NCT03751020

Title of Research Project: Development and preliminary trial of a brief, portable health intervention for rural sexual minority emerging adults

Protocol Date 4.2.2019

YALE UNIVERSITY IRBs
Application for Full or Expedited IRB Review of a Study Involving Human Participants in Social or Behavioral Science or Educational Research

100 FR 28 (2015-1)

NOTE: IF YOUR STUDY INVOLVES:

Genetic Testing
Blood Draws → ***Do not use this form. Use the biomedical HIC application***
MRI scans

Secondary analysis of data → ***Use the Request for Approval of Secondary Analysis of Data***

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).***

SECTION I: ADMINISTRATIVE INFORMATION

Title of Research Project: Development and preliminary trial of a brief, portable health intervention for rural sexual minority emerging adults			
Principal Investigator: John Pachankis, PhD		Yale Academic Appointment: Associate Professor of Public Health	
Department: Chronic Disease Epidemiology, Social & Behavioral Sciences			
Campus Address: 60 College Street (LEPH), Rm 316			
Campus Phone: 203-785-3710			**E-mail:** john.pachankis@yale.edu
Protocol Correspondent Name & Address (*if different than PI*):			
Campus Phone:		**E-mail:**	

Faculty Advisor: (required if PI is a student, resident, fellow or other trainee) ☐ **NA**		**Yale Academic Appointment:**	
Campus Address:			
Campus Phone:			**E-mail:**

Investigator Interests:

Does the principal investigator, or do any research personnel who are responsible for the design, conduct or reporting of this project or any of their family members (spouse or dependent child) have an incentive or interest, financial or otherwise, that may affect the protection of the human participants involved in this project, the scientific objectivity of the research or its integrity? Note: The Principal Investigator (Project Director), upon consideration of the individual's role and degree of independence in carrying out the work, will determine who is responsible for the design, conduct, or reporting of the research.

See Disclosures and Management of Personal Interests in Human Research
http://www.yale.edu/hrpp/policies/index.html#COI

❑ Yes ❑ **No** X

Do you or does anyone on the research team who is determined by you to be responsible for the design, conduct or reporting of this research have any patent (sole right to make, use or sell an invention) or copyright (exclusive rights to an original work) interests related to this research protocol?

❑ Yes ❑ **No X**

If yes to either question above, list names of the investigator or responsible person:

The Yale University Principal Investigator, all Yale University co-investigators, and all Yale University individuals who are responsible for the design, conduct or reporting of research must have a current financial disclosure form on file with the University's Conflict of Interest Office. Yale New Haven Hospital personnel who are listed as co-investigators on a protocol with a Yale University Principal Investigator must also have a current financial disclosure form on file with the University's Conflict of Interest Office. If this has not been done, the individual(s) should follow this link to the COI Office Website to complete the form: http://www.yale.edu/coi/

NOTE: The requirement for maintaining a current disclosure form on file with the University's Conflict of Interest Office extends primarily to Yale University and Yale-New Haven Hospital personnel. **Whether or not they are required to maintain a disclosure form with the University's Conflict of Interest Office, all investigators and individuals deemed otherwise responsible by the PI who are listed on the protocol are required to disclose to the PI any interests that are specific to this protocol.**

SECTION II: GENERAL INFORMATION

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

   36 months: Expected start date: 04/01/2016; Expected End Date: 06/31/2019.

2. **Study location:** State where the study will take place and in what setting.
If international, complete and submit International checklist (http://www.yale.edu/hrpp/forms-templates/behavioral.html) 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.

This first part of this study consists of focus groups and interviews that will be conducted in-person and by telephone and an intervention that will be conducted online with participants recruited from South and Central Appalachia (Southern West Virginia, Eastern Kentucky, Western Virginia, Eastern Tennessee). In-person focus groups will be conducted at East Tennessee State University in Dr. Williams' research office in the Department of Psychology.

During the second part of this study, we will test a writing intervention online. Data analysis will occur at Yale University in New Haven, CT (PI John Pachankis), College of the Holy Cross in Worcester, MA (PI Stephanie Chaudoir), and East Tennessee State University in Johnson City, TN (Subaward PI Stacey Williams).

3. **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 III: FUNDING, RESEARCH TEAM AND TRAINING

Funding Source: Indicate all of the funding source(s) for this study. Check all boxes that apply. Provide information regarding the external funding source. This information should include identification of the PI ***on the award***, agency/sponsor, the funding mechanism (grant or contract), and whether the award is pending or has been awarded. Provide the Yale institutional proposal number and Agency name (if grant-funded). If the funding source associated with a protocol is "pending" at the time of the protocol submission to the IRB (as is the case for most NIH submissions), the PI should note "Pending" in the appropriate section of the protocol application, provide the Yale institutional proposal number and Agency name (if grant-funded) and further note that University (departmental) funds support the research (until such time that an award is made).

PI of grant (if applicable)	Title of Grant (if applicable)	Name of Funding Source (i.e. Dept name or Fellowship)	Funding type	Funding Mechanism
John Pachankis, PhD	Development and preliminary trial of a brief, portable health intervention for rural sexual minority emerging adults	NIH / NICHD Exploratory/Developmental Research Grant Program: R21 MH113860-01A1 (pending)	☐Yale fellowship ☐Yale department ☐No funding (student projects, etc.) ☒ **Federal** ☐ State ☐ Non Profit ☐ Industry ☐ Other For Profit ☐ Other	☒Grant: NICHD R21 MH113860-01A1 (pending) ☐Contract# ☐Contract Pending ☐ Investigator/Department Initiated ☐ Sponsor Initiated ☐ Other, Specify:

Note – IRB fees are charged for projects funded by Industry or Other For-Profit Sponsors. Provide the name and Address of the Sponsor Representatives to whom the invoice should be sent. *The PI's home department will be billed if this information is not provided.* N/A

1. **Research Team:** List all members of the research team. Indicate under the affiliation column whether the investigators or study personnel are part of the Yale faculty or staff, or part of the faculty or staff from a collaborating institution, or are not formally affiliated with any institution. **ALL members of the research team MUST complete Human Subject Protection Training (HSPT) and Health Insurance Portability and Accountability Act (HIPAA) training (if applicable) before they may be listed on the protocol. See NOTE below.**

	Name	Affiliation: Yale/Other Institution (Identify)	Net ID
Principal Investigator	John Pachankis, PhD	Yale School of Public Health	Jep69
Role: Co-PI	Stephanie Chaudoir, PhD	College of the Holy Cross	
Role: Co-PI	Stacey Williams, PhD	East Tennessee State University	
Role: Project Assistant	Katie Wang, PhD	Yale School of Public Health	Pw255
Role: Project Assistant	Roxanne Winston, MPH	Yale School of Public Health	Rw527
Role: Project assistant	Sarah Job	ETSU	
Role: Project assistant	Abbey Mann, PhD	ETSU	
Role: Project assistant	TJ Sullivan	Yale School of Public Health	Tjs66
Role: Project assistant	Erin McConocha	Yale School of Public Health	
Role: Project assistant	Nicholas Fasanello	ETSU	
Role: Project assistant	Samantha Stone	ETSU	
Role: Project assistant	Emily Clark	ETSU	
Role: Project assistant	Cal Brisbin	Yale School of Public Health	
Role: Project Assistant	Charles Burton, PhD	Yale School of Public Health	
Role: Project Assistant	Ingrid Solano, MA		Ias26
Role: Project Assistant	Tenille Taggard, MA		TT443
Role: Project Assistant	Craig Rodriguez-Seijas, MA		Cr672
Role: Project Assistant	Colin Kimberlin		Ck624
Role: Project Assistant	Ann Mondi		
Role: Project Assistant	Sarah Barr		
Role: Project Assistant	Michael Andre		

NOTE: The HSC will remove from the protocol any personnel who have not completed required training. A request to change study personnel will need to be submitted when training is completed.

SECTION IV: RESEARCH PLAN

1. **Statement of Purpose:** State the scientific aim(s) of the study, or the hypotheses to be tested.

   Aim 1 (Conduct elicitation research, phase 1):
   We will conduct focus groups and structured interviews with 20 rural lesbian, gay, and bisexual (LGB) emerging adults and LGB community leaders in order to create appealing, culturally resonant intervention materials for rural Appalachian LGB emerging adults (aged 18-29 years).

   Aim 2: (Use elicitation research findings to adapt interventions, phase 2):
   We will interview 10 LGB emerging adults and LGB community leaders to further refine Expressive Writing (EW), Self-Affirmation (SA), and Control (C) online writing interventions for use among LGB emerging adults in rural Appalachia.

   Aim 3: (Intervention feasibility, acceptability, and preliminary efficacy testing, phase 3):
   We will examine the feasibility, appeal, and preliminary efficacy of EW and SA interventions relative to control. The primary outcomes of interest will include depressive symptoms, suicidality, substance use, and HIV sexual risk behaviors at the 3-month post-intervention assessment.

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.

   Lesbian, gay, and bisexual (LGB) emerging adults (ages 18-29) report significantly greater depression, suicidality, substance use, and HIV risk behaviors than heterosexuals (1,2). These disparities are magnified among LGB emerging adults who live in rural or nonurban areas in the US (3). Indeed, rural LGB emerging adults are more likely to binge drink, use illegal drugs, and report depression than their urban LGB peers (4,5). These disparities are particularly severe in Appalachia, a cultural context characterized by negative attitudes and interpersonal discrimination towards LGBs (6,7), mental and physical health outcomes among the poorest in the nation (8), and limited access to mental and physical health providers (9).

   This proposal is designed to adapt and test the feasibility and efficacy of online Expressive Writing (EW) and Self-Affirmation (SA) writing interventions that offer two low-cost, portable vehicles capable of mitigating mental health and behavioral risk disparities among Appalachian LGB emerging adults.

   1. Expressive Writing (EW) interventions prompt individuals to write about personally stressful events, enabling cognitive-affective stress processing. Our own pilot work and other recent

studies demonstrate that EW reduces depression (10) and alcohol and illicit drug use (11, 12) and can, in combination with other techniques, reduce HIV sexual risk (13) among urban LGB emerging adults.

2. Self-Affirmation (SA) writing interventions prompt individuals to write advice to a (hypothetical) and similarly stigmatized person regarding how best to cope with stigma-related stress. By affirming one's own stigmatized identity through the process of helping another similarly stigmatized person (14, 15), SA has been shown to reduce alcohol use (11) and stress hormones (e.g., cortisol) (16,17) closely associated with depression among emerging adults.

In this exploratory research project, we propose to adapt and test the comparative efficacy of these brief, low-cost, and portable interventions to improve mental health and health risk behaviors among Appalachian LGB emerging adults, one of the most vulnerable populations in the U.S. Moreover, we apply Minority Stress Theory (18) to identify and test two plausible mechanisms through which EW and SA might mitigate mental and behavioral health disparities faced by LGB individuals.

We propose that sexual minority stressors increase *psychobiological stress* and deplete emotional and behavioral *self-regulation*, thereby contributing to LGB disparities. Previous research has speculated (but not tested) that EW and SA interventions are effective because they reduce *psychobiological stress* and improve emotional and behavioral *self-regulation*, respectively. Therefore, in a novel test of these hypotheses, our pilot study will directly examine psychobiological stress and self-regulation as the putative mechanisms by which EW and SA interventions are efficacious and by which LGB disparities are generated.

To accomplish these research goals, this project will pursue the following aims:

Specific Aim 1: Conduct elicitation research with 20 Appalachian LGB emerging adults and LGB community leaders in order to develop effective intervention materials and stress targets. Participants will be asked to describe the type and frequency of sexual minority stressors faced by LGB emerging adults in their region (to create EW prompts and SA vignettes) and strategies to enhance the LGB-affirmative look-and-feel of the Phase 3 online platform.

Specific Aim 2: Present Specific Aim 1 results to 10 Appalachian LGB emerging adults and LGB community leaders to refine the EW prompts and SA vignettes and the LGB-affirmative, culturally relevant look-and-feel of the online platform. Identify, with these leaders, the most effective venues and materials for participant recruitment and retention, and identify the most effective modalities for future intervention dissemination.

Specific Aim 3: Pilot test feasibility and efficacy of writing interventions. 108 Appalachian LGB emerging adults will be randomized to complete one of three writing interventions (EW, SA, Control). They will be asked to complete outcome measures (depressive symptoms, suicidality, use of alcohol and illicit drugs, HIV risk behavior) and measures of proposed mediators (self-reported and biological stress, behavioral and emotional self-regulation) and moderators (e.g., social support,

identity centrality) at baseline, post-intervention, and three-month follow-up. In addition, structured interviews with 15 intervention participants will be used to refine study procedures as we scale up this intervention for a future RCT. Primary analyses will determine efficacy; secondary analyses will determine the moderating role of social support, gender, and other psychosocial factors (e.g., baseline risk) and estimate the effect sizes of the mediators of intervention efficacy for use in a subsequent RCT to determine the long-term efficacy and mechanisms of these interventions.

Despite evidence indicating that mental and physical health disparities are most severe among LGB emerging adults living in rural areas of the U.S., there are currently no evidence-based psychological interventions designed to mitigate sexual minority stress effects among this population (19). The proposed culturally-relevant, theory-based interventions are poised to reduce this gap and, therefore, address one of the most pressing public health goals of the U.S. Department of Health and Human Services (20, 21).

References

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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.

We will conduct focus groups with 20 Appalachian LGB emerging adults and LGB community leaders to create culturally relevant intervention materials that can be feasibly implemented in rural contexts. We will utilize elicitation research findings from Aim 1 to adapt Expressive Writing (EW), Self-Affirmation (SA, and Control (C) online writing interventions for use among rural LGB emerging adults in rural Appalachia. Interviews with 10 Appalachian LGB emerging adults and LGB community stakeholders will additionally inform the intervention content as well as recruitment strategies. Finally, we will examine the efficacy of EW and SA relative to C. The primary outcomes of interest will include depressive symptoms, suicidality, substance use, and HIV risk behaviors at 3-month post-intervention.

PHASE/AIM 1:

For phase 1, we will recruit 20 rural LGB emerging adults (aged 18-29) and LGB community leaders who (i) self-identify as LGB, and (ii) currently live in South or Central Appalachia. We will recruit participants for a focus group of up to five participants through postings and ads on geo-targeted websites (e.g., Craigslist, Facebook), bulletin boards and listservs at regional colleges and universities (e.g., gay-straight alliance [GSA] listserv); and in-person announcement and flyers at local community centers, bars, and the GSA of area schools. After emailing/calling our research team, potential participants will speak with a trained research assistant (RA) who will explain the study purpose and procedures, verify eligibility, and assess consent. Age eligibility will be verified by photo ID, requiring each participant to email a snapshot of themselves holding their photo ID (note: age criterion applies only to the emerging adults, not to the LGB community leaders). Participants will use their phone to

email a photo of their IDs and these emails will be securely on Yale Secure box after received and then the record of the photo will be deleted from research staff emails after the photo is verified and stored. In our experience, an LGB sexual orientation identity is difficult to fake, especially in interviews such as ours that assess LGB cultural knowledge and contexts specific to LGB individuals.

We will aim to conduct four focus groups of five participants each (20 total participants). Two of the focus groups will be comprised of LGB emerging adults and two of the focus groups will be comprised of the LGB community leaders (LGB community leaders have already indicated their support for this Phase with letters of support on file for NIH funding application). These community leaders live in the targeted geographic region and are affiliated with an online- or community-based organization that provides support services to Appalachian LGB emerging adults. Community leaders were recruited to advise this study through in-person invitations to local LGB advocates and health providers in Dr. William's professional network (e.g., ETSU GSA, Northeast State GSA, PFLAG Tri-Cities, Tennessee Equality Project).

If Phase 1 eligible participants are not available to come in for an in-person focus group, they will have the option to do a phone interview for Phase 1 or, alternatively, will be invited to participate in Phase 2 or Phase 3.

Drs. Williams, Chaudoir, and Pachankis will conduct the focus groups, with the aid of research assistants. Participants will be presented with information about the preliminary goals of the intervention and will be asked to describe the type and frequency of sexual minority stressors faced by LGB emerging adults in their region (to create EW prompts and SA vignettes) and strategies to enhance the LGB-affirmative look-and-feel of the Phase 3 online writing session. Phase 1 participants will not be eligible for Phase 3, however five of the 10 LGB community leaders will be invited back to participate in Phase 2.

All focus groups will be audiotaped and transcribed by a trained research assistant or professional transcription company. Drs. Williams, Chaudoir, and Pachankis will use thematic coding to analyze data and identify overarching assertions for modifying the SA intervention using qualitative data analysis software (e.g., NVivo, Atlas.ti). Data will be indexed and coded using open and axial coding. Axial coding will address research questions guiding our interview, while open coding will identify themes emerging from participants' perspectives. The investigative team will review Phase 1 codes to create EW prompts and SA intervention vignettes, and ensure LGB-affirmative look-and-feel of the online intervention materials and platform.

PHASE/AIM 2:
We will conduct 10 in-person interviews with LGB emerging adults and LGB community leaders to further refine Expressive Writing (EW), Self-Affirmation (SA), and Control (C) online writing interventions for use among rural LGB emerging adults in rural Appalachia.

After incorporating Phase 1 feedback, the intervention materials will be presented to five LGB emerging adults (not repeat participants from Phase 1) and five LGB community

leaders (repeat participants from Phase 2) (LGB community leaders have already indicated their support for this Phase with letters of support on file for NIH funding application), in order to further gather, through interviews with Drs. Williams, Chaudoir, and Pachankis, adaptations that appeal to the community for whom this intervention will ultimately be disseminated. These community members and leaders will also describe the acceptability of the intervention dosage and the most effective modalities for future intervention dissemination (see Appendix). These community leaders meet the eligibility criteria and are affiliated with an online- or community-based organization that provides support services to Appalachian LGB emerging adults. Community leaders were recruited to advise this study through in-person invitations to local LGB advocates and health providers in Dr. William's professional network (e.g., ETSU GSA, Northeast State GSA, PFLAG Tri-Cities, Tennessee Equality Project). Phase 2 enrollment and interview materials will follow those described for Phase 1 (see Appendix).

PHASE/AIM 3:

We will recruit 108 Appalachian LGB emerging adults (36 per group) who (i) are aged 18-29, (ii) self-identify as a sexual minority (e.g., lesbian, gay, bisexual, pansexual, queer), (iii) currently live in Eastern Tennessee counties of Washington, Sullivan, Carter, Unicoi, Greene, or Hawkins County, and (iv) have daily personal internet access. Participants will be recruited, screened, and consented for an online writing intervention using Phase 1 strategies. Recruited individuals will be directed to complete a brief online screener gauging eligibility where they will consent to share their information with the research team. Those who consent to the online screener and meet the study eligibility criteria will then receive a call from a research team member who will share additional information about the study and gain consent for study participation. During the consent call, study staff will confirm participant age, contact information (such as phone number and address), and give participants the option to provide a secondary contact. After providing consent, participants will be emailed a link to complete an online baseline assessment (Study Task 1), then randomized to one of the three online writing interventions to be completed daily for three days starting the Monday of the following week (Study Task 2-Study Task 4). Participants will have up to two weeks to complete the three days of writing prompts. If the participant has not begun their first writing day (Study Task 2) within 24 hours of receiving the prompt than they will receive one email reminder per day for three days encouraging them to complete their writing prompt. If they still have not completed their writing prompt by the fifth day, then a research team member will try calling or texting the participant to remind them to complete the task. Upon completion of the first writing day (Study Task 2), the participant will have 24hrs to complete the second writing day (Study Task 3). If the participant does not complete the second writing day (Study Task 3) within 24 hours, then study staff will use the same email, text, and call reminder system as with writing day one (Study Task 2) to encourage them to complete writing day two (Study Task 3). The same communication and reminder protocol will be followed to encourage the participant to complete the third writing day (Study Task 4). Cumulatively, participants will have 14 days to complete the three writing prompts, but participants will not be invited to move on to the second writing prompt without first completing the prompt from writing day one, nor will they be prompted to complete the third writing task without submitting the second writing task. Seven days after completing their final writing task, or seven days after the close of the

two week writing window participants will be emailed a link to complete the post-intervention survey (Study Task 5). 30 days after completion of the first survey, and 30 days after completing the 3-month online follow-up assessment survey, participants will be mailed materials to collect a hair sample in order to assay for cortisol. At 3 months after completion of the post-intervention survey, participants will receive and complete a follow-up assessment via online survey. Lastly, we will randomly select 15 participants from Phase 3 for a follow up one-hour phone or internet-based interview where we will ask about participant experience with the writing sessions.

Expressive Writing (EW) Intervention:
In the Expressive Writing (EW) intervention, participants will be instructed to continually write for 20 minutes in a free-form manner about the most stressful or traumatic LGBT+ related event that they have encountered across three, ideally, consecutive days. The EW writing prompt will ask the participant to expressively write about their most personally stressful minority stress event. As part of the prompt, common examples facing Appalachian LGBT+ emerging adults will be provided based on Phase 1 and Phase 2 feedback.

Self-Affirmation (SA) Intervention:
The Self-Affirmation (SA) intervention will ask participants to read a brief description, over the course of 3 writing days, of a (hypothetical) LGBT+ youth who is facing stigma-related stress. Each day's description will contain a different LGBT+ youth facing a different stigma-related stressor derived from Phase 1 and Phase 2 interviews. Drawing on their personal experiences, participants will then be asked to write a letter for 20 minutes to advise the LGBT+ youth how best to cope with stigma-related stress. The youth description and his or her stigma-related stress experiences will be developed using Phase 1 and Phase 2 input. The gender, race/ethnicity, and sexual orientation of the described LGBT+ emerging adult will match that of the participant.

Control (C) Intervention:
Participants randomly assigned to the control condition will be asked to write about what they have done since waking up that morning for 20 minutes across 3 Writing Days. This mundane control matches the time and activity of the EW and SA arms.

The online program that captures participants' writing will ensure that each participant writes for 20 minutes by not allowing the participant to advance until 20 minutes have passed. After each writing session, participants will be provided with the contact information of a local mental health resource center and a research assistant will review each submission within 24 hours to ensure each participant's safety. If participant expresses intentions of self-harm or harm towards others the research assistant will contact 911 in the Eastern Tennessee region. PI Pachankis, a licensed clinical psychologist, will also contact participants who indicate threat to self or others or severe emotional distress.

Drs. Williams and Pachankis will train a graduate research assistants at ETSU to administer the consent process, tracking database, and online intervention systems. Phase 3 assessments

and interventions will be delivered via Qualtrics.com, for which Yale University has an ongoing subscription. Research assistants will be trained to check the account once per day to ensure the safety of participants by reviewing their writing and to send reminder emails, text messages, and calls to participants who skipped a day. Drs. Williams and Pachankis will perform biweekly review of all systems to verify RA protocol adherence.

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

   Participants in this study will be Appalachian sexual minority (LGBTQ+) emerging adults who (i) are aged 18-29, (ii) self-identify as LGBTQ+, and (iii) currently live in Eastern Tennessee counties of Washington, Sullivan, Carter, Unicoi, Greene, or Hawkins County. (Note: there is no age-restriction for the pre-identified community leaders/stakeholders in Phase 1 and Phase 2.)

   Phase 1 and Phase 2 LGBTQ+ community leaders will meet the above criteria (with the exception of age) and are also affiliated with an online- or community-based organization that provides support services to Appalachian LGBTQ+ emerging adults. Community leaders were recruited to advise this study through in-person invitations to local LGBTQ+ advocates and health providers in Dr. William's professional network (e.g., ETSU GSA, Northeast State GSA, PFLAG Tri-Cities, Tennessee Equality Project). LGBTQ+ community leaders have already indicated their support for this project and we have their letters of support on file for the NIH funding application.

   For Phase/Aim 3, participants must also have access to a minimum of 20 minutes per day of uninterrupted personal internet access.

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

   We will recruit participants for a focus group or individual interviews through postings and ads on geo-targeted websites (e.g., Craigslist, Facebook, Reddit), bulletin boards and listservs at regional colleges and universities (e.g., gay-straight alliance [GSA] listserv); and in-person announcement and flyers at local community centers, bars, and the GSA of area schools. After completing the online screener, potential participants will be contacted by a trained research assistant (RA) who will explain the study purpose and procedures, verify eligibility, and assess consent. Age eligibility will be verified by photo ID, requiring each participant to email a snapshot of themselves holding their photo ID. In our experience, an LGB sexual orientation identity is difficult to fake, especially in interviews such as ours that assess LGB cultural knowledge and contexts specific to LGB individuals.

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 ☐ Non-English Speaking ☐ Prisoners
☐ Economically disadvantaged
☐ Decisionally Impaired ☐ Employees ☐ Pregnant women
☐ Yale Students
☐ Other vulnerable population (who?):
☐ Psychology Pool

NOTE: Is this research proposal designed to enroll children who are wards of the state as potential participants? ☐ Yes ☒ No (If yes, see HRPP Policy 310.4 for further requirements)

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

Participants in this study will be Appalachian lesbian, gay, and bisexual (LGB) emerging adults who (i) are aged 18-29, (ii) self-identify as a sexual minority (LGBTQ+), and (iii) currently live in Eastern Tennessee counties of Washington, Sullivan, Carter, Unicoi, Greene, or Hawkins County. For Phase/Aim 3, participants must also (iv) and have access to a minimum of 20 minutes per day of personal internet access. (Note: there is no age-restriction for the pre-identified community leaders/stakeholders in Phase 1 and Phase 2.)

Phase 1 and Phase 2 LGB community leaders have already indicated their support for this project and we have their letters of support on file for the NIH funding application.

SECTION V: RECRUITMENT/CONSENT AND ASSENT PROCEDURES

1. Recruitment Procedures:

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

We will recruit participants through postings and ads on geo-targeted websites (e.g., Craigslist, Facebook, Reddit), bulletin boards, and listservs at local colleges and universities (e.g., gay-straight alliance [GSA] listserv); mobile social networking apps (e.g., Grindr, Growlr, Instagram); and in-person announcement and flyers at local community centers, bars, community events, and through the GSAs of local area schools. Also, Dr. Williams, at ETSU, maintains a "research repository" for people who sign up at community events to participate in future research studies. We will email the eligible LGBTQ+ individuals on this list with our study screener to determine their interest in participating in the present study. After completing the online screener, potential participants will be contacted by a trained research assistant (RA) who will explain the study purpose and procedures, verify eligibility, and review consent materials. Age eligibility will be verified by photo ID, requiring each participant to email a snapshot of themselves holding their photo ID. In our experience, an LGB sexual orientation identity is difficult to fake, especially in interviews such as ours that assess LGB cultural knowledge and contexts specific to LGB individuals.

The Phase 1 and Phase 2 LGB community leaders have already indicated their support for this project and we have their letters of support on file for the NIH funding application.

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.)*

Interested potential participants will complete an online screener through Qualtrics with consent assessed at the start of the screener. Those determined eligible by the online screener will receive a call from study staff, who will explain to the potential participant the study purpose and procedures, verify eligibility, and assess consent. (See attached online screener text and consent form.)

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

☒ Flyers
☒ Posters
☐ Letter
☐ Newspaper
☐ Through local NGO or other local contact
☐ Classroom recruitment
☐ Table set-up / in-person recruitment of public
☒ Snowball sampling
☒ Internet/Web Postings
☒ Mass E-mail Solicitation
☐ Departmental/Center Website
☒ Social Media (Facebook, Twitter)
☐ Radio
☐ Telephone
☐ Television
☒ Other (describe): Also, Dr. Williams, at ETSU, maintains a "research repository" for people who sign up at community events to participate in future research studies. We will email the eligible LGBTQ+ individuals on this list with our study screener to determine their interest in participating in the present study.

3. **Targeted Enrollment: Give the number of participants:**
   a. Targeted for enrollment at Yale for this protocol 0/not applicable
   b. If this is a multi-site study, give the total number of participants targeted across all sites 133 online (15 +10 +108)

4. **How was this estimate derived?**

15 LGB emerging adults (10 in Phase 1 and 5 in Phase 2) and 10 community leaders (10 in Phase 1, five of whom will repeat in Phase 2) is the estimated number of participants needed to develop and refine the intervention materials before saturation is reached, as per our previous similar intervention development research (e.g., Pachankis et al., 2013; Pachankis, 2014).

Phase 3 of the project, which aims to recruit 108 participants (36 per each of three conditions: EW, SA, C), is powered primarily to examine feasibility and acceptability. This phase will allow us to determine the preliminary efficacy of the interventions. Our sample size provides sufficient power (1- β = .8) to detect intervention effects consistent with effect size estimates identified in a meta-analysis of EW interventions across general population samples in which the average effect size (*d*) was .47 across physiological, psychological, self-reported health, and health behavioral outcomes. In order to detect an effect of .47 we need 36 participants per group. This sample size will also afford sufficient power (1- β = .8) to detect moderation effects found in previous examinations of EW moderation (e.g., social support) (i.e., $d = .46$[10]), and estimate the direct path to and from the proposed mediators (stress and self-regulation), as secondary aims.

References

Pachankis, J. E. (2014). Uncovering clinical principles and techniques to address minority stress, mental health, and related health risks among gay and bisexual men. Clinical Psychology: Science and Practice, 21, 313-330.

Pachankis, J.E., Lelutiu-Weinberger, C, Golub, S. A., & Parsons, J.T. (2013). The development of an online risk-reduction intervention for young gay and bisexual men using social networking technology. AIDS and Behavior, 17, 2986-2998.

5. **Consent Personnel:** List the names of all members of the research team who will be obtaining consent/assent.

John Pachankis, PhD
Stephanie Chaudoir, PhD
Stacey Williams, PhD
Abbey Mann, PhD
Sarah Job
TJ Sullivan
Roxanne Winston
Charles Burton
Erin McConocha
Nicholas Fasanello
Samantha Stone
Emily Clark
Cal Brisbin
Ann Mondi
Sarah Barr
Michael Andre

6. **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.

Informed consent will be obtained for all participants before completing the phone screener with a trained research assistant.

For Phase 1, participants will receive a consent form. Study subjects who participate in the in-person focus groups will be given and verbally read the respective consent form and for participation, will be required to sign the consent form. For Phase 1 participants opting for a telephone interview, a research assistant will read the consent form to the participant and a verbal consent will be required to participate.

For Phase 2, participants will receive a consent form. Study subjects who participate in the in-person interview will be given and verbally read the respective consent form and for participation, will be required to sign the consent form. Although Phase 2 participants are encouraged to interview in-person, research staff may opt to do the interview via phone for participants who are unable to attend in person, in which case a study staff member will read the consent form to the participant and a verbal consent will be required to participate.

For Phase 3, interested participants will consent to share their information with study staff through the online screener to determine if they are eligible. Of those interested participants who have screened in as eligible, they will receive a call from a research staff member to confirm participant information, hear more about the study to attain verbal consent from the participant for Phase 3, which, if they agree to, will then lead to the online portal of the Phase 3 intervention. The consent form will require an electronic endorsement of consent before proceeding to the intervention.

For Phase 3 follow-up participants, 15 participants selected at random will be e-mailed to schedule a follow-up interview. Participants will be asked to provide verbal consent over the phone to participate in the interview.

7. **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

After expressing interest in study participation through the online screener, potential participants will be contacted by a trained research assistant (RA) who will explain the study purpose and procedures, verify eligibility, and assess consent. Ability to provide consent will be assessed during the phone call with a trained research team member, and participants will complete in-person, verbal, or online consent (depending on the Phase of participant) before participating in their respective phase of the study.

8. **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.

We will collect consent before: (1) collecting potential participant information via online screener (2) during the study consent and enrollment phone call, (3) focus groups and structured interviews

(Phase 1 and Phase 2), and (4) intervention participation and related outcome assessments (Phase 3). For Phase 3 follow-up interviews, consent will be obtained verbally over the phone.

See attached.

9. **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).**

   Only English-speaking participants will be enrolled in the study.

10. 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.

    Although this study is unlikely to yield information subject to mandatory reporting, Tennessee law requires any person with knowledge of child abuse to report such information to the Tennessee Department of Children's Services (by calling the Central Intake Child Abuse Hotline at 877-237-0004).

    Tennessee law does not require mandatory reporting for self-harm or suicidality (T.C.A. § 33-3-210); however, 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 (Dr. Pachankis and Dr. Burton are licensed clinical psychologists), study staff will contact 911 to dispatch police or paramedics. Only the minimal necessary identifying information will be provided to these personnel.

    Participants will be notified of the reporting requirements under these circumstances during the consent process.

11. **Consent/Consent Waiver: 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.

    ☐ **I plan to obtain signed consent**
    ☐ **I plan to obtain verbal or online consent**
    ☒ **I plan to obtain signed consent for part of the study, and verbal or online consent for another part of the study.**
    ☐ **I do not plan on obtaining consent due to the nature of the study (explain):**

    We will collect documentation of consent for focus groups and interviews (on paper) and the intervention (electronically). However, we will obtain verbal consent for the phone screen (built into the screening guide) and from any Phase 1 and 2 participants who select to participate by phone.

☒ **Requesting a waiver of documentation of consent** (Note that an information sheet may be required.)

If requesting a waiver of documentation of consent, please address the following:
a. Would the signed consent form be the only record linking the participant and the research? ☐ Yes ☒ No
b. Does a breach of confidentiality constitute the principal risk to participants?
☒ Yes ☐ No

OR

a. Does the research pose greater than minimal risk? ☐ Yes ***If you answered yes, stop. A waiver cannot be granted.*** ☒ No

AND

b. Does the research include any activities that would require signed consent in a non-research context? ☐ Yes ☒ No

☐ **Requesting a full waiver of consent**

If requesting a full waiver of consent, please address the following:

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

SECTION VI: PROTECTION OF RESEARCH PARTICIPANTS

Confidentiality & Security of Data:

1. What participant information will you be collecting?

briefly listed below, see Appendix for detailed information on each

Demographics: During Phase 3 we will collect the following demographic information through our online screener, baseline survey, and hair cortisol collection survey: age, sexual orientation, gender identity, regional domicile, ethnicity, racial identity, relationship status, HIV risk behavior and status, height, weight, and socioeconomic status markers.

Study Measures:

Mental Health and Risk

Center for Epidemiological Studies -- Depression Scale (CESD), Brief Symptom Inventory (BSI), Beck Anxiety Inventory (BAI), Suicidality, Suicidal Ideation Attributes Scale (SIDAS), Self-Injury, Alcohol Use Disorders Identification (AUDIT), Short Inventory of Problems-Modified for Drug Use (SIP-DU), Sexual Behavior with Main Partner (SB-MP), Sexual Behavior with Casual Partners (SB-CP), Health Care Access and Experiences

Moderators
Ruminative Response Scale—Brooding Subscale (RRS), Multidimensional Scale of Perceived Social Support (MSPSS), Beck Hopelessness Scale (BHS), LGBTQ Identity Centrality, Developmental Milestones (Baseline Only)

Mechanisms
Cortisol Samples, Perceived Stress Scale (PSS), Barratt impulsiveness Scale (BIS), Columbia Card Task

Sexual Minority Stress
Gay-Related Rejection Sensitivity Scale (GRRS), Parental Attitudes Toward Child's Sexual Orientation, Outness Inventory (OI), internalized Homophobia Scale (IHS), Everyday Discrimination—Sexual Orientation (EDSO), LGBT Victimization Experiences

Religiosity
Religious Affiliation, Religious Strain Scale (RSS)

Qualitative Phone Interview Post-Session Questions

2. Will any of the following identifiers be collected?
☒ Names
☒ All geographic subdivisions smaller than a State, including: street address, city, county, precinct, zip codes
☒ Telephone numbers
☐ Fax numbers
☒ E-mail addresses
☐ Social Security numbers
☐ Medical record numbers
☐ Health plan beneficiary numbers
☐ Account numbers
☒ All elements of dates (except year) for dates related to an individual, including: birth date, admission date, discharge date, date of death, all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older
☐ Certificate/license numbers
☐ Vehicle identifiers and serial numbers, including license plate numbers
☐ Device identifiers and serial numbers
☐ Web Universal Resource Locators (URLs)
☒ Internet Protocol (IP) address numbers
☒ Biometric identifiers, including finger and voiceprints
☒ Full face photographic images and any comparable images
☐ Any other unique identifying numbers, characteristics, or codes

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. If applicable, what methods and procedures will be used to safeguard the confidentiality and security of the identifiable study data and the storage media indicated above during and after the participant's participation in the study?

Do all portable devices contain encryption software? ☒ Yes ☐ No

If no, see http://its.yale.edu/secure-computing/protecting-yales-data/data-encryption and http://hipaa.yale.edu/guidance/policy.html

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/herself or another person. Additionally, we are required by state law to report suspected cases of child 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. Study staff will be briefed on maintaining participants' privacy and confidentiality and will be in possession of valid human subjects research training certificates. The emails verifying participant age with a photo of the participant and their ID will be stored on the secure study server. Once age has been verified and the image has been stored on our secure server the original email will be deleted from study staff emails and inbox trash will be emptied to protect participant 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 study 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 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 research staff with 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.

4. How will the research data be collected, recorded and stored?

Research data will be collected via telephone, submitted electronically, and mailed via postal service (hair samples for cortisol testing).

Screening data will be collected via telephone for Phase 1 and 2, whereby a study staff member asks the potential participant a series of eligibility questions and enters this information into an electronic database at our research offices. Phase 1 and Phase 2 data will be audio-recorded and stored electronically on secured encrypted hard drives; these data will be sent electronically to a professional transcription service. Phase 3 participants will complete the baseline surveys electronically at home, and will complete the writing assignments at home on their personal computer or tablet and will electronically submit the writing samples to our offices. Data from post-study qualitative interviews will be audio-recorded, professionally transcribed, and stored electronically on secured encrypted hard drives.

Hair specimens will be identified with participant ID number, not with participant name. The diagnostic laboratory that will test cortisol levels will not have access to participant identifying information. All information collected from participants, including biomarker data, will be kept in a password protect file on our secure server. Hair samples will be discarded after cortisol level tests.

All study computers will be encrypted and password protected. Online surveys (yale.qualtrics.com) will use an encrypted web service (https).

5. How will the digital data be stored? ☐ CD ☐ DVD ☐ Flash Drive ☐ Portable Hard Drive ☒ Secured Server ☒ Laptop Computer ☒ Desktop Computer ☒Audiotaping ☐ Videotaping ☒Handwritten notes ☐ Other

6. If applicable, how will transfer of data to Yale be completed? See http://its.yale.edu/secure-computing/protecting-yales-data/data-and-information-classification-yale-university

   Data will be transferred among study universities (Yale, ETSU, Holy Cross) using the HIPAA compliant Yale Secure Box.

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. Three years after study completion, the link to personal identifiers will be destroyed. After three years, the audio recordings from the phase 1 and phase 2 interviews and focus groups, as well as the phase 3 follow-up interviews, will also 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)*

   A Certificate of Confidentiality has been obtained.

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. One risk of the proposed study is that some participants in the Phase 1 interviews and Phase 3 expressive writing condition will experience emotional discomfort as a result of talking or writing about their most stressful or traumatic LGB-related event. Although unlikely, it is possible that some participants may experience emotional discomfort in completing the

quantitative assessments. Some participants might also experience physical discomfort from providing a section of their own hair. Breach of participants' confidentiality presents another possible risk. The investigative team's strategies to protect against both risks are described below.

Minimizing Risks: Describe the manner in which the above-mentioned risks will be minimized.

Protection Against Emotional Discomfort. It is possible that participants may experience emotional discomfort in responding to self-report measures, talking about minority stressors, or completing the expressive or self-affirmation writing. 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. All research team members will be thoroughly trained in appropriate responses to participant distress by a licensed clinical psychologist. This training will address the appropriate handling of imminent threats and provision of referrals to free counseling services in less imminent clinical situations.

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. To protect participants' confidentiality, we will obtain a Federal Certificate of Confidentiality prior to enrolling participants. All members of the research team have undergone rigorous training in maintaining participants' privacy and confidentiality and are in possession of valid Collaborative Institutional Training Initiative (CITI) certificates. 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 stored on a secure server. 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 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 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.

2. Data and Safety Monitoring Plan: *All studies require the inclusion of a Data and Safety Monitoring Plan (DSMP) with an explicit statement of overall risks (e.g., minimal, greater than minimal/moderate, or high), a means to address attribution and grading of adverse events and a description of procedures for monitoring the ongoing progress of the research and reporting adverse events. The Data and Safety Monitoring Plan should describe how the principal investigator intends to provide ongoing supervision and evaluation of the activities of the study including whether appropriate progress is being made. It*

should document the procedures and means to protect the welfare and safety of subjects and protect the integrity of the data.
The plan must include provisions for data review and performance of safety reviews, at a specified frequency, as well as the plan for reporting to the HSC and/or other internal or external organizations. When participating in a multi-site study, the Yale principal investigator must indicate how safety reports and/or reporting of serious adverse events from other sites will be provided to the Yale HSC.

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? Minimal

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

c. **Copy, paste, and then tailor an appropriate Data and Safety Monitoring Plan from http://www.yale.edu/hrpp/forms-templates/biomedical.html** for

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

The principal investigator is responsible for monitoring the data, assuring protocol compliance, and conducting the safety reviews quarterly. During the review process the principal investigator will evaluate whether the study should continue unchanged, require modification/amendment, or close to enrollment.

The principal investigator and the Institutional Review Board (IRB) 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 (e.g., through regular study meetings, via email as they are reviewed by the principal investigator.) The protocol's research monitor(s), e.g., NIH, will be informed of serious or unanticipated adverse events 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?

ii. What provisions are in place for management of interim results?
iii. What will the multi-site process be for protocol modifications?

Drs. Chaudoir (co-PI at College of the Holy Cross) and Williams (Co-I at East Tennessee State University) will conduct biweekly conference calls to review study progress. During these calls, any necessary protocol modifications will be discussed and submitted to all institutions' IRBs for review. Drs. Chaudoir and Williams will report any adverse event and unanticipated problem involving risks to subjects to Dr. Pachankis within 24 hours so that the IRB of each institution can be notified within 48 hours and so that NIH, if required, can be notified within five days.

3. **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.)*

Mental and physical health disparities among nonurban LGBTQ+ emerging adults is a clear public health concern. There is strong theoretical and empirical evidence to suggest that nonurban LGBTQ+ emerging adults in the expressive writing and self-affirmation conditions will experience salutary mental and physical health effects by participating in this research. Benefits to society in general are anticipated through the dissemination of research findings regarding the salutary effects of online writing interventions on mental and physical health for nonurban LGBTQ+ emerging adults. Results will better inform local and national public health agencies about potentially effective outreach that can be delivered to rural LGBTQ+ emerging adults. In sum, the potential benefits outweigh the potential risks to subjects, which are minimal.

SECTION VIII: RESEARCH ALTERNATIVES AND ECONOMIC CONSIDERATIONS

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

Study staff will be equipped with a list of resources to refer participants and potential participants to, including resources of medical, HIV/STD testing, psychological, substance use, and housing support services.

2. **Payments for Participation (Economic Considerations):** Describe any 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; 4) that there are no restrictions to winning.

Phase 1 focus group participants and Phase 2 interview participants will each receive $30 as a thank you for participating in the study.

For Phase 3, participants will be paid $10 for each of 3 writing sessions and will be entered into a sweepstakes drawing for $100 if they complete all 3 writing sessions. Participants will receive graduated payment for completing the baseline ($20), post-intervention ($30), and 3-month follow-up assessments ($40). They will receive $20 each for completing the first and second hair cortisol sample and will be entered into a second sweepstakes drawing for $100 if they complete all assessments. Assuming all participants complete all writing assignments and submit both hair samples, there will be a 1/108 odds of winning each $100 sweepstakes drawing. The use of graduated payment plans, sweepstakes drawings for intervention and assessment completion, and close communication with participants between follow-up assessments, have proven to be effective strategies to ensure 83-100% retention in our previous longitudinal research. Participants will receive compensation at four points: (1) upon completion of the baseline survey, (2) upon completion of writing samples and post-intervention survey, (3) after the first hair cortisol sample, (4) and after the second hair cortisol sample. Participants will have the option to receive their payments either through Venmo or emailed Amazon gift card.

Participants who choose to complete post-study qualitative interviews will be paid $30 for a 60-minute phone interview. Participants will again have the option to receive their payments either through Venmo or emailed 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.

   Participation in this study will generate no costs for participants, as it will be conducted entirely online.

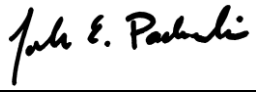
SECTION IX:
PRINCIPAL INVESTIGATOR AGREEMENT

As the **principal investigator** of this research project, I certify that:

- The information provided in this application is complete and accurate.
- I assume full responsibility for the protection of human participants and the proper conduct of the research.
- Subject safety will be of paramount concern, and every effort will be made to protect participants' rights and welfare.
- The research will be performed according to ethical principles and in compliance with all federal, State and local laws, as well as institutional regulations and policies regarding the protection of human participants.
- All members of the research team will be kept apprised of research goals.
- I will obtain approval for this research study and any subsequent revisions prior to my initiating the study or any change and I will obtain continuing approval of this study prior to the expiration date of any approval period or submit a request to close the study prior to its expiration..
- I will report to the HSC any unanticipated problems involving risk to participants.
- I am in compliance with the requirements set by the University and qualify to serve as the principal investigator of this project or I have a faculty advisor.
- I will identify a qualified successor should I cease my role as principal investigator and facilitate a smooth transfer of investigator responsibilities, if applicable

John Pachankis, PhD — PI Name (PRINT)

12/10/2015 — Date



Signature

SECTION X
FACULTY ADVISOR AGREEMENT

As the **faculty advisor** of this research project, I certify that:

- The information provided in this application is complete and accurate.
- This project has scientific value and merit and that the student or trainee investigator has the necessary resources to complete the project and achieve the aims.
- I will train the student investigator in matters of appropriate research compliance, protection of human subjects and proper conduct of research.
- The research will be performed according to ethical principles and in compliance with all federal, state and local laws, as well as institutional regulations and policies regarding the protection of human subjects.
- The student investigator will obtain approval for this research study and any subsequent revisions prior to initiating the study or revision and will obtain continuing approval prior to the expiration of any approval period.

- The student investigator will report to the HIC any serious injuries and/or other unanticipated problems involving risk to participants.
- I am in compliance with the requirements set forth by the University and qualify to serve as the faculty advisor of this project.
- I assume all of the roles and responsibilities of a Principal Investigator even though the student may be called a PI.

_____ _____
Advisor Name (PRINT) Date

_____
Signature

For School of Medicine Applications only:

SECTION XI
DEPARTMENT CHAIR'S ASSURANCE STATEMENT

Do you know of any real or apparent institutional conflict of interest (e.g., Yale ownership of a sponsoring company, patents, licensure) associated with this research project?
☐ Yes (provide a description of that interest in a separate letter addressed to the HIC.)
☐ No

As Chair, do you have any real or apparent protocol-specific conflict of interest between yourself and the sponsor of the research project, or its competitor or any interest in any intervention and/or method tested in the project that might compromise this research project?
☐ Yes (provide a description of that interest in a separate letter addressed to the HIC)
☐ No

I assure the HIC that the principal investigator and all members of the research team are qualified by education, training, licensure and/or experience to assume participation in the conduct of this research trial. I also assure that the principal investigator has departmental support and sufficient resources to conduct this trial appropriately.

_____ _____
Chair Name (PRINT) and Signature Date

_____
Department

SECTION XII
YNHH HUMAN SUBJECTS PROTECTION ADMINISTRATOR ASSURANCE STATEMENT

Required when the study is conducted solely at YNHH by YNHH health care providers.

As Human Subject Protection Administrator (HSPA) for YNHH, I certify that:
- I have read a copy of the protocol and approve it being conducted at YNHH.
- I agree to notify the IRB if I am aware of any real or apparent institutional conflict of interest.

- The principal investigator of this study is qualified to serve as P.I. and has the support of the hospital for this research project.

_____ _____ _____

YNHH HSPA Name (PRINT) and Signature Date

For HIC Use Only

_____ _____

Date Approved **Human Investigation Committee Signature**

This protocol is valid through _____