NCT03721276

Title of Research Project: Project EQuIP: Empowering Queer Identities in Psychotherapy

Date 6.25.19

HRP-503E– Protocol for Social or Behavioral Science or Educational Research (2017-1)

Protocol Title: ESTEEM-W

Principal Investigator: Dr. John Pachankis

Version Date: 6.25.19

(*If applicable***) Clinicaltrials.gov Registration #:** Click or tap here to enter text.

INSTRUCTIONS
This template is intended to help investigators prepare a protocol that includes all of the necessary information needed by the IRB to determine whether a study meets approval criteria. **Read the following instructions before proceeding:** 1. Use this protocol template for a PI initiated study that includes direct interactions with research subjects. Additional templates for other types of research protocols are available in the system Library: • If the study involves genetic testing, blood draws, or MRIs, do not use this form. Use the biomedical protocol template. • If the study involves secondary analysis of data, use the Secondary Analysis of Data protocol. • For activities that may qualify as exempt research, use the Request for Exemption form (which includes a decision tree to determine whether or not your study qualifies as exempt). 2. If a section or question does not apply to your research study, type "Not Applicable" underneath. 3. Once completed, upload your protocol in the "Basic Information" screen in IRES IRB system.

SECTION I: GENERAL INFORMATION

1. **Probable Duration of Project:** State the expected duration of the project, including all follow-up and data analysis activities. May 2017-May 2018

2. **Study location:** State where the study will take place and in what setting. ESTEEM Laboratory 220 East 23rd Street New York, NY 10010

3. If international, complete and submit **International checklist** (http://your.yale.edu/policies-procedures/forms/450-ch-1-international-research-checklist) Note: If your research involves interactions with any embargoed countries you should contact the Director of Corporate Contracts and Export Control Licensing (Donald.Deyo@yale.edu or call 203.785.3817) for guidance on how to proceed. N/A

4. **Help us categorize your research**. Are you using any of the following?

☐ Class Project
☐ Participant Observation
☒ Interviews
☒ Surveys
☐ Focus groups (study is not anonymous)
☐ Research in K-12 schools (submit a School Agreement form for the study)
☐ Deception (submit a Debriefing sheet)
☒ Audiotaping, videotaping or photography of individuals (study is not anonymous)
☐ Public viewing of videotapes or photographs
☐ Yale Psychology Pool (study does not qualify for exemption)
☐ International research sites (attach the International Checklist)
☒ Online (web-based) activities
☒ Social networks

SECTION IV: RESEARCH PLAN

1. **Statement of Purpose:** State the scientific aim(s) of the study, or the hypotheses to be tested. The aim of this study is to develop an evidence-based psychosocial intervention for sexual minority women. This intervention will specifically target the adverse mental and behavioral health outcomes disproportionately experienced by sexual minority women, including depression, suicidality, and alcohol abuse, which are known to be driven by stigma-related stressors associated with their sexual orientation (i.e., minority stress processes).

2. **Background:** Describe the background information that led to the plan for this project. **Provide references** to support the expectation of obtaining useful scientific data.

Sexual minority women face significant psychosocial health disparities relative to both the general population and heterosexual, cisgender women (Cochran et al., 2001; Cochran et al., 2003; Sandfort et al., 2001). Specifically, sexual minority women experience an increased risk for depression, suicidality, and alcohol abuse (Gilman et al., 2001; King et al., 2008; Matthews et al., 2002; Sandfort et al., 2001; Wilsnack et al., 2008). Minority stress theory posits that stigma, prejudice, and discrimination create a stressful environment that leads to adverse mental health outcomes and substance abuse problems in LGB populations (Meyer, 2003). Despite these well-documented disparities, there have been few resources and limited research dedicated to developing evidence-based psychosocial interventions targeted specifically to sexual minority women (Rutherford et al, 2008).

ESTEEM (Effective Skills to Empower Effective Men), developed by Dr. John Pachankis, is a transdiagnostic, cognitive behavioral intervention that focused on improving health outcomes linked to minority stress processes in sexual minority men (Pachankis, 2015). Preliminary data suggest that ESTEEM has been effective in improving mental health outcomes and reducing risky sexual behavior in gay and bisexual men (Pachankis et al., 2015). One of the benefits of ESTEEM is its ability to target the co-occurring health risks that are driven by common minority stress pathways (Pachankis, 2015). Thus, a model based on ESTEEM could help to simultaneously target the multiple adverse health outcomes sexual minority women disproportionately face, including depression, suicidality, and alcohol abuse, that are linked to minority stress processes (Meyer, 2003).

References

Cochran, S. D., Keenan, C., Schober, C., & Mays, V. M. (2000). Estimates of Alcohol Use and Clinical Treatment Needs Among Homosexually Active Men and Women in the U.S. Population. Journal of Consulting and Clinical Psychology, 68(6), 1062–1071.

Cochran, S. D., Mays, V. M., & Sullivan, J. G. (2003). Prevalence of mental disorders, psychological distress, and mental health services use among lesbian, gay, and bisexual adults in the United States. J Consult Clin Psychol, 71(1), 53-61.

Gilman, S. E., Cochran, S. D., Mays, V. M., Hughes, M., Ostrow, D., & Kessler, R. C. (2001). Risk of psychiatric disorders among individuals reporting same-sex sexual partners in the National Comorbidity Survey. American Journal of Public Health, 91(6), 933–939.

Meyer, I. H. (2003). Prejudice, Social Stress, and Mental Health in Lesbian, Gay, and Bisexual Populations: Conceptual Issues and Research Evidence. Psychological Bulletin, 129(5), 674–697. http://doi.org/10.1037/0033-2909.129.5.674

King, M., Semlyen, J., Tai, S. S., Killaspy, H., Osborn, D., Popelyuk, D., & Nazareth, I. (2008). A systematic review of mental disorder, suicide, and deliberate self harm in lesbian, gay and bisexual people. BMC Psychiatry, 8, 70. http://doi.org/10.1186/1471-244X-8-70

Matthews, A. K., Hughes, T. L., Johnson, T., Razzano, L. A., & Cassidy, R. (2002). Prediction of Depressive Distress in a Community Sample of Women: The Role of Sexual Orientation. American Journal of Public Health, 92(7), 1131–1139.

Pachankis, J. E. (2015). A Transdiagnostic Minority Stress Treatment Approach for Gay and Bisexual Men's Syndemic Health Conditions. Archives of Sexual Behavior, 44(7), 1843–1860. http://doi.org/10.1007/s10508-015-0480-x

Pachankis, J. E., Hatzenbuehler, M. L., Rendina, H. J., Safren, S. A., & Parsons, J. T. (2015). LGB-Affirmative Cognitive-Behavioral Therapy for Young Adult Gay and Bisexual Men: A Randomized Controlled Trial of a Transdiagnostic Minority Stress Approach. Journal of Consulting and Clinical Psychology, 83(5), 875–889. http://doi.org/10.1037/ccp0000037

Rutherford, K., McIntyre, J., Daley, A., & Ross, L. E. (2012). Development of expertise in mental health service provision for lesbian, gay, bisexual and transgender communities. Med Educ, 46(9), 903-913. doi:10.1111/j.1365-2923.2012.04272.x

Sandfort, T. M., de Graaf, R., Bijl, R. V., & Schnabel, P. (2001). Same-sex sexual behavior and psychiatric disorders: Findings from the netherlands mental health survey and incidence study (nemesis). Archives of General Psychiatry, 58(1), 85-91. doi:10.1001/archpsyc.58.1.85

Wilsnack, S. C., Hughes, T. L., Johnson, T. P., Bostwick, W. B., Szalacha, L. A., Benson, P., . . . Kinnison, K. E. (2008). Drinking and drinking-related problems among heterosexual and sexual minority women. J Stud Alcohol Drugs, 69(1), 129-139.

3. **Research Plan:** Summarize the study design and research procedures using non-technical language that can be readily understood by someone outside the discipline. If working with a Non-Government Organization (NGO) or other organization, be sure to highlight which are research-only activities and which activities would occur regardless of the research. If working with survey firms, please specify what research activities the research firm will be responsible for.

This study will begin with two phases.

Phase 1 will involve conducting interviews with 20 sexual minority women (SMW) who report experiencing depression, suicidality, and alcohol abuse. We hope to use information from these interviews to gather insight from participants that can help inform the adaptation of a cognitive-behavioral treatment approach to specifically target sexual minority women's unique experiences with minority stress. This study will entail recruitment of 20 participants (through online recruitment methods and passive poster recruitment), as well as participant incentives, recording of interviews, and transcription and analysis of these interviews. Recruitment will take place in New York City, and interviews will take place in New York at the ESTEEM lab office under the supervision of Dr. John Pachankis and ESTEEM staff. Interviews will be conducted by student research assistants and staff. An additional 10 interviews will be conducted with sexual minority women in order to further explore some of the key themes identified during the initial 10 interviews that were conducted. These participants will be recruited and compensated using the same methods and guidelines as the first 20 Phase 1 participants.

Phase 2 will involve consultation interviews with 10 community-based mental health experts who treat psychosocial health problems among at-risk SMW. Involvement of key community members in intervention design optimizes intervention dissemination and allows frontline professionals to shape the intervention that they would be most willing to implement. We are seeking the input of mental health experts working with the SMW community in order to translate existing, but largely untapped, clinical wisdom regarding SMW's minority stress experiences, mental health, and alcohol use into the development of the intervention. This type of consultation bridges the research-practice divide that has hampered evidence-based intervention dissemination and increases the likelihood that primary stakeholders will implement evidence-based practice. Mental health experts will be invited to participate based on their specialization in clinical practice and their publication history. This phase will involve

recruitment of mental health experts, participant incentives, recording of interviews, and transcription and analysis of these interviews. Members of the ESTEEM lab's clinical team will conduct the interviews. **Phase 3** will involve pilot testing the adapted cognitive-behavioral treatment through a randomized controlled trial with 60 SMW who report experiencing depression, anxiety, and alcohol abuse. The SMW will be randomized to either therapy or waitlist. Individuals assigned to therapy will receive 10 weekly individually-delivered sessions, directly after baseline assessment, that address minority stress mechanisms underlying SMW's depression, anxiety, and alcohol abuse. Individuals assigned to waitlist will be put on a waitlist for 3 months after baseline assessment, after which they will also receive the same treatment as the therapy group. While they are on waitlist, they are allowed to receive other treatment/therapy. There are no restrictions for participants on the waitlist. At their baseline appointment (and subsequently at their first therapy session) they will receive a list of community referrals containing sexual health and mental health resources. Participants on waitlist will not be re-assessed for eligibility once the 3 months have passed. At therapy, participants will be given questions to answer to track their progress (OASIS, ODSIS, and Heavy Drinking- these measures can be found in the therapy manual and measurements packet). At baseline, 3 months, and 6 months, participants will complete self-report surveys at home prior to coming in to their appointment. When participants are in the office, they will be given self-report assessments of mental and behavioral health outcomes and minority stress mechanisms, computerized behavioral tasks (Implicit Associations Task, Emotional Go No-Go Task, and Self-Referent Encoding Task), and a Time-Line Follow Back (TLFB) interview of past-90-day heavy alcohol use (all of which will be administered by trained research assistants). The TLFB will be recorded for quality assurance purposes and will only show the interviewers face and capture the participants voice. Incentives will be offered for each study visit: $25 at baseline, $25 at 3-month follow-up, $75 at 6-month follow-up, and $10 for each therapy session (therapy manual has been uploaded with this application). This study will entail the recruitment of 60 SMW participants through online recruitment methods, passive poster recruitment, and an existing list of SWMs who have expressed interest and consented to be contacted for any future research studies we conduct. All aspects of Phase 3 will take place at the Yale-sponsored ESTEEM lab in New York City under the supervision of Dr. John Pachankis. Therapy sessions will be recorded and conducted by members of the ESTEEM lab's clinical team. Therapy sessions that are videotaped will only contain the therapists face, not the participants, but will catch the participants voice. These video recordings are for supervision and quality assurance purposes. Recordings of both therapy and the TLFB are not optional. Additionally, 15-20 participants enrolled in the study will be invited at random via e-mail to complete a follow-up qualitative phone interview about their experience in the study. These interviews will be audio recorded. Participants will be receive a $40 Amazon gift card for completing a follow-up interview.

4. **Participant Population:** Provide a detailed description of the types of participants who will be recruited into this study.

Phase 1: Participants who will be recruited for Phase 1 are sexual minority women ages 18-35 who reside in NYC and have experienced a history of depression, suicidality, and alcohol abuse.

Phase 2: Participants who will be recruited for Phase 2 are clinical experts across mental health professions (e.g., clinical psychology, psychiatry, substance use treatment) who report specializing in both evidence-based psychosocial treatment and clinical practice with SMW.

Phase 3: Participants who will be recruited for Phase 3 are sexual minority women ages 18-35 who reside in NYC and have experienced depression or anxiety (≥ 2.5 on the BSI-4), as well as alcohol abuse (i.e., ≥ 4 drinks in one sitting), in the past 90 days.

5. **Describe** how access to the population will be gained in the study.

Phase 1: SMW recruitment will occur through active and passive targeted, community-based sampling approaches. We will recruit through advertisements placed on social networking apps (i.e. Facebook, Scissr) and flyers and screening at SMW venues. We will use a multi-stage screening approach (i.e., online

screening, phone screening prior to first baseline) to maximize our pool of potentially eligible SMW participants. For our largest recruitment event, Manhattan Pride, we will hold a sweepstakes for people who complete our online screening survey in person. We will pool the contact information for all people who completed the survey during our event (noted by timestamp) and will use a random number generator to select people to win the prize. The sweepstakes prize will be a $25 Amazon giftcard that will be emailed to them immediately after the selection of the winners.

Phase 2: Community health experts will be identified by searching public academic databases (e.g., PubMed, PsycINFO) to identify individuals who have published clinical research, case studies, or other clinical accounts of treating SMW. Phase 2 experts will also be identified by searching membership rosters of professional organizations serving SMW populations.

Phase 3: SMW recruitment will occur through targeted, community-based sampling approaches. We will recruit through advertisements placed on social networking apps (i.e. Facebook, Scissr) and flyers and screening at SMW venues. We will also recruit from an existing list of SMWs who have previously expressed interest in participating in future studies we are conducting and have given us their contact information. Some SMW on this list were also in Phase 1 of the study and have consented to be re-contacted. We will assess eligibility through an online screening assessment prior to scheduling participants' first appointments.

6. **Participant classification:** Check off all classifications of participants that will be <u>specifically recruited for enrollment</u> in the research project. Will participants who may require additional safeguards or other considerations be enrolled in the study? If so, identify the population of participants requiring special safeguards and provide a justification for their involvement.

☐Children	☐ Healthy	☐Fetal material, placenta, or dead fetus
☐Non-English Speaking	☐ Prisoners	☐Economically disadvantaged persons
☐Decisionally Impaired	☐ Employees	☐Pregnant women and/or fetuses
☐Yale Students	☐ Females of childbearing potential	

Click or tap here to enter text.

NOTE: Is this research proposal designed to enroll children who are wards of the state as potential participants? ☐Yes ☒ No

7. **Inclusion/Exclusion Criteria:** What are the criteria used to determine participant inclusion or exclusion?

   Phase 1 Inclusion Criteria: Eligible participants will meet the following criteria: 1) age 18-35; 2) self-identification as lesbian or bisexual; 3) symptoms of depression within the past three months (≥ 2.5 on the BSI-2); 4) past-3-month passive suicidal ideation (≥ 3 on the SBQ-4); 5) at least one instance of past-3-month heavy drinking (i.e., ≥ 4 drinks in one sitting); 7) English fluency.

   Phase 1 Exclusion Criteria: Participants will be excluded for: 1) current active suicidality or homicidality (defined as active intent or concrete plan, as opposed to passive suicidal ideation; 2) evidence of active, untreated mania, psychosis or gross cognitive impairment;

   Phase 2 Inclusion/Exclusion Criteria: 10 clinical experts across mental health professions (e.g., clinical psychology, psychiatry, substance use treatment) will be identified through a review of membership rosters of national professional organizations that promote either 1) evidence-based psychosocial treatment approaches (e.g., Association for Behavioral and Cognitive Therapies) or 2) affirmative

psychosocial treatment approaches for SMW (e.g., Association of Gay and Lesbian Psychiatrists). These rosters will be searched for those members who report specializing in both evidence-based psychosocial treatment and clinical practice with SMW. Scholarly search engines (e.g., PsycINFO, PubMed) will then be utilized to determine who among the identified individuals has also published theoretical, conceptual, or case study accounts of mental and behavioral health of SMW. Those 10 professionals who have published most extensively in this area will be invited as experts to participate in a telephone interview.

Phase 3 Inclusion Criteria: 1) age 18-35; 2) self-identification as queer, lesbian, or bisexual; 3) symptoms of anxiety or depression within the past 90 days (≥ 2.5 on the BSI-4 for either anxiety or depression); 4) at least one instance of past-90-day heavy drinking (i.e., ≥ 4 drinks in one sitting); 5) 6-month NYC residential stability and availability; 6) English fluency.

Phase 3 Exclusion Criteria: 1) active psychosis or active mania; 2) active suicidality or active homicidality; 3) currently in mental health treatment exceeding one day per month; 4) having received any cognitive-behavioral therapy treatment in the past 12 months; 5) evidence of gross cognitive impairment.

SECTION V: RECRUITMENT/CONSENT AND ASSENT PROCEDURES

1. Recruitment Procedures:

a. Describe how potential participants will be identified and contacted, and by whom.

Phase 1: Actively recruited participants will be asked to complete a brief screening instrument on a tablet at the venue in which they were recruited or will be given an information card highlighting the goals of the project with a link to the online screening instrument and phone number to contact should they want to participate. Passively recruited participants will be informed of the study through posted flyers containing identical information as the information card used for active recruitment. The phone number will be staffed five days per week during normal business hours. After hours, potential participants will be instructed to provide a contact phone number or to call during business hours. Upon contacting the research center, potential participants will be screened for potential eligibility using the same online screening instrument included on the tablet used for the venue-based active recruitment. Those who screen as preliminarily eligible for the study will be contacted to complete a phone screening with a staff member. Those who remain eligible following the phone survey will be scheduled for an assessment. Those who do not qualify for the study based on the initial screen will be referred to appropriate community resources.

Phase 2: A member of the ESTEEM lab's clinical team or the Project Coordinator will first call or email each identified expert to explain the process by which they were identified and the purpose of their invited participation in this phase of the study. Once an expert expresses interest in participation, a clinical team member of the Project Coordinator will direct them to an online consent form describing the details of participation, confidentiality of personal information, and associated risks and benefits.

Phase 3: Actively recruited participants will be asked to complete a brief screening instrument on a tablet at the venue in which they were recruited or will be given an information card highlighting the goals of the project with a link to the online screening instrument and phone number to contact should they want to participate. Passively recruited participants will be informed of the study through posted flyers containing identical information as the information card used for active recruitment. The phone number will be staffed five days per week during normal business hours. After hours, potential participants will be instructed to provide a contact phone number or to call during business hours. Upon contacting the research center, potential participants will be screened for potential eligibility using the same online

screening instrument included on the tablet used for the venue-based active recruitment. Those who screen as eligible for the study will be contacted by a staff member to give more information about the study and schedule the first appointment. After the participant has completed the online screener, regardless of eligibility, will be given a list of mental health and sexual health community resources. Recruitment of individuals from our existing list of potentially interested participants will involve sending a recruitment email to these potential participants containing the same information provided on our flyers and information cards. Upon contacting the research center, potential participants will complete an identical process as described above. Participants will be recruited before we obtain the CoC. When the CoC is obtained, all participants that have consented will be notified.

Are you collecting any information about the individuals prior to their signing a consent form?
Yes ☒ No ☐

If yes, indicate what information you will be collecting and how it will be gathered *(phone screen, paper questionnaire, etc.)*
We will use an online screening instrument to collect the following information: age, NYC residential stability and availability, gender identity, sexual identity, depressive symptoms, anxiety symptoms, and alcohol use. Participants will provide consent before completing this eligibility screen.

2. Indicate recruitment methods below. Attach copies of any recruitment materials that will be used.

☒ Flyers
☒ Posters
☐ Letter
☒ Through local NGO or other local contact
☒ Table set-up / in-person recruitment of public
☐ Classroom recruitment
☐ Other:

☒ Internet/web postings
☒ Mass email solicitation
☐ Departmental/Center website
☐ Departmental/Center research boards
☐ Snowball sampling

☒ Social Media (Twitter/Facebook):

☐ Radio
☐ Telephone
☐ Television
☐ Newspaper

3. Targeted Enrollment: Give the number of participants:
a. Targeted for enrollment at Yale for this protocol
Phase 1: 20 sexual minority women **Phase 2:** 10 SMW experts **Phase 3:** 60 sexual minority women
b. If this is a multi-site study, give the total number of participants targeted across all sites N/A

4. How was this estimate derived?
For both Phase 1 and Phase 2, estimates were derived based on the number of interviews required to reach saturation in previous intervention development studies. **For Phase 3,** this part of the study is powered primarily to examine feasibility and acceptability. This phase will also allow us to determine the preliminary efficacy of the intervention. We will use Cohen's d and Hedge's g corrected for sample size, both of which express the average amount of individual change between intervention and control groups in terms of units of standard deviation. Group means on continuous variables typically begin to stabilize by 20-30 participants, and our waitlist design enables us to estimate effect sizes both by comparing intervention and control conditions at 3-months (n = 30/condition) and by examining pre-post effect sizes for the entire sample (n = 60). Our sample size provides sufficient power (1 - β=.8) to detect

intervention effects consistent with effect size estimates identified in our intervention research with sexual minority men in which the relative reduction in depression was 0.55 between intervention and control groups.

5. Process of Consent/Assent *(NOTE: When a study includes minors, parent provide permission [not consent] for the child's participation, and the child provides assent for participation)*

Describe the setting and conditions under which consent/assent will be obtained, including parental permission or surrogate permission and the steps taken to ensure participants' independent decision-making.

Phase 1: A trained staff member will assess participants' consent in a private room. The staff member will ensure that the participant understands the risks associated with the disclosure of information that could indicate imminent threat to self or others. Staff members, if not PI Pachankis, will be instructed to contact PI Pachankis or the project coordinator if they are unsure about any participant's capacity to consent.

Phase 2: Potential participants who have been identified as SMW mental health experts and therefore meet eligibility criteria for inclusion for this phase of the study will be contacted over the phone and provided detailed information about participation requirements. The trained staff member will read the consent form along with the prospective Phase 2 participant, who will concomitantly be able to access the form online. Verification of comprehension of informed consent will be accomplished by asking participants to recall central points in the consent process; points of confusion will be clarified. Once participants have fully understood the consent, they will be asked to electronically sign and submit the consent form online. A copy will then be mailed to them.

Phase 3: Participants will electronically consent to the online screener. If eligible, the participant will be contacted to schedule their first appointment and to learn more about the study. At the beginning of the initial phone call, participants will be informed that they are preliminarily eligible for our study and be asked if they would like to continue the call to hear more about the study and potentially consent. If more than two weeks have lapsed since they screened eligible, participants will be rescreened for eligibility. There will be 2 consent portions to this study. At the end of the first phone call (which reviews key aspects of participation), participants will be informed that they will receive a consent form electronically via Qualtrics. They are instructed to read the consent form and to call us back if they have any questions. If the participant signs the consent form, they will be re-directed to the first set of at-home surveys to complete before their first scheduled appointment. Both the consent form and at-home surveys will be given via Qualtrics. The consent form and at-home surveys will be completely separate forms, where the participants name is not located with the same data as the responses to the at-home surveys. To know which participant filled out which survey, we will connect the consent form and the first set of at-home surveys using a unique participant ID number. The consent form itself will only contain the participant's electronic signature. However, the participant ID will be attached securely to the consent form in the "backend" of Qualtrics in the data and kept completely confidential. When the participant comes in for their first appointment, the participant will meet with the staff member in a private room and do a review of the consent form that has been signed, including administering consent comprehension quiz questions to ensure complete understanding of study participation. The participant will then sign this comprehension quiz form if they would still like to participate in the rest of the study. This form will be locked in a filing cabinet that only PI Pachankis and research staff will have access. The staff member will ensure that the participant understands the risks associated with the disclosure of information that could indicate imminent threat to self or others. Staff members, if not PI Pachankis, will be instructed to contact PI Pachankis or the project coordinator if they are unsure about any participant's capacity to consent. For participants that are waitlisted, they will not be re-consented. Participants get a signed copy of the consent form to take home with them. Additionally, they will have their therapy appointments scheduled

3 months in advance and get monthly reminder emails regarding their first therapy appointment, along with a reminder email of their 3-month follow-up appointment.

6. Evaluation of Participant(s) Capacity to Provide Informed Consent/Assent: Indicate how the personnel obtaining consent will assess the potential participant's ability and capacity to consent to the research being proposed, if applicable.
Phases 1, 2, and 3: Participants will be asked if they understand the information presented to them and asked to verbally summarize the consent documentation (e.g., procedures, risk, benefits, voluntariness, compensation, eligibility, principal investigator).

7. Documentation of Consent/Assent: Specify the documents or verbal scripts that will be used during the consent/assent process. Copies of all documents should be appended to the protocol, in the same format that they will be given or spoken to participants.
Phases 1, 2: PI Pachankis will retain a copy of the signed consent forms in a locked filing cabinet across the duration of the study.
Phase 3: Copies of electronically signed consent forms will be kept secure and confidential on Qualtrics and only accessible by research staff members. Copies of the signed consent comprehension questions will be kept in a locked file cabinet that only PI Pachankis and research staff will have access. For follow-up interviews, verbal consent will be obtained and recorded in Yale Qualtrics.

8. Non-English Speaking Participants: Explain provisions in place to ensure comprehension for research involving non-English speaking participants. Translated copies of all consent materials must be submitted for approval prior to use. **Do you speak the local language? Will you require a translator? (If so, please elaborate on how the translators will be trained).**
N/A

9. Are any of the study procedures likely to yield information subject to mandatory reporting requirements? (e.g. HIV testing – reporting of communicable diseases; parent interview -incidents of child abuse, elderly abuse, etc.). Please verify to whom such instances will need to be reported.
While the likelihood is minimal, if a participant reports a clear intention to harm himself or another person, health professionals are required to report this. Additionally, health care professionals are required by state law to report suspected cases of abuse or neglect.

Our ESTEEM clinical protocol successfully guides reporting of instances of suicidality, homicidality, emotional distress, and violence in our ESTEEM pilot trial. We will employ the same protocol in this study. The clinical protocol is attached. The protocol specifies that, in the event that a participant is at imminent risk of harming themselves or another person, as determined by a study staff member with mental health training, study staff will contact 911 to dispatch police or paramedics. Only the minimal necessary identifying information will be provided to these personnel. In less imminent instances of distress, we will refer distressed participants to local mental or behavioral health services. All self-report questionnaires assessing suicidality will be given in-office where participants can be monitored by a clinical staff member. Clinical staff members will receive an alert if the participant answers the online questionnaires in a manner that signals distress; such participants will be met by the clinical staff member on site to assess risk.

10. Waiver of Consent/Documentation of Consent: In certain circumstances, the IRB may grant a waiver of documentation of consent, or a full waiver of consent, depending on the study. If you will request either a waiver of consent, or a waiver of signed consent for this study, complete the appropriate section below.

☐**Not Requesting any consent waivers**

☒**Requesting a waiver of signed consent (e.g., verbal or online consent only):**

☒ **Recruitment/Screening only** *(if for recruitment, the questions in the box below will apply to recruitment activities only)*

☐ **Entire Study (**Note that an information sheet may be required.)

For a waiver of signed consent, address the following:

- Would the signed consent form be the only record linking the subject and the research? YES ☐ NO ☒
- Does a breach of confidentiality constitute the principal risk to subjects? YES ☐ NO ☒

OR

- Does the research pose greater than minimal risk? YES ☐ NO☐
- Does the research include any activities that would require signed consent in a non-research context? YES ☐ NO ☐

Consent will be obtained for all study components either verbally or signed or online as described above.
Phase 1: We will not require participants to provide their name when consenting to complete the brief screen to be administered via electronic tablets at local venues (e.g., gay bars, clubs, parks). This brief (4 min) screen will assess age, substance use risk behavior, and depression symptoms to determine preliminary eligibility for this study. This brief screen does not pose greater than minimal risk. Before completing this screen, participants will be told via online text that this screen will ask several personal questions to determine eligibility for a larger study and that participants can choose to provide their name and contact information after they have found out if they are eligible via the electronic screen. Preliminarily eligible participants will be asked to provide their name and contact information in order to receive a call or email containing more information on how to complete a more comprehensive phone screen to verify study eligibility. Participants' identifying information, including their name, will be kept in a separate database from the remainder of their study responses. Participants will provide consent before completing this more comprehensive phone screen, as described above.
Phase 2: Experts who agree to participate in this study will be given an online consent form to complete.
Phase 3: We will not require participants to provide their name when consenting to complete the brief screen to be administered via electronic tablets at local venues (e.g., gay bars, clubs, parks). This screen will assess age, NYC residential stability and availability, gender identity, sexual identity, depressive symptoms, anxiety symptoms, and alcohol use to determine eligibility for this study. This screen does not pose greater than minimal risk. Before completing this screen, participants will be told via online text that this screen will ask several personal questions to determine eligibility for a larger study. Eligible participants will be asked if they would like to provide their name and contact information in order to

receive a call to schedule the first assessment appointment. Participants' identifying information, including their name, will be kept in a separate database from the remainder of their study responses. Participants will provide consent before completing this more comprehensive phone screen.

☐ **Requesting a waiver of consent (if you are not obtaining ANY consent):**

☐ **Recruitment/Screening only** *(if for recruitment, the questions in the box below will apply to recruitment activities only)*
☐ **Entire Study**

For a waiver of consent, please address all of the following:

- Does the research pose greater than minimal risk to subjects?
  ☐ Yes *If you answered yes, stop. A waiver cannot be granted.*
  ☐ No
- Will the waiver adversely affect subjects' rights and welfare? YES ☐ NO☐
- Why would the research be impracticable to conduct without the waiver?
  Click or tap here to enter text.
- Where appropriate, how will pertinent information be returned to, or shared with subjects at a later date? Click or tap here to enter text.

SECTION VI: PROTECTION OF RESEARCH PARTICIPANTS

1. Confidentiality & Security of Data: Describe the steps that will be taken to secure the data during storage, use and transmission as outlined in the below sections. NOTE: Data can include paper files, data on the internet or websites, computer files, audio/video files, photographs, etc. and should be considered in the responses to the below sections. Click or tap here to enter text.

Phase 1: To protect participants' confidentiality, all counselors and research assistants (RAs) have undergone rigorous training in maintaining participants' privacy. Further, immediately upon providing consent, all participants will be assigned an identification number, which will only be kept on an electronic database that will be password protected and located on a designated ESTEEM computer. This information will not be stored with any other data and no other identifying information will appear on any form. All contact with participants will be made by counselors and research staff under explicit guidelines to preserve confidentiality when telephoning, emailing, or mailing information to participants. All materials with identifying information will be kept in one password protected electronic file. Participants will provide ESTEEM with contact information (email, phone numbers, and mailing address) for compensation purposes. This information will be treated in the same confidential manner as all participant information, as described here. **Phase 2:** The 10 SMW experts consulted will be given the option of being acknowledged for their contributions, which could potentially involve sharing their names in any publications and presentations that may arise from this project. If they choose to keep their interview confidential, the procedures described for maintaining confidentiality and security of data for Phase 1 will be followed.

Phase 3: To protect participants' confidentiality, all counselors and research assistants (RAs) have undergone rigorous training in maintaining participants' privacy. Further, immediately upon providing

consent, all participants will be assigned an identification number, which will be kept on an electronic database that will be password protected and located on a designated ESTEEM computer, as well as on a secure survey website (Qualtrics). This information will not be stored with any other data and no other identifying information will appear on any form. All contact with participants will be made by counselors and research staff under explicit guidelines to preserve confidentiality when telephoning, emailing, or mailing information to participants. All materials with identifying information will be kept in one password protected electronic file. Participants will provide ESTEEM with contact information (email, phone numbers, and mailing address) for compensation purposes. This information will be treated in the same confidential manner as all participant information, as described here.

2. What participant information will you be collecting? Describe the identifiers that will be included or associated with the data and/or specimens (e.g., names, addresses, telephone/fax numbers, email addresses, dates (date of birth, admission/discharge dates, etc.), medical record numbers, social security numbers, health plan beneficiary numbers, etc.)
Basic demographic questions, such as age, race, gender identity, sexual orientation, and city of residence will be collected. Participants will also provide contact information (name, email, phone numbers) for scheduling and compensation purposes, but this information will be stored in a separate database from any demographics information we collect. In addition, videotapes of the interviews will be collected. This information will be treated in the same confidential manner as all participant information.

Other potentially identifying information to be collected:
☒Audiotapes
☒Videotapes
☐Faces (focus groups, photographs or other way that an individual would be physically recognized)
☐Potential for identification from the bulk of the information, even if direct identifiers are not collected (deductive disclosure).

3. How will the research data be collected and recorded?
Phase 1: All interviews will be audio recorded and reviewed for protocol adherence and quality of protocol delivery.
Phase 2: All interviews will be audio recorded with an audio recorder capable of capturing conversations by phone.
Phase 3: Research data will be collected via telephone, on electronic tablets, electronic databases, survey websites, paper-and-pencil, electronic documents, and video recording. Screening data will be collected in the field using online tablets as well as collected on a secure survey website (Qualtrics.com). During the first appointment scheduling phone call, we will verify contact information in one of our password protected electronic databases at our research office. Participants will complete surveys at our study sites/offices via yale.qualtrics.com. Participants themselves will enter most data into Qualtrics.com directly. However, study staff will enter interviewer-based data (timeline follow-back of past 90 day alcohol abuse) into Qualtrics.com and one of our electronic databases during the interview. Timeline follow-back sessions will be videotaped for quality control (showing only the interviewer's face) and will be downloaded to Yale's HIPAA-compliant Secure Box drive upon retrieval from study cameras. Participant session notes will be stored in a binder unique to each participant; these binders will be stored in a locked filing cabinet. Participant and therapist post-session surveys will be entered directly into Qualtrics.com on electronic tablets. Participant tracking and scheduling data will be

recorded on a study database. One password-protected linking database containing participant names and ID codes will be kept on Secure Box and accessible only by study staff.

All study computers will be encrypted and password protected. All filing cabinets will be locked. Online surveys (yale.qualtrics.com) will use an encrypted web service (https) and will not ask participants' name or other identifying information, only participant ID number. The linking database will be kept separate from study data and will be password protected.

4. If identifiers will be associated with the data and/or specimens, describe whether a record or list containing a code (i.e., code number, pseudonyms) will be used, where the list will be stored, who will have access to the list and when it will be destroyed.
Immediately upon providing consent, all participants will be assigned an identification number, which will only be kept on an electronic database that will be password protected and located on a designated ESTEEM computer. This information will not be stored with any other data and no other identifying information will appear on any form. All contact with participants will be made by counselors and research staff under explicit guidelines to preserve confidentiality when telephoning, emailing, or mailing information to participants. All materials with identifying information will be kept in one password protected electronic file. Participants will provide ESTEEM with contact information (email, phone numbers, and mailing address) for compensation purposes. This information will be treated in the same confidential manner as all participant information, as described here.

5. Describe where, how and for how long the data (hardcopy (paper) and/or electronic data) and/or specimens will be stored.
All data (video recordings or electronic data) will be stored on a secured server and will be password protected. The database with contact information will be deleted 3 years after completion of the study, unless they have expressed interest in being informed of possible future studies. All other data provided for this study, including any video recordings that may be used for training or educational purposes, will be maintained securely for a minimum of three years.

All portable devices must contain encryption software, per University Policy 5100. If there is a technical reason a device cannot be encrypted please submit an exception request to the Information Security, Policy and Compliance Office by clicking on url http://its.yale.edu/egrc or email it.compliance@yale.edu

6. Identify who will have access to the data and/or specimens. *If the data and/or specimens will be transferred to and/or from outside collaborators, identify the collaborator to whom the data and/or specimens will be transferred and how the data and/or specimens will be transferred.*

Role: Principal Investigator	Dr. John Pachankis	Yale School of Public Health	Jep69
Role: Co-Investigator	Dr. Katie Wang	Yale School of Public Health	Pw255
Role: Project Coordinator	Erin McConocha	Yale School of Public Health	Em795
Role: Senior Research Assistant	Kriti Behari	Yale School of Public Health	kb936

Role: Protocol Deliverer	Jillian Scheer	Yale School of Public Health	jrs265
Role: Protocol deliverer	Alex Belser	Yale School of Public Health	Ab2922
Role: Research Assistant	Dr. Charles Burton	Yale School of Public Health	Clb79
Role: Protocol deliverer	Tenille Taggart	Yale School of Public Health	TT443
Role: Research Assistant	Meghan Michalski	Yale School of Public Health	MM3536
Role: Research Assistant	Cal Brisbin	Yale School of Public Health	CB2254
Role: Research Assistant	Colin Kimberlin	Yale School of Public Health	CK624
Role: Research Assistant	Arjan Van Der Star	Yale School of Public Health	AV564
Role: Protocol deliverer	Nitzan Cohen	Yale School of Public Health	Nc545
Role: Protocol deliverer	Zach Rawlings	Yale School of Public Health	Zr63
Role: Research Assistant	Benjamin Fetzner	Yale School of Public Health	bf347

There will be no outside collaborators for this study.

7. What will be done with the data when the research is completed? Are there plans to destroy the identifiable data or the link to personal identifiers? If yes, describe how, by whom and when identifiers will be destroyed. If no, describe how the data and/or identifiers will be secured.
After study completion, data will be stored on an encrypted, password-protected server at the Yale School of Public Health. The identifiable data will remain separate from the remainder of participant data. After five years of study completion, the link to personal identifiers will be destroyed.

8. Will a Certificate of Confidentiality be needed? (*See also the NIH Certificate of Confidentiality Kiosk, http://grants.nih.gov/grants/policy/coc/index.htm)* Yes, we will notify the HSC once the CoC has been issued.

SECTION VII: POTENTIAL RISKS AND BENEFITS

1. **Risks:** Describe the reasonably foreseeable risks, including risks to participant privacy, discomforts, or inconveniences associated with participants participating in the research. *Note: All studies have the potential for risk, if not physical, there may be psychological, reputational, or financial risks or risks to breach of confidentiality.*

The study participants are at minimal risk for harm as a result of participation in the proposed research study. Although unlikely, one risk of the proposed study is that participants will experience emotional discomfort as a result of completing the survey or interview questions. These questions might cause the participant temporary embarrassment, worry, anxiety, or depressed mood. Breach of participants' confidentiality presents another possible risk. Such a breach could cause damage to one's

reputation and associated mental distress. The investigative team's strategies to protect against both risks are described below.

2. **Minimizing Risks:** Describe the manner in which the above-mentioned risks will be minimized.
Protection Against Risk:
Protection Against Emotional Discomfort: It is possible that participants may experience emotional discomfort in responding to the self-report measures. While every possible step will be taken to minimize such risk, consent documentation will make it clear that, if participants have any concerns about any aspect of the study, they may refuse to continue with the study at any time without penalty. In addition, we will remind participants during the course of their assessments that they can refuse to answer any questions and may discontinue participation at any time. Clinical staff members at the Esteem Research Program are thoroughly trained in appropriate responses to participant distress through regular trainings by this study's Yale University PI, John Pachankis, Ph.D., a licensed clinical psychologist. This training addresses the appropriate handling of imminent threats and provision of referrals to free counseling services in less imminent clinical situations. A designated staff member with an advanced degree in a mental health profession is always on site to enact the Clinical Protocol. The Clinical Protocol clearly outlines procedures for assessing participant emotional distress and referring participants to appropriate care resources.

Protection Against Breach of Confidentiality: The primary potential risk to participants is breach of confidentiality. Breaches of confidentiality will occur if a participant reports a clear intention to harm himself or another person. Additionally, health care professionals are required by state law to report suspected cases of abuse or neglect. The likelihood that any additional breaches of confidentiality would occur is minimal, as steps will be taken to guard against this risk. All the Esteem Research Program counselors and research assistants (RAs) have undergone rigorous training in maintaining participants' privacy and confidentiality. Further, immediately upon providing consent, all participants will be assigned an identification number, which will only be kept on an electronic database that will be password protected and located on a designated the Esteem Research Program computer. This information will not be stored with any other data and no other identifying information will appear on any form. All contact with participants will be made by counselors and research staff under explicit guidelines to preserve confidentiality when telephoning, emailing, or mailing information to participants. All materials with identifying information will be kept in one password protected electronic file. Participants will provide the Esteem Research Program with alternative contact information (email, phone numbers, and mailing address) for compensation and study retention purposes. This information will be treated in the same confidential manner as all participant information, as described here.

3. **Data and Safety Monitoring Plan:** Include an appropriate Data and Safety Monitoring Plan (DSMP) based on the investigator's risk assessment stated below. (Note: the HSC will make the final determination of the risk to subjects.).
   a. What is your assessment of the overall risk level for subjects participating in this study?
   This study proposes to ask participants a series of questions assessing their life experiences as gay, bisexual, or other women who have sex with women. Empirical data suggest that answering questions regarding sex and mental health is associated with minimal risk.[1]
   [1]Yeater, E., Miller, G., Rinehart, J., & Nason, E. (2012). Trauma and sex surveys meet minimal risk standards: implications for institutional review boards. Psychol Sci, 23(7), 780-787. doi:10.1177/0956797611435131

b. If children are involved, what is your assessment of the overall risk level for the children participating in this study? N/A

c. **Include an appropriate Data and Safety Monitoring Plan. Examples of DSMPs are available here http://your.yale.edu/policies-procedures/other/data-and-safety-monitoring-plan-template** for

i. Minimal risk
ii. Greater than minimal/moderate risk

We consider our study as minimal risk. The principal investigator and the research assistants are responsible for monitoring the data, assuring protocol compliance, and conducting the safety reviews daily. During the review process, the principal investigator will evaluate whether the study should continue unchanged, require modification/amendment, or be closed to enrollment.
The principal investigator, the Institutional Review Board (IRB), and Yale School of Public Health (YSPH) have the authority to stop or suspend the study or require modifications.
This protocol presents minimal risks to the subjects and Unanticipated Problems Involving Risks to Subjects or Others (UPIRSOs), including adverse events, are not anticipated. In the unlikely event that such events occur, Reportable Events (which are events that are serious or life-threatening and unanticipated (or anticipated but occurring with a greater frequency than expected) and possibly, probably, or definitely related) or Unanticipated Problems Involving Risks to Subjects or Others that may require a temporary or permanent interruption of study activities will be reported immediately (if possible), followed by a written report within 5 calendar days of the Principal Investigator becoming aware of the event to the IRB (using the appropriate forms from the website) and any appropriate funding and regulatory agencies. The investigator will apprise fellow investigators and study personnel of all UPIRSOs and adverse events that occur during the conduct of this research project through regular study meetings or via email as they are reviewed by the principal investigator. The protocol's research monitor(s), the PI's faculty supervisor, YSPH will be informed of any adverse events such as unanticipated reaction from the participants (e.g. suicidal ideation) within 5 days of the event becoming known to the principal investigator.

d. For multi-site studies for which the Yale PI serves as the lead investigator:

i. How will adverse events and unanticipated problems involving risks to subjects or others be reported, reviewed and managed? N/A
ii. What provisions are in place for management of interim results? N/A
iii. What will the multi-site process be for protocol modifications? N/A

4. **Potential Benefits:** Identify any benefits that may be reasonably expected to result from the research, either to the participant(s) or to society at large. (*Payment of participants is not considered a benefit in this context of the risk benefit assessment.)*
Benefits to participants: All participants in the present study will be exposed to information about how minority stress can contribute to depression, alcohol abuse, and other stressors. Also, this study will potentially contribute to the development of an evidence-based psychosocial intervention targeted specifically to sexual minority women.

Benefits to society: The mental and behavioral health disparities experienced by sexual minority women constitute a clear public health concern. Benefits to society in general are anticipated through the

dissemination of intervention findings. Results will better inform local and national public health agencies about potentially effective outreach and prevention strategies that can be delivered to gay, bisexual, and other women who have sex with women who also experience mental health problems, such as depression, suicidality, and alcohol abuse.

SECTION VIII: RESEARCH ALTERNATIVES AND ECONOMIC CONSIDERATIONS

1. **Alternatives:** What other alternatives, if any, are available to the study participants outside of the research?
N/A

2. **Payments for Participation (Economic Considerations):** Describe payments that will be made to participants, if any, the amount and timing of payments, and the conditions for receiving this compensation (if applicable). If you plan to hold a drawing, be sure to include the following on any consent or recruitment materials mentioning the lottery: 1) the value of the prize; 2) the sponsor of the prize (this cannot be a federal funding source); 3) the odds of winning; and 4) that there are no restrictions to winning.
Phase 1: Participants will be paid $50 for completing a Phase 1 interview. Participants who come in to the Esteem Research Lab but who are deemed ineligible to begin an interview will be compensated $10 to cover their travel expenses.
Phase 2: Participants will be paid $100 for providing their feedback and completing an interview with an ESTEEM lab clinical team member.
Phase 3: Participants will be paid at each study visit: $25 at baseline, $25 at 3 month follow-up, $75 at 6 month follow-up, and $10 for each therapy session. Additionally, as part of retention efforts, upon randomization, we will be providing all participants with an "EQuIP Swag Bag" that includes candy, safer sex supplies, and study-branded pens and stress balls in a tote bag. Participants who complete a follow-up qualitative interview about their experience in the study will receive a $40 Amazon gift card.

3. **Costs for Participation (Economic Considerations):** Clearly describe the participant's costs associated with participation in the research, if any, and the interventions or procedures of the study that will be provided at no cost to participants.
Study participation will generate no cost for participants. The study treatment will be provided free of charge to all study participants.