers.
- g) **Handling of published data and reports.** No individual, identifying information will be including in any publication or presentation of the data collected for this project. Published data will be aggregated and statistically analyzed across participants.

9.3. If you will be sharing data with others, describe how data will be transferred (e.g., courier, mail) or transmitted (e.g., file transfer software, file sharing, email). If transmitted via electronic networks, describe how you will secure the data while in transit.

Sharing Dried Blood Spot (DBS) cards with the lab processing facility. As we have done with the IN-VOICE study, DBS cards will be shipped to the United States Drug Testing Laboratory (USDTL) at 1700 South Mount Prospect Road, Des Plaines, IL, 60018. DBS cards will be shipped to USDTL in sealed individual packs (e.g., ziplock bags) in a regular shipping box, via USPS. DBS cards will be labeled with ID numbers only and will not contain any identifying information. An invoice will be included with the shipment to confirm the number of samples in the shipment. Because DBS cards are considered non-infectious, they do not have to be shipped via any special handling requirements.

Sharing the results of the PEth test conducted by the USDTL. The results of the PEth testing will be delivered to Dr. Woolf-King via her Syracuse University email account in an excel spreadsheet or pdf file that does not contain any identifying information. The file will be immediately stored on our Syracuse University laboratory-based server.

Sharing hair samples cards with the lab processing facility. Hair samples will be shipped to the Hair Analysis Laboratory (HAL) at the University of California, San Francisco (<http://hairlab.ucsf.edu>): 505 Parnassus Ave, San Francisco, CA 94143. Hair samples will be shipped to the HAL in sealed ziplock bags in a regular shipping box, via USPS. Hair sample cards will be labeled with ID numbers and will not contain any identifying information. An invoice will be included with the shipment to confirm the number of samples in the shipment. Because hair samples are considered non-infectious, they do not have to be shipped via any special handling requirements.

Sharing the results of the hair analysis conducted by the HAL at UCSF. The results of the hair analysis will be delivered to Dr. Woolf-King via her Syracuse University email account in an excel spreadsheet or pdf file that does not contain any identifying information. The file will be immediately stored on our Syracuse University laboratory-based server

Sharing nail samples with the lab processing facility. Nail samples will be delivered to Co-Investigator Kestutis G Bendinskas at SUNY Oswego for analysis via either PirateShip.com mailed packages or in-person delivery via lab personnel.

Sharing the results of the hair analysis conducted by SUNY Oswego. The results of the nail analysis will be delivered to Dr. Woolf-King via her Syracuse University email account in an excel spreadsheet or pdf file that does not contain any identifying information. The file will be immediately stored on our Syracuse University laboratory-based server.

9.4. If you plan to code the data, describe the method in which it will be coded and indicate who will have access to the key to the code.

No identifying information will be recorded on the self-report questionnaires. Participants will be assigned an ID number linking their identification with survey data. Participant names will not be stored with the data. The list linking participant identification number to name and participant tracking information will be stored in a separate secure, password protected, REDCap database. Only Dr. Woolf-King, Dr. Maisto, and approved study team members will have access to this database.

9.5. How will you educate research staff to ensure they take appropriate measures to protect the privacy of participants and the confidentiality of data collected.

All research assistants have received extensive training and supervision from Drs. Woolf-King and Maisto, both licensed clinical psychologists who have conducted HIV and alcohol-related research for many years. Dr. Woolf-King will also supervise the research assistants in the proper recruitment, survey administration, and debriefing. All study staff will be required to demonstrate competencies in recruitment, survey administration, and debriefing to Dr. Woolf-King in mock sessions.

Privacy can be defined in terms of having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

9.6. Describe what provisions are in place to protect the privacy interests of participants, where “privacy interest of participants” refers to the participant’s desire to limit interventions or interactions with others and to limit access of others to their private information. Examples include: location of data collection (private location vs. public location), method of data collection (focus groups vs. one-on-one interview, questionnaires vs. interviews, telephone, email and mail communications), type of information (written vs. oral), recruitment methods and cultural norms.

Each participant will complete the questionnaires in a one-on-one telephone or Zoom-based video interview in a private location of their choosing with a trained RA who will also be in a private location of their choosing. Qualitative interviews were conducted in a private room in our lab space or at the IHS clinic. The RA will conduct the telephone-based intervention sessions in a private room, and participants will be encouraged to engage in the session in a private location as well. FG participants were reminded about the importance of confidentiality at the beginning of the discussion. Any participant who did not feel comfortable with the FG format may have requested to have an individual interview instead. The FGDs occurred in a private room in our laboratory space. We will do our best to accommodate the participant's preference for time/day to complete study activities.

9.7. Will audio, video or film recording be used?

☐ No. (Skip to Section 12)

☒ Yes. If yes, specify type of recording: Digital audio recordings

9.7.1. Describe the storage of the recordings. Include in your description who will have access to the recordings, as well as how and where they will be stored.

Qualitative interviews, FGDs, and interventions sessions will be audio recorded with a digital recorder. Immediately after the completion of the interview/FGD/session, the recording will be uploaded to a secure, password protected server and stored according to the REDCap ID number. The electronic recorder will be erased immediately after upload. Debriefs and transcriptions of the interviews will be stored according to ID number, not name, and only the PI and designated research staff will have access to these recordings, transcripts, and debriefs which will be stored on the same password-protected server.

9.7.2. How long will the recordings be kept and what is the disposition of the recordings once the research is complete.

All recordings will be destroyed 10 years after study completion.

NOTE: Specific permission for each type of recording must be sought in the consent form and should be indicated at the end of the document using checkboxes (_ I agree to be audio taped, _ I do not agree to be audio taped, _ I agree to be video taped, _ I do not agree to be video taped, etc.)

10. Risk to Participants

10.1. Describe in detail any possible physical, psychological, social, political, legal, economic, or other risks to the participants, either immediate or long range. Risk may be minimal but never totally absent. Do not say "No Risk".

Risks associated with Aim 1

The most immediate risk associated with participation in the qualitative interviews and focus group discussions is loss of confidentiality.

- (1) **Loss of confidentiality.** As stated previously, there is a slight but present chance of a breach of confidentiality inherent in any research study. We asked to audio record the interviews and FGDs, which could be identifiable if confidentiality is breached. Participants in FGDs were with a group of other people living with HIV who are hazardous drinkers and we cannot ensure that each group member maintained the confidentiality of other groups members. Loss of confidentiality may lead to unintentional disclosure of HIV status. Stigma associated with such disclosure may include social harms (e.g., breakup of couples following HIV detection), discrimination (e.g., a loss of employment or status in community), and psychological harm such as embarrassment

Risks associated with Aim 2

The most immediate risks associated with participation in Aim 2 are: (1) loss of confidentiality, (2) emotional discomfort associated with answering sensitive questions and participating in mindfulness-based exercises, (3) mild physical discomfort from the finger prick.

- (1) **Loss of confidentiality.** There is the very slight but present chance of a breach of confidentiality inherent in any study that handles confidential data. Participation in the research will be contingent upon HIV+ status and admission of hazardous alcohol consumption, and due to the novel telephone-based treatment delivery, participants in the study may be identifiable to other community members. Loss of confidentiality may lead to

unintentional disclosure of HIV status. Stigma associated with such disclosure may include social harms (e.g., breakup of couples following HIV detection), discrimination (e.g., a loss of employment or status in community), and psychological harm such as embarrassment. Finally, participants may disclose illegal drug use during the TLFB which, if unintentionally disclosed, could result in discrimination, employment loss, psychological harms (e.g., stigma and shame), and legal consequences.

- (2) **Emotional discomfort** It is possible that participants may experience some emotional discomfort answering questions about sensitive, personal information (e.g., alcohol use, symptoms of anxiety and depression). Regarding the issue of emotional discomfort, we expect this to be minimal as both the ACCEPT and BI interventions are focused on drinking reduction and behavioral skills for enacting a drinking reduction plan; however the ACCEPT participants will be asked to use mindfulness skills as a way of coping with uncomfortable emotions/thoughts/urges, which will require the experience, rather than avoidance, of these private experiences. This may produce a temporary increase in symptoms of anxiety (or other undesirable emotional states). This discomfort is expected to be minimal given that participants are asked similar questions during routine HIV-related medical care. Also, we conducted mindfulness exercises with participants in the IN-VOICE study and did not have a participant report significant emotional discomfort as a result.
- (3) **Mild physical discomfort.** Participants will likely experience mild physical discomfort from the finger prick used to collect the dried blood spots (DBS). This discomfort is expected to be brief and minimal.

10.2. Describe what procedures will be used to minimize each risk you have stated above. Also, include in your description the availability of medical or psychological resources that participants might require as a consequence of the research, if applicable. If participants need to be debriefed at the end of the study, a copy of the debriefing statement must be attached.

Sections 4, 6, and 11 describe how we will protect against a breach in confidentiality by:

- using a unique subject ID to label all study materials
- properly training research staff,
- securely storing data,
- conducting all interviews, FGDs and telephone-based sessions in a private interview space,
- immediately uploaded and deleting from the recording device all audio recordings, and
- discussing the importance of confidentiality at all focus group discussions and reminding participants at the beginning of the FGD (in addition to in the informed consent) that by participating in a group discussion we cannot ensure that every group member will respect the confidentiality of everyone else.

To reduce the risk of emotional discomfort we will remind each participant that he or she may elect to not answer any question that he/she finds too personal and may discontinue or take a break from the study without penalty.

For participants in the ACCEPT intervention, at randomization we will remind participants that exposure to uncomfortable thoughts and feelings as a result of mindfulness exercises may result in a temporary increase in anxiety (or another undesirable emotional state). Each participant will be reminded that he/she may elect to discontinue any exercise he/she finds too distressing and/or discontinue the intervention at any time without penalty. This information will also be included in the informed consent.

We will provide a list of counseling and HIV-related community services to interested participants as we have done in our IN-VOICE study (see **Appendix X**). In the unlikely event that a participant experiences acute distress during study participation, the on-site research assistant will immediately contact one of the project PIs (Dr. Woolf-King or Dr. Maisto) for consultation regarding appropriate next steps. If a participant is judged to be in a high level of distress or in danger of harming self or others, emergency psychiatric services will be sought by contacting 911.

10.3. Does this research involve more than minimal risks to participants?

☒ **No. (Skip to Section 13)**

☐ **Yes. If yes, please provide plan for monitoring the data collected to ensure the safety of participants. (Your data safety monitoring plan must include the following: Description of who will monitor the data, what data will be monitored, how frequently will it be monitored, what analysis will be performed on the data, what decision rules (e.g. stopping rules) will be considered, if unexpected harms will be detected promptly, if an increased frequency or severity of unexpected**

harms will be detected promptly, if the protocol will be stopped once harms are proven to outweigh benefits.).

11. Benefits

Note: Course credit or payment is an inducement to participate in the study and should not be described as a benefit of the research.

11.1. Describe any benefits to the participants in general.

Participants may experience psychological benefit (e.g., reduced alcohol use, reduced symptoms of stress and anxiety) and benefit to HIV-related disease management (e.g., increased adherence, lower viral load) from participation in the research study. Our previous experience conducting qualitative research with HIV+ adults also indicates that participants generally enjoy discussing their opinions and perspectives about health-related topics, particularly topics that directly relate to HIV-treatment and care. Given that risks of study participation are mild we view them as reasonable in relation to the anticipated benefits to the participants and to the larger community of people living with HIV

11.2. Society at large.

The results from the proposed research will be used to create an innovative alcohol intervention for people living with HIV, which has the potential to reduce alcohol use, reduce symptoms of anxiety and depression, enhance HIV care, and reduce the risk of onward HIV transmission. If successful, the intervention can also be implemented in medical settings for people not living with HIV but who struggle with hazardous alcohol use.

11.3. Explain how the benefits outweigh the risks involved.

We expect that the overall cost/benefit ratio to be highly favorable. The risks associated with participating in this research are minimal and the risks that do exist will be mitigated through the use of clearly explained procedures, written consent procedures, careful training and supervision of research team members, secure data storage, and a set of procedures to protect participant confidentiality. All participants will have the opportunity to benefit directly from their participation, and the research promises to deliver important new knowledge that will benefit society at large.

A number will be assigned to your protocol. Please refer to it whenever calling or writing for information.

- **All supporting documentation including list of references, consent and/or assent form(s), survey instruments, interview questions, recruitment materials, letters of support, IRB approvals from other institutions, etc. must be included with the application.**

Return Completed Protocol To:

**Office of Research Integrity and Protections
214 Lyman Hall
Syracuse University
Syracuse, NY 13244
Phone: 315-443-3013**

Please send IRB notifications by:

- ☐ **Hard copy campus mail. All correspondence mailed to the PI/faculty member's address.**
☒ **Email notification (Only the original hard copies of date stamped consent/assent documents will be returned.)**

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