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: A randomized controlled trial of online LGBTQ-affirmative cognitive behavioral therapy to reduce depression and associated health risks amoung young adults			
Principal Investigator: John Pachankis, Ph.D.		**Yale Academic Appointment: Associate Professor**	
Department: Social and Behavioral Sciences, YSPH			
Campus Address: 60 College St., Ste. 316			
Campus Phone: 203-785-3710			**E-mail:** john.pachankis@yale.edu
Protocol Correspondent Name & Address (*if different than PI*): Zach Soulliard, Ph.D.			
Campus Phone:		**E-mail:** zachary.soulliard@yale.edu	

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

SECTION II: GENERAL INFORMATION

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

August 1, 2019 to July 31, 2022

2. **Study location:** State where the study will take place and in what setting.
This primary study site is Dr. Pachankis' Yale-affiliated off-campus lab in New York City (220 East 23rd St., Suite 405, New York, NY 10010). Participation wil occur online and participants will be recruited in high-need locales across the US, as specified below in the recruitment section.

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 IV: RESEARCH PLAN

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

Project EQuIP (Empowering Queer Identities in Psychotherapy) is a 10-session skills-building intervention designed to reduce young sexual minorities' (e.g., those who identify as lesbian, gay, bisexual, or report persistent same-sex attractions or behaviors; hereafter referred to as LGBTQ) co-occurring mental health risks by reducing the underlying cognitive, affective, and behavioral pathways through which minority stress impairs LGBTQ mental health. EQuIP is based on the Unified Protocol, a cognitive-behavioral therapy (CBT) approach with efficacy across mental health (e.g., depression, anxiety) and associated risk behaviors (e.g., suicidality, substance abuse, sexual risk). The Unified Protocol changes underlying stress pathways using motivational interviewing, emotional and situational exposure, cognitive restructuring, mindfulness, and self-monitoring exercises. To create EQuIP, our team adapted the Unified Protocol by conducting interviews with 33 LGBTQ-expert mental health providers and 39 LGBTQ young adults at high mental and behavioral health risk. These stakeholders helped our team infuse the Unified Protocol with minority stress coping content. EQuIP aims to normalize the adverse impact of minority stress, reduce internalized homophobia and rejection schemas, reduce LGBTQ people's unhealthy avoidance tendencies (e.g., substance abuse, condom use non-assertion), and validate LGBTQ

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unique strengths. In a preliminary trial of an in-person intervention delivered to young adult gay and bisexual men (*n*=63), this intervention significantly reduced participants spectrum of interrelated health threats, making it the first evidence-based intervention to simultaneously improve mental health, substance use, and sexual health outcomes among young adult gay and bisexual men. Two ongoing RCTs are ongoing, including one waitlist trial that extends to women this first trial delivered to men and one that represents a larger extension of the original waitlist trial with men. We are confident that our revised treatment applies to all genders because we have conducted formative qualitative interviews with all genders to ensure the treatment's relevance. Also, our first trial was limited to men only because of gender inequities in NIH funding for LGBTQ-focused research, in which the majority of funding is devoted to research pertaining to gay and bisexual men rather than sexual minority women.

Because this treatment has only been tested using an in-person treatment in NYC and Miami, this precludes reaching LGBTQ young adults across geographic locales, including those locales that might not provide LGBTQ-affirmative brick-and-mortar services. Therefore, we propose to test an online version of EQuIP in high-stigma, low-resource geographies across the US. At the same time, whether LGBTQ-specific adaptations are required for treatment efficacy remains unknown. Perhaps standard CBT that does not include LGBTQ-specific adaptations are equally efficacious, which would provide the treatment field with essentiall guidance, including whether existing (non-LGBTQ-adapted) treatments can be distributed to LGBTQ youth in need.

To evaluate the preliminary efficacy of an LGBTQ-affirmative online CBT treatment and whether such an LGBTQ-affirmative focus adds benefit, we propose a 2-arm RCT that would examine (1) whether online EQuIP demonstrates significant mental health improvements compared to self-monitoring of stress and mood, and (2) whether participant baseline LGBTQ-specific stress exposure moderates treatment efficacy, such that participants with the most LGBTQ-specific stress exposure benefit more from online EQuIP than self-monitoring of stress and mood."

Our primary outcomes are depressive symptoms, anxiety symptoms, substance abuse, sexual risk behavior, and suicidality, all of which disproportionally affect LGBTQ young adults. Secondary outcomes include hypothesized cognitive, affective, and behavioral minority stress mechanisms, such as internalized homophobia, rejection sensitivity, concealment, social isolation, and emotional dysregulation.

In preparation for this RCT, we will deliver the online EQuIP treatment to 14 LGBTQ young adults who meet all eligibility criteria for the full trial. The purpose of this initial test is to ensure acceptability of the treatment content and usability of the technical platform.

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

Clear and consistent evidence now suggests that LGBTQ young adults disproportionately experience depression, anxiety, suicidality, substance abuse, and sexual risk compared to heterosexual, cisgender individuals. Diverse methods locate the source of these disparities in LGBTQ young adults' exposure to minority stress—the stress associated with stigma-related social disadvantage. In fact, minority stress, mental health problems, substance use disparities, and sexual

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risk fuel each other, forming a synergistic threat to LGBTQ young adults' health. Yet, until our team's work, no existing evidenced-based intervention existed to addresses minority stress and its impact on LGBTQ young adults' mental and behavioral health.

Minority stress theory suggests that stigma compromises LGBTQ young adults' mental, behavioral, and sexual health health through several cognitive, affective, and behavioral pathways. These pathways emerge early in development and include negative thinking styles, unhealthy emotion regulation habits, low behavioral self-efficacy, and behavioral avoidance. Some of these processes are LGBTQ-specific, such as internalized homophobia and expectations of LGBTQ-related rejection; others are universal but elevated among LGBTQ young adults, such as low self-worth and unassertiveness. All are related to poor mental health, suicidality, substance abuse, and sexual risk. Our conceptual model suggests that an intervention that reduces these minority stress processes could simultaneously improve the full spectrum of LGBTQ young adults' mental and behavioral health risks.

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 propose to test the efficacy of an online CBT intervention (EQuIP) that addresses the pathways through which minority stress compromises LGBTQ young adults' co-occurring mental (e.g., depression) and behavioral (e.g., substance use, condomless anal sex) health problems. In this RCT, we expand upon the initial success of our pilot trial of our in-person treatment delivered solely to young adult gay and bisexual men and lessons learned from our other ongoing RCTs of our in-person treatments with LGBTQ young adults to determine if the treatment is efficacious when delivered online and if its efficacy exceeds that of the self-monitoring control.

To conduct this test, 120 participants will be randomly assigned to one of two conditions:

1) Self-monitoring control: In this control condition, participants will be asked to indicate their past 7-day mood; stress experiences; and mental and behavioral health on an online survey. This type of self-monitoring has been shown to yield improvement in behavioral health outcomes. Self-reporting LGBTQ stress experiences has also been shown to produce reductions in depression symptoms over time. Participants will record these experiences once per week for 10 weeks.
2) Online EQuIP: This online CBT treatment consists of 10 weekly modules that participants will complete over the course of 10 weeks. Modules contain weekly psychoeducational text and vignettes about minority stress and mental health; brief videos illustrating the CBT skills; and homework exercises that therapists review and provide feedback on. Homework exercises include weekly tracking of stressful situations and mood, practicing new skills (e.g., mindfulness, cognitive restructuring), and exercises related to considering the origins of stress and negative emotions that participants may be experiencing. Therapists provide feedback after each homework assignment, including reviewing each participant's treatment goals as part of the first session's homework. Therapists who support this condition will be instructed to incorporate LGBTQ-specific content and feedback into

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homework reviews. Therapists will either be postdoctoral fellows in the Pachankis lab or clinical/counseling psychology interns/externs in the Pachankis lab who possess an advanced degree in a mental health field with significant prior experience treating LGBTQ young adults with mental health concerns. Modules were adapted directly from the in-person materials (e.g., therapist manual, participant handouts) used in our previously successful trials of this treatment. A team of six therapists and supervisors of the original in-person treatment adapted the text for the online modules, including realistic vignettes and easy-to-follow skills training. A video production company created accompanying videos with our clinical team's close input.

At baseline, immediately post-treatment (4-month followup), and 8-month followup, participants will complete online surveys assessing their mental and behavioral health. Automatically generated alerts will immediately be sent to project staff in response to a participant indicating suicidality in response to suicidality assessments, at which point the study staff will implement the cinical protocol.

After completing the baseline assessment, participants will be assigned a study therapist and will be contacted by their therapist to schedule a 30-minute introductory call via Zoom video conferencing or telephone. During this conversation, therapists will explain the structure of the study and briefly discuss the participant's motivations and goals for participating in the study. Participants will then complete one session (self-monitoring, online EQuIP, or enhanced online EQuIP) per week. If particpiants miss a session, as determined by daily therapist and RA review of session access and self-monitoring or homework completion, they will receive a reminder to complete the session. Participants will also be asked to schedule a check-in phone call with their study therapist two-weeks post-randomization to discuss their progress throught the study sessions. Participants will have a window period of four months to complete all 10 sessions. At 8-month followup, 20 participants randomized to the Online EQuIP condition who completed the treatment will be contacted and invited to participate in a 45-60 minute phone interview. The purpose of this phone interview is to ask participants to answer questions in regard to their experience in completing the treatment (e.g., things they liked, things they did not like, things they would change).

Before we randomize participants into the full trial, we will pilot-test the online EQuIP treatment with 14 LGBTQ young adults who meet all eligibility criteria planned to be employed for the full trial. In addition to completing 10 online EQuIP sessions, these participants will complete baseline and immediate post-treatment (3-month followup) assessments as well as a qualitative interview about their experience at 3-month followup. These participants will not complete any additional follow-up assessment.

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

Inclusion criteria. Eligible participants will meet the following criteria: (1) aged 16-25, (2) identify as lesbian, bisexual, gay, or another sexual minority identity (e.g., pansexual, demisexual) (3) past-week symptoms of depression or anxiety using the Brief Symptom Inventory-4 cutoff of 2.5 on either the depression subscale or anxiety subscale; (4) weekly access to internet on a laptop, desktop,

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or tablet device; (5) ability to read, write, and speak in English; and (6) provision of informed consent.

Exclusion criteria. Participants will be excluded for any of the following: 1) current active suicidality or homicidality (defined as active intent or concrete plan, as opposed to passive suicidal ideation); 2) evidence of active mania, psychosis, or gross cognitive impairment that could interfere with the participant's ability to volitionally consent to research or interfere with their ability to safely and reliably complete research; 3) current enrollment in an intervention study; 4) current enrollment in intensive mental health treatment (i.e., receiving mental health treatment more than once per month or 8 or more sessions of CBT within the past year.

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

We will advertise for our study online, via our past study participants who expressed interest in knowing about future studies, via advertisements sent to local LGBTQ-serving organizations, and through study participants' word of mouth. Advertisements will engage treatment-seeking LGBTQ by emphasizing the study as a safe venue for addressing mental health and associated risks.

6. **Participant classification:** Check off all classifications of participants that will be specifically recruited for enrollment 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?

Inclusion criteria. Eligible participants will meet the following criteria: (1) aged 16-25, (2) identify as LGBTQ or report persistent patterns of same-sex attraction (3) past-week symptoms of depression or anxiety using the Brief Symptom Inventory-4 cutoff of 2.5 on either the depression subscale or anxiety subscale; (4) weekly access to internet on a laptop, desktop, or tablet device; (5) ability to read, write, and speak in English; and (6) provision of informed consent.
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Exclusion criteria. Participants will be excluded for any of the following: 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; 3) current enrollment in an intervention study; 4) current enrollment in intensive mental health treatment (i.e., receiving mental health treatment more than once per month or 8 or more sessions of CBT within the past year.

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 employ a number of strategies to recruit participants. These strategies are designed to recruit an ethnically diverse sample from multiple types of venues in which LGBTQ young adults are likely to be accessed (e.g., online social networking apps and websites).

1) Online recruitment. We have successfully utilized online recruitment for our past existing studies. The proposed study's ads will target LGBTQ young adults who are 16-25 years old and who experience symptoms of depression or anxiety. We will advertise on LGBTQ-oriented social media groups (e.g., Facebook) and mobile apps (e.g., Grindr, Scruff, BGCLive, Growlr, Scissr) and LGBTQ-focused media (e.g., Craigslist, Reddit, Tumblr, Twitter). We will also reach out to community-based organizations to share study advertisements within their online social media networks, once their permission is obtained. Recruitment advertisements will contain information such as the study name, goals, and contact information for those interested in screening for eligibility. From the advertisements, potential participants will link to our study website, read details about the study, and complete an eligibility screener. All collected information will be stored on physically secure, password-protected encrypted data storage systems within actively monitored network firewalls. For both the 14-person pilot study and larger RCT, data from the eligibility screener will be stored in Yale's secure Qualtrics server.

2) Recruitment of participants from past studies. At the end of several of our previous studies (Urban Migration, Self-Regulation, and Drug Abuse and HIV Risk Among Young Men, Protocol #: 1405013946; Gay Community Stressors Among Gay, Bisexual, and Queer Men, Protocol #:1512016893; Online Social Network Study, Protocol #: 1611018686l, Development and preliminary trial of a brief, portable health intervention for rural sexual minority emerging adults, Protocol # 1512016952), we asked participants whether they would be willing to be contacted for future studies. We will recruit participants who consented to be contacted for future research using contact information they provided.

3) Letters and postcards sent to community organizations. We will send a letter and postcards to community organizations, including community-based organizations supporting the LGBTQ community and local college counseling centers. The letter will ask these organizations to distribute the postcards in their waiting areas and to potentially eligibile individuals. The letter will also contain the online link to our study description and screener that these organizations can

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also distribute to potentially eligibile individuals.

4) Peer-recruitment and referrals by previous and current study participants. Participants in the study will be asked to distribute study recruitment materials to peers who may be interested in participating in the study. Participants will be reminded that staff will never disclose any information about an individual's participation in the study, but that participants are free to disclose information about their own participation to whomever they desire. Participants are not required to distribute recruitment materials as a condition of study participation and the strictly voluntary nature of this request will be emphasized by study staff.

Recruitment text and images are attached to this 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.)*

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
☐ Other (describe):

☒ Internet/Web Postings
☒ Mass E-mail Solicitation
☐ Departmental/Center Website
☒ Social Media (Facebook, Twitter)

☐ Radio
☒ Telephone
☐ Television

3. **Targeted Enrollment: Give the number of participants:**
   a. Targeted for enrollment for this protocol: 120 (plus an additional 14 participants who will pilot the study)
   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?**

We aim to recruit 120 participants into this study. Our primary aim is to demonstrate a greater reduction in 4-month follow-up in depressive symptoms in the online EQuiP condition compared to the self-monitoring control. Using a 1:1 randomization, we will randomly assign 60 participants to each of the two conditions (i.e., online EQuIP and the self-monitoring control). Assigning 60 participants into each condition will allow us to detect a difference ($\beta = 0.2$, $p < .05$) consistent with the average effect of online CBT involving therapist support (compared to a weak control condition) found across meta-analyses of online CBT: .61 (Andersson & Cuijpers, 2009), .83

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(Sztein, Koransky, Fegan, & Himelhoch, 2018), and 1.00 (Spek, Cuijpers, et al., 2007). This estimate accounts for 25% attrition at 3-month follow-up, consistent with the attrition rate in our current in-person treatment study of 254 young gay and bisexual men and exceeding that found in our previous online intervention research (e.g., Pachankis & Goldfried, 2010).

Before we randomize participants into the full trial, we will pilot-test the online EQuIP treatment with 14 LGBTQ young adults who meet all eligibility criteria employed for the full trial. The purpose of this initial test is to ensure acceptability of the treatment content and usability of the technical platform.

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.

Informed consent will be obtained for all participants at three points – before completion of the online screener, phone screener, and baseline survey.

Before completing the online screener, participants will review an online consent form describing the screening purpose and risks/benefits and indicate their consent by selecting the commensurate button. Participants' identifying information, including their name, will be kept in a separate database from the remainder of their study responses. Participants who are deemed preliminarily eligible based on the online screener will be contacted by our study staff to confirm eligibility by phone screen.

Before administering the phone screener, a project staff member will first assess participants' willingness and capacity to consent to completing the screener to determine eligibility. Participants will provide their verbal consent for the phone screener. Participants' identifying information, including their name, will be kept in a separate database from the remainder of their study responses.

For the 14-person pilot study and larger RCT, the phone screener will be completed using Yale's secure Qualtrics server. Participants who are deemed eligible based on the phone screener will then be e-mailed a PDF copy of the consent form by the research assistant conducting the phone screen. The research assistant and participant will schedule a time to review the consent form via telephone, including details of the full study and study risks and precautions against risk, and address any points of confusion. The participant will then be given the opportunuity to provide verbal consent. Participants will then be given a username and password to log in to the secure online platform and asked to confirm that they were able to successfully access this platform. Upon receipt of this confirmation, participants will be sent their baseline surveys. Thereafter, study participation begins when the participant completes their baseline surveys. After completion of these surveys, participants will be randomized to one of two conditions.

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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

Prior to sending the link for the baseline survey, a trained research assistant will assess participants' consent by phone. The RA will ensure that the participant understands the risks associated with the disclosure of information that could indicate imminent threat to self or others. 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 provide verbal consent. RAs will be instructed to contact the PI or project coordinator if he or she is unsure about any participant's capacity to consent.

For the phone screener, participants will be asked to provide verbal consent prior to answering the screener questions.

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.

Please find attached a copy of the: 1) online screener consent text, 2) phone screener consent text, and 3) full study consent text administered before the baseline survey.

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).**

At this point, only English speakers will be enrolled in this study.

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.

Reporting requirements might be invoked in the case of participants reporting suicidality, homicidality, severe distress, or violence. For participants under 18, reporting requirements might be invoked in the case of a participant reporting that they are being or have been harmed or abused by others.

Our lab's clinical protocol has successfully guided reporting of instances of suicidality, homicidality, severe emotional distress, and violence in our other randomized controlled trials. We will employ a similar protocol in this study, adapted for the online, geographically diffuse sampling strategy and to address mandatory reporting requirements for participants unders 18. 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 ask the participant and connect the clinical team

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member with a trusted social network member for the clinical team member to counsel about next steps. In the event that the participant cannot identify or connect the clinical team member with an available person in their support network (such as a family member, partner, or friend), the clinical team member will contact 911 to dispatch local 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 available in their area. All therapy homework will be reviewed by a clinical staff member trained in suicide assessment. Research and clinical staff members will receive an alert if the participant answers the online questionnaires in a manner that signals distress; such participants will be called by a clinical staff member to assess risk. A clinical team member will also be on-call during phone screeners and will be asked to speak with any participant who reports imminent distress to the research team member conducting the phone screener. The protocol also outlines a step by step procedure for reporting suspected child abuse.

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

10. **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):**

☒ **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

Consent will be obtained for all study components either verbally or online as described above. However, we will not require participants to provide their name when consenting to completing the brief online screening survey administered to determine study eligibility. This brief (4 min) screen

will assess age, depression and anxiety symptoms, substance use, and sexual behavior. 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 verbal consent before completing this more comprehensive phone screen, as described above. Data from the eligibility screener will be stored in Yale's secure Qualtrics server. For participants who are ineligible, we will retain their screening information if they indicate interest in a being contacted about future studies. If they do not indicate interest in being contacted about future studies, we will delete their data from the server.

☐ **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?

The full packet of study measures and assessments is attached to this application. We propose to collect information about participants' general mental health status, including demographics; depressive and anxious symptoms and suicidality; substance use; sexual-risk behavior; HIV status; experiences with stigma-related stress; cognitive, affective, and interpersonal functioning (e.g., rumination, social support, impulsivity, assertiveness); mental health treatment history and perspectives; and perceptions of intervention helpfulness. For participants in the active treatment conditions (online EQuIP), we will also collect participants' homework assignment text regarding the above topics and therapists' homework feedback. Therapists will document all phone contact on a password-protected file stored on Yale's HIPAA-compliant Secure Box.

Participants will provide the following data at baseline, 4-month (immediate post-treatment) follow-up, and 8-month follow-up appointments: quantitative assessments, previously used with LGBTQ young adults, of mental health, suicidality, substance use, sexual-risk behavior, and stigma-related stress, and (at 4- and 8-month follow-ups only) intervention acceptability.

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The 20 participants from the Online EQuIP condition will provide feedback in regard to their experience in completing the treatment (e.g., things they liked, things they did not like, things they would change). Pending consent from participants, these interview will be audiorecorded.

The 14 participants who will take part in the initial pilot trial will complete baseline and immediate post-treatment (3-month followup) assessments as well as a qualitative interview about their experience at 3-month followup. These participants will not complete the 6-month followup assessment.

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, seehttp://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 themselves 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 for the full randomized contral trial. All therapists and research assistants (RAs) will undergo rigorous training in maintaining participants' privacy and confidentiality and will be 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 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 therapists and research staff under explicit guidelines to preserve confidentiality when telephoning, or emailing 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. All of our research lab's portable devices have been encrypted by Yale ITS.

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

Research data will be collected via telephone, electronic databases, and survey websites. All collected information will be stored on physically secure, password-protected encrypted data storage systems within actively monitored network firewalls. For the phone interviews at 8-month followup for 20 participants in the Online EQuIP condition, participant's name will not be linked to the information they provide, except in the event that participants report any intent to harm themselves, another person, or child. In such cases, the clinical protocol discussed in Section 9 of this protocol and previously attached in the Supporting Documents will be followed. Information from the phone interview will be kept in a password-protected file. The audio recordings will be kept in a password-protected folder within actively monitored network fireweall, which no one will have access to other than approved study staff. The audio recordings will be transcribed using GoTranscript, a confidential external transcription service. The audio recordings and transcripts will be kept for three years after the study is completed, at which point they will be destroyed.

For the 14-person pilot and larger RCT, screening data will be collected and stored on a secure survey website (Qualtrics.com) and via telephone, 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. Participants will also complete baseline and follow-up surveys Qualtrics. Participants themselves will enter most data into this platform directly where it will be stored on this secure server. All of this data will also be downloaded to Yale's HIPAA-compliant Secure Box.

Session homework assignment and weekly mood tracking data will be received at the Karolinska Institutet's server, which hosts the online platform for the the active conditions (i.e., online EQuIP,

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online Unified Protocol). This session homework assignment data will also be downloaded to Yale's Secure Box drive upon retrieval from the Karolinska Institutet server; it will also remain on the Karolinska Institutet server after transfer to Yale. Participant session notes will be stored on Yale's Secure Box. Participant tracking and scheduling data will be recorded on a study database stored on Yale's Secure Box. One password-protected linking database containing participant names and ID codes will be kept on Yale's Secure Box and accessible only by study staff.

Yale's secure Qualtrics server meets recognized security standards for storing participant data. The Karolinska Institutet's secure server used in several prior and current trials of internet-based CBT also meets recognized security standards for storing participant data. Details about the security of this server have been submitted in conjunction with this protocol and include intensive physical and digital system access control and data separation control.

Participants will be identified with participant ID number, not with participant name.

All study computers will be encrypted and password protected. 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.

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

Session homework data will be transferred from the the Karolinska Institutet to Yale using the HIPAA-compliant Yale Secure Box. This homework data will not contain participant identifying information; only study ID.

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 three years of study completion, the link to personal identifiers will be destroyed.

Deidentified audio recordings, labeled only with study IDs, will be transcribed using GoTranscript, a confidential external transcription service. GoTranscript protects audio files with 2048-bit SSL encryption. Audio files for transcription are cut into 5-10 minute chunks and transcribed by different transcriptionists who have each signed non-disclosure agreements. Audio files are deleted from GoTranscript servers upon transcript completion and will then be uploaded by study staff to

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Yale's Secure Box folder. After three years from study completion, audio transcripts 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)*

We will request an NIH Certificate of Confidentiality for the full randomized control trial.

SECTION VII: POTENTIAL RISKS AND BENEFITS

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

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 quantitative assessments, intervention, and phone interviews. Breach of participants' confidentiality presents another possible risk. The investigative team's strategies to protect against both risks are described below.

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

Recruitment and Informed Consent: The investigative team has conducted a number of studies involving LGBTQ young adults, which have involved asking participants to complete potentially sensitive interviews and self-report measures. Thus, we have extensive protocols in place for all aspects of the study. All staff complete IRB (re)certification as required. All new staff and research volunteers will receive training in issues pertinent to research among LGBTQ young adults, and will sign a confidentiality pledge prior to any contact with participants or data. No identifying information is collected prior to the moment at which a participant provides informed consent.

Participants will be recruited into the study by online advertisements, emails, or flyers containing a link to our brief screening instrument online. Participants who pass the online screening instrument will be called by a research assistant. Before completing phone screening questions, participants will be provide verbal consent specific to the screening.

At the end of the phone screening, research assistants will e-mail eligible participants a PDF copy of the consent form and review the consent document with them. The RA will ensure that the participant understands the risks associated with the disclosure of information that could indicate imminent threat to self or others. 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 provide verbal consent. RAs will be instructed to contact the PI or project coordinator if he or she is unsure about any participant's capacity to consent.

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Protection Against Emotional Discomfort. It is possible that participants may experience emotional discomfort in responding to assessments or session material. 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. Staff members at our lab will be thoroughly trained in appropriate responses to participant distress through tri-annual trainings by a licensed clinical psychologist. This training will address the appropriate handling of imminent threats and provision of referrals to counseling services in less imminent clinical situations. We have developed protocols for mitigating such risks as employed in our other and in-person online treatment studies with LGBTQ young adults. One such study recently took place in rural Appalachian Tennessee with no adverse events (Protocol # 1512016952).

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. All study therapists and research assistants will undergo rigorous training in maintaining participants' privacy and confidentiality and will be 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 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 therapists 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 on Yale Secure Box. 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.

11. 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.

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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.).

12. What is your assessment of the overall risk level for subjects participating in this study?

minimal

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

minimal

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. High

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, the Institutional Review Board (IRB) or the Data Safety Monitoring Board (DSMB) 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 DSMB will be informed of serious or unanticipated adverse events within 5 days of the event becoming known to the principal investigator.

14. 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?

Yale University is the only site at which participants will be enrolled.

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15. **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 health problems and associated behavioral health risks (e.g., substance abuse, suicidality, sexual risk) among LGBTQ young adults is a clear public health concern in need of easy-to-disseminate solutions. All participants in the present study will be exposed to information about mental and behavioral health in relation to social stress. We anticipate that participants will acquire knowledge and skills and will receive support needed to improve their capacity for managing mental and behavioral health risk. Benefits to society in general are anticipated through the dissemination of intervention findings and community trainings in the EQuIP treatment approach. Results will better inform local and national public health agencies about potentially effective outreach and prevention strategies that can be delivered to LGBTQ young adults who experience stress-sensitive mental health disorders, such as depression and anxiety, and related behavioral risks. In sum, the potential benefits outweigh the potential risks to subjects.

We propose to further test a preliminarily efficacious intervention, this time online, to help LGBTQ young adults manage their mental and behavioral health. Findings from this study can be used to help guide prevention efforts for both LGBTQ young adults and other socially disadvantaged groups who experience stress-sensitive mental health disorders. Given the public health importance addressed by this project and the potential benefit of the information to be gained, we believe that the risk to subjects is reasonable. Further, the information from this intervention can serve to benefit more widespread mental health promotion efforts. Specifically, information from this study will inform public health agencies regarding the effectiveness of an intervention that addresses co-occurring mental and behavioral health risks. This test will lay the groundwork for future studies examining the strategic implementation of this intervention.

SECTION VIII: RESEARCH ALTERNATIVES AND ECONOMIC CONSIDERATIONS

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

All participants and potential participants will be provided with a list of community referrals, including, as available in each participants' region, psychological, medical, HIV/STD testing, substance use, and housing supports. Notably, we intentionally recruit participants from low-resources regions as a matter of the capacity of our intervention to serve as a needed public health response.

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 sweepstakes: 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.

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Participants will receive $30 for completing the baseline assessments, $30 for completing the 3-month follow-up assessments, $10 for each weekly session or mood tracking survey completed, and $30 for completing the 6-month follow-up assessment (total = $190). Payment will be prorated for partial study completion (i.e., participants will only be paid for the parts of the study that they completed). Participants who participate in the phone interview will receive $30. All study payments will be in the form of e-mailed Amazon gift cards or Venmo payments. Venmo payments will be sent to participants from the private @Yale-Study account and will be accompanied with the text "Thank you for your time."

Starting in September 2021, as participants start to become eligble to complete their final follow-up assessments, we will hold a monthly sweepstakes for all randomized participants who successfully completed their 8-month follow-up assessment in the past month. Each month, the sweepstakes winner will be selected using a random number generator. Winners will receive $100 via Amazon gift cards or Venmo payments (as per their indicated preference) and will be notified via email directly after the selection of the sweepstakes winner. We will hold this monthly sweepstakes each month from September 2021 until February 2022, when the last randomized participant will have completed their final follow-up assessment.

All randomized participants will be notified about the sweepstakes via email in September 2021, including the sweepstakes prize, frequency of sweepstakes and odds of winning. Following that, participants will be notified about the monthly sweepstakes in their follow-up reminder emails from the EQuIP research team.

For participants who have previously completed their 8-month follow-up assessment (i.e., a total of 10 participants as of 8/26/21), we will hold a retrospective sweepstakes in order for these participants to have the same opportunity of receiving $100. In the same way as described above, these participants will be notified via email about the sweepstakes. We will hold this one-time retrospective sweepstakes at the beginning of September 2021.

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. All study treatment (online EQuIP, online Unified Protocol) will be provided free of charge to all study participants.

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SECTION IX: PRINCIPAL INVESTIGATOR AGREEMENT

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

1. The information provided in this application is complete and accurate.
2. I assume full responsibility for the protection of human participants and the proper conduct of the research.
3. Subject safety will be of paramount concern, and every effort will be made to protect participants' rights and welfare.
4. 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.
5. All members of the research team will be kept apprised of research goals.
6. 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..
7. I will report to the HSC any unanticipated problems involving risk to participants.
8. 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.
9. 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, Ph.D._____ April 30, 2019

PI Name (PRINT) Date

John E. Pachankis

_____

Signature

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

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conduct this trial appropriately.

_____ _____

Chair Name (PRINT) and Signature Date

_____

Department

For HIC Use Only

_____ _____

Date Approved **Human Investigation Committee Signature**

This protocol is valid through _____

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