The BH-Works Suicide Prevention Program for Sexual and Gender Minority Youth

NCT05922670

December 9th, 2024

Study Protocol

Appended: Statistical Analysis Plan

INSTRUCTIONS:

- *Use this "TEMPLATE PROTOCOL (HRP-503)" to prepare a study protocol outlining your research plan.*
- *Depending on the nature of your study, some major sections might not be applicable to your research. If so, simply mark as "N/A." For example, a simple survey might have many sections with "N/A." For subsections (e.g., 1.x or 8.x) you can mark as "N/A"if you are certain that the subsection is not applicable.*
- *Once the IRB/HRPP approves your submission, your latest approved version of the protocol will be stored in the IRB Protocol Management online system.*
- *If your research plan changes and you need to modify the protocol, please submit an amendment to Protocol Management with the requested modifications. Download your current protocol from Protocol Management and indicate the changes/revisions using the track changes feature in order to make review of the modifications easier to follow. If you are unable to use track changes, please create a new paragraph wherever you need to make a change, and indicate "Amendment: Date" before making a change to any section. Protocol management will store the older versions of your protocol if the IRB or HRPP staff need to compare them during the review.*

PROTOCOL TITLE:

Include the full protocol title.

The BH-Works Suicide Prevention Program for Sexual and Gender Minority Youth

PROTOCOL NUMBER:

Include the number assigned in Protocol Management (verify this has been added before submitting protocol to HRPP).

22-079

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Table of Contents

1.0 Study Summary

Study Title	The BH-Works Suicide Prevention Program for Sexual and Gender Minority Youth
Study Design	Quasi-experimental. Effectiveness-Implementation Hybrid Type 2 design with a control group.
Primary Objective	**To test the feasibility, acceptability, and preliminary effectiveness of BH-Works within the LGBTQ organizations and their BH partners.**
Secondary Objective(s)	Informed by the Consolidated Framework for Implementation Research (CFIR; Damschroder et al., 2009), we will pilot test a sequenced implementation strategy. This strategy focuses on building partnerships and involves a) promoting engagement, b) strengthening relationships, and c) creating sustainability. In Years 1 and 2, we will collect treatment as usual data, and work with stakeholders to adapt BH-Works policy, content, practices, and workflow. We will also train staff in suicide risk management, family engagement, and affirmative care. In Years 3 and 4, we will test the adapted SGM BH-Works Program and examine several essential program targets and outcomes, which are outlined in our aims. Three aims focus on engagement, adaptation, and feasibility/acceptability of SGM BH-Works. ***Aim #1: Engage LGBTQ organization staff and partnering behavioral health providers.*** This aim focuses on: a) engaging a stakeholder advisory group, and b) initiating our implementation strategy. ***Aim #2: Adapt and pilot the BH-Works Program for LGBTQ organizations and partnering behavioral health sites.*** The adapted BH-Works Program will be implemented into LGBTQ organizations' workflow for a one-month open trial. Qualitative and quantitative data will be collected to evaluate initial feasibility and acceptability as well as to explore barriers and facilitators to usability in urban and rural organizations. The manual will undergo revisions. ***Aim #3: Test the feasibility, acceptability, and preliminary effectiveness of the SGM BH-Works Program compared to a historical control group.*** This quasi-experimental design will test the relationships between targets (training impact, partnership development, software usability) and outcomes (successful referral, program satisfaction, caregiver involvement, suicide

	identification). The proposed research responds to the growing national need to identify and refer vulnerable youth at risk for suicide.
Study Population	SGM adolescents (14-17) and emerging adults (18-19), Caregivers of SGM adolescents/emerging adults, LGBTQ center staff, and behavioral health providers.
Sample Size	Staff and administrator recruitment (7/15/24-8/15/26): 24 (for all project aims) Youth recruitment (12/1/24-8/15/26): 160-200 (for all project aims) Caregiver recruitment (12/1/24-8/15/26): 50-90 (for all project aims)
Research Intervention(s)/ Investigational Agent(s)	Qualitative interview data, focus group data, questionnaires, surveys, assessment tools (appended).
Study Duration for Individual Participants	Staff and administrator participants will engage in study activities from 7/15/24-8/15/26. Adolescent (14-17) and emerging adults (18-19) and caregiver participants will be asked to engage in follow-up assessments (quantitative and qualitative) for no more than one month after consent.
Acronyms and Definitions	SGM= Sexual and Gender Minority Youth BH-Works= Behavioral Health Works program LGBTQ= Lesbian, Gay, Bisexual, Transgender, Queer DCI= Diversity Camp, Inc. FTC= Family Therapy Center of Virginia Tech

2.0 Objectives

2.1 Describe the purpose, specific aims, or objectives of this study:

Suicide is the second leading cause of death for 15-to-24-year-olds in the United States (U.S.) (Hoyert, 2012). Yet, only 14% of youth with suicidal ideation and 22% of those who make a suicide attempt, report receiving mental health services (Nock et al., 2013). The circumstances that sexual and gender minority (SGM) youth face are particularly alarming. Compared to their heterosexual and cisgender peers, SGM adolescents report far higher rates of suicidal ideation and suicide attempts (Bauer et al., 2015; Haas et al., 2011; Perez-Brummer et al., 2017; Toomey

et al., 2018). Consequently, adoption of effective suicide prevention programs, that increase identification and referral in organizations serving this population, are sorely needed.

Unfortunately, many barriers complicate the implementation of suicide prevention for SGM communities. SGM youth often report feeling unwelcome and misunderstood in traditional behavioral health service organizations (Guss et al., 2019; Qureshi et al., 2018). Consequently, treatment attendance and retention remain low (Olson-Kennedy, 2016). Instead, this population generally seeks mental health services in community organizations for lesbian, gay, bisexual, transgender, and queer (LGBTQ) youth (Fish et al., 2019; Pachankis et al., 2021). Unfortunately, these organizations are often unprepared for this clinical challenge. Specifically, they lack a) training in risk assessment, b) standardized screening tools, and c) access to behavioral health (BH) services that staff trust (Allen et al., 2012; Skaer et al., 2009; Diamond et al., 2011; Wintersteen & Diamond, 2013; Williams, et al., 2009). In addition, staff in LGBTQ organizations express concern that many BH providers lack the SGM-sensitivity needed to work with this high risk, vulnerable population. ***Given these challenges, suicide prevention for SGM youth requires a multi-faceted program aimed to improve resources within these organizations and relationships between service systems***.

A potential solution to this challenge is the Behavioral Health-Works (BH-Works) suicide risk management system (Diamond et al., 2010, 2017, 2021; Fein et al., 2010). Similar to the identify, treat and refer structure of SBIRT for substance use (SAMHSA, 2012), BH-Works includes support for policy development, staff training, suicide and behavioral health screening, technology-assisted safety planning, an electronic patient referral system, real-time data management for program monitoring, and a learning collaborative structure to support sustainability. All functions are supported on a web-based platform that facilitates cross-system communication, implementation, adoption, and expansion. BH-Works has been used in both clinical and non-clinical settings. In this project, we will adapt BH-Works for SGM adolescents presenting in LGBTQ organizations and use data from the web-based screening and EMR systems to measure targets and outcomes. We will employ the Enhancing Engagement trajectory, from Lau's (2006) cultural adaptation framework for this purpose. Lau recommends that adaptation of EBTs is necessary when contextual processes (e.g. discrimination, caregiver support, mistrust of health systems) contribute to unique vulnerabilities in specific populations, particularly those living in contexts where fewer specialized services exist. This project builds upon partnerships with two LGBTQ organizations (Mazzoni Center, in Philadelphia, and Diversity Camp Inc., in rural Southwest, Virginia) and their respective BH partners (Thomas Jefferson and Carilion Clinic).

We will use an Effectiveness-Implementation Hybrid Type 2 design (Curran et al., 2013), with a historical comparison group, to test the feasibility, acceptability, and preliminary effectiveness of BH-Works within the LGBTQ organizations and their BH partners. Informed by the Consolidated Framework for Implementation Research (CFIR; Damschroder et al., 2009), we will pilot test a sequenced implementation strategy. This strategy focuses on building partnerships and involves a) promoting engagement, b) strengthening relationships, and c) creating sustainability. In Years 1 and 2, we will collect treatment as usual data, and work with

stakeholders to adapt BH-Works policy, content, practices, and workflow. We will also train staff in suicide risk management, family engagement, and affirmative care. In Years 3 and 4, we will test the adapted SGM BH-Works Program and examine several essential program targets and outcomes, which are outlined in our aims.

Three aims focus on engagement, adaptation, and feasibility/acceptability of SGM BH-Works. ***Aim #1: Engage LGBTQ organization staff and partnering behavioral health providers.*** This aim focuses on: a) engaging a stakeholder advisory group, and b) initiating our implementation strategy. ***Aim #2: Adapt and pilot the BH-Works Program for LGBTQ organizations and partnering behavioral health sites.*** The adapted BH-Works Program will be implemented into LGBTQ organizations' workflow for a one-month open trial. Qualitative and quantitative data will be collected to evaluate initial feasibility and acceptability as well as to explore barriers and facilitators to usability in urban and rural organizations. The manual will undergo revisions. ***Aim #3: Test the feasibility, acceptability, and preliminary effectiveness of the SGM BH-Works Program compared to a historical control group.*** This quasi-experimental design will test the relationships between targets (training impact, partnership development, software usability) and outcomes (successful referral, program satisfaction, caregiver involvement, suicide identification). The proposed research responds to the growing national need to identify and refer vulnerable youth at risk for suicide.

2.2 State the hypotheses to be tested:

Hypothesis #1:All stakeholder partners will approve the adapted manual.

This hypothesis will be tested by evaluated the number of stakeholders who approved the manual on our advisory board.

Hypothesis #2: LGBTQ staff and behavioral health providers will report increased preparedness, likelihood of skill use, and self-efficacy.

Hypotheses #3a: LGBTQ staff will report increased confidence referring SGM patients to partnering behavioral health providers.

Hypothesis #3b: Behavioral health providers will report increased confidence working with SGM patient referrals.

Hypothesis #4: LGBTQ staff and behavioral health providers will report increased software usability.

To test these four hypotheses, we will use a mixed-effects linear model to estimate the pre-training and post-training changes in staff training impact outcomes. Because of the repeated

measurements of the dependent variable, we will treat the multiple observations as nested within individuals. We will also cluster the standard errors to account for any differences between the two study sites. An identical approach will be used for analysis of other outcomes such as comparing the trajectories of the outcomes over the consultation time period (three times points of data).

Hypothesis # 5: The SGM BH-Works program will increase the percentage of identification of SGM adolescents at-risk for suicide, compared to a historical comparison group.

Hypothesis #6: The SGM BH-Works program will increase percentages of successful referrals to behavioral health providers, compared to a historical comparison group.

To determine whether participating in the SGM BH-Works program changes these percentages, we will compare the differences in proportions on the outcome variables (proportion identified as at-risk; proportion of successful referrals) based on the phase of the study (i.e., historical control vs. intervention), using a two-sample test of proportions. We will report the z-statistics (Prtest in STATA). We will also compare differences in primary outcomes across sites. If significant differences are found between program sites, then the proportional tests will be conducted separately for both sites.

Hypothesis #7: All participant groups will report satisfaction with SGM BH-Works program elements.

We will test this by running descriptive statistics on the AIM for consumer groups. Program satisfaction for staff/providers will be measured using AIM at three time points. Change in program satisfaction over time will be estimated using mixed models. Standard errors will be clustered to account for differences between the two study sites. Interview data will be transcribed verbatim and imported into MAXQDA, qualitative data analysis software. Interview transcripts and staff/provider free responses will be analyzed by two coders using theoretical thematic analysis procedures as outlined by Braun and Clarke (2006). The coding will be guided by the primary research question: What are patient and caregiver perceptions of the SGM BH-Works program?

Hypothesis #8: The SGM BH-Works program will increase the percent of caregivers involved in their child's referral process, compared to a historical comparison group.

To explore this mechanism of change, we will compare the percent of caregivers involved in their child's referral process to a historical comparison group, using the two-sample proportional test (Prtest).

3.0 Background

3.1 Summarize the relevant prior research on this topic and gaps in current knowledge within the field of study:

A. SIGNIFICANCE

Suicide is a serious, growing, and multidimensional public health problem in the United States. It is particularly serious in youth populations (adolescents and emerging adults) where it is the second leading cause of death for 15-to-24-year-olds, and the fourth leading cause of death for 5-to-14-year-olds (Hoyert, 2012). In 2011, an estimated 12.1% of youths contemplated suicide, 4.0% made a plan, 4.1% made an attempt, and 4,688 youths died by suicide (Nock et al., 2013; Hoyert, 2012). Sexual and gender minority (SGM) youth are particularly at risk (Liu & Mustanksi, 2012; Price et al., 2017). These youths report higher rates of both suicidal ideation and suicide attempts than their heterosexual (Fergusson, Horwood, & Beautrais, 2005; Haas et al., 2011; Russell & Joyner, 2001; Russell, 2003) and cisgender counterparts (James et al., 2016). While the majority SGM youths are healthy, functioning, and resilient (Savin-Williams, 2005), between 15% and 40% make a suicide attempt each year (Fergusson, Horwood, & Beautrais, 2005; Liu et al., 2020; Russell & Joyner, 2001; Russell, 2003; Zhao et al., 2010). The Minority stress theory may help explain why SGM youth are more vulnerable to suicide (Meyer, 2003). These stressors, high in this population, include gender dysphoria, family rejection, identity-based victimization, bullying, stigma, discrimination, and abuse (Aranmolate et al., 2017; Hall, 2018; Russon et al., 2021). Given the high risk of suicide in this population effective suicide prevention programs are sorely needed. Unfortunately, many barriers prevent SGM youth from obtaining suicide prevention services.

A.1. Patient Barriers. SGM youths do not present for clinical trials, nor do they seek services in traditional mental health settings (Lerner & Robles, 2017; Institute of Medicine, 2011; Reisner et al., 2016). When SGM youth do seek behavioral health services, they often feel unwelcome and misunderstood (Guss et al., 2019; Kano et al., 2015; Synder et al., 2016; Qureshi et al., 2018). Thus, retention is low (Olson-Kennedy, 2016). Consequently, this population receives the bulk of their care in LGBTQ organizations and/or gender-affirming medical services.

A.2. Provider Barriers. Unfortunately, Many LGBTQ organizations are unprepared for suicide identification and management. Specifically, there is lack of a) training in risk assessment, b) use of standardized screening tools and c) access to mental health services that staff trust (Allen et al., 2012; Skaer et al., 2009; Diamond et al., 2011; Diamond & Wintersteen, 2013; US Preventive Services Task Force, 2009; Williams, et al., 2009). Staff in LGBTQ organizations express concerns that behavioral health providers lack the SGM-sensitivity to work with this high risk, vulnerable population (Russon et al., 2021). Staff often worry that the experience of an emergency department will traumatize SGM youth, given hospital staff insensitivity (e.g., use of dead names or wrong pronouns, restriction of access to gender neutral bathrooms, inadvertently outing youth to family members). In our preliminary studies, we have found that LGBTQ organizations also under refer because they become habituated to severe mental health distress and suicidality, given the high and chronic rates in SGM populations (Russon et al., 2021).

A.3. Family Involvement. Suicide risk management for SGM youthis further complicated by conflicts about family involvement Generally, when youth are in suicidal crises, contacting and involving caregivers is a critical “safety net” procedure and serves to ensure treatment follow-up (G.M. Diamond et al., 2021). Unfortunately, SGM youths often attribute their suicidal thoughts

and behaviors to a) the conflicts in their relationship with their caregiver(s), b) family rejection of their identity, c) negative familial events unrelated to identity and d) incidents of extra-familial victimization to which family members are unable or unwilling to respond (G.M. Diamond et al., 2011; 2012). Even when family factors are not the cause of distress, many SGM youth do not turn to their caregivers for help with victimization or bullying, fearing caregivers will not protect them (Hammelman, 1993; Hunter & Schaecher, 1987; Savin-Williams, 1989; 1994). This situation becomes particularly complicated for staff and providers when caregivers are unaware of the youth's sexual orientation and/or gender identity. Staff at LGBTQ organizations must navigate these challenges when deciding to involve caregivers in risk management strategies when youth present with STB. Unfortunately, often LGBTQ provider view family involvement negatively (Russon et al., 2021).

Given these multi-layered challenges, suicide prevention for SGM youth requires a multi-faceted program aimed to improve resources within these organizations and relationships between LGBTQ and behavioral health service systems. Unfortunately, to date, no rigorous studies have explored suicide risk management tools, practices, and policies in LGBTQ organizations, nor is there published information describing how these organizations navigate the unique challenges described above. Research clearly identifies the need for integrating suicide management programs into general medical practice (Asarnow & Miranda, 2014), but we have found no research focused on importing this "technology" into services that work with this vulnerable population.

A.4. Current Study. Fortunately, over the past 15 years, this research team has worked closely with this community on suicide prevention and has developed, tested, and extensively disseminated a suicide risk management program that could be imported into these LGBTQ organizations. Similar to the SBIRT program for drug treatment (SAMHSA, 2012) and informed by the implementation sensitivity of Zero Suicide (Richards et al., 2021), we have developed a web-based, multi-component, systems change approach for youth suicide prevention. The Behavioral Health-Works (BH-Works) suicide prevention program has been successfully used in schools, primary care, emergency rooms, college counseling centers, and mental health facilities (Diamond et al., 2017; Diamond et al., 2021; Fein et al., 2010). In this project, we will adapt and import this program into LGBTQ organizations. This project builds upon robust partnerships with two diverse LGBTQ organizations (Mazzoni Center, in Philadelphia, Pennsylvania and Diversity Camp Inc., in rural Roanoke, Virginia) and their behavioral health partners (Thomas Jefferson psychiatry, in Philadelphia and Carilion Clinic psychiatry, in Roanoke). The PI also has extensive relationships with several nationally-known LGBTQ organizations that will advise us as we adapt BH-Works to meet the needs of these organizations and the SGM youth they serve.

While the BH-Works program has demonstrated success in a variety of settings, we expect there to be unique implementation challenges for organizations serving SGM youth. It has become well-recognized that the gap between science and practice is wide and deep (Aarons, Hurlburt, & Horwitz, 2011; Hoagwood, 2013), particularly in organizations that serve vulnerable youth (Fish, 2020). In order to account for the human and organizational factors influencing program implementation (Fixsen et al, 2005), we draw on the CFIR framework (Damschroder et al., 2009). Working for 20 years in multiple service contexts, this framework has helped us map our program onto the culture of our agency partners. Domains to consider in this framework

include: outer settings (external policy, local context, patient needs), inner settings (resources, fit, leadership), staff characteristics (training, knowledge, beliefs), intervention characteristics (complexity, relative advantage), and implementation processes (facilitation, planning, coaching). These considerations mirror those laid out in the SBIRT implementation manual developed by the National Center on Addictions and Substance Abuse at Columbia University (2012). In this project, we aim to focus primarily on staff characteristics (e.g., staff preparedness, self-efficacy) and inner settings (e.g., utilization of program, partnerships). CFIR suggests a sequenced approach to program implementation with new target populations. Guiding principles include involvement from key stakeholders and the integration of feedback. Both these principles are carried forward in this project. We begin our project with stakeholder engagement. Our community partners, consultant, and national advisory board will support the adaptation of the BH-Works program for SGM youth. We will also collect treatment as usual data at LGBTQ sites. Next, we will train our partnering organizations in suicide risk management, use of the BH-works system, and affirmative care practices. Finally, we will test the effectiveness of the program using an Effectiveness-Implementation Hybrid Type 2 design (Curran et al., 2013) with a historical comparison group to pilot the BH-Works program within LGBTQ organizations.

3.2 Describe any relevant preliminary data:

This section illustrates the PI's extensive foundational work introducing suicide prevention and intervention strategies into LGBTQ organizations and with SGM consumers.

Effective collaboration efforts. The American Foundation for Suicide Prevention awarded the PI a two-year postdoctoral fellowship to implement an empirically supported, family-based suicide treatment (attachment-based family therapy, ABFT; Diamond et al., 2014, 2019) into several LGBTQ organizations in Philadelphia. She spent a year conducting focus groups with administrators, providers, adolescents, and caregivers (parents and families of choice) in these organizations. These focus groups aimed to better understand barriers and facilitators for SGM youth needing suicide care (Russon, et al., 2021). She then modified the delivery of ABFT for LGBTQ organizations and conducted a pilot study of the treatment (Russon et al., 2021). Besides the important findings resulting from this research (described below), these efforts demonstrate the PI's ability to conduct research in collaboration with the SGM community, which remains quite ambivalent about outsiders, and academics in particular.

Focus groups with providers, adolescents, and parents. The PI conducted interviews and focus groups with key stakeholders and consumers in LGBTQ organizations [adolescents/young adults (n= 9), caregivers (n= 11), providers (n= 32), administrators (n= 10)] (Russon et al., 2021). These interviews were coded and analyzed using thematic analysis. Several key findings from each stakeholder group were revealed. First, SGM youth reported mistrust of healthcare systems and clinicians. They described experiences of discrimination outside of LGBTQ organizational settings. Second, caregivers of SGM youth expressed a desire for more engagement in their child's care. Third, providers reported varying levels of comfort assessing suicidality and engaging in empirically supported treatments. They had mixed feelings about screening tools and manualized treatments. Many felt unprepared to care for youth with STB in their organization, citing a lack of psychiatric and clinical supports. The PI found that providers

had become habituated to the presentations of severe mental health distress and suicidality in the youth they were serving. They were, however, reluctant to make referrals to behavioral health centers citing concerns that these settings lacked competency working with SGM populations. These providers had mostly negative views of SGM youths' family members, seeing them as a source of stress rather than a resource, even during times of crisis (e.g., suicide). Finally, administrators emphasized the need for SGM-affirmative suicide prevention services. They were concerned that behavioral health providers were mandated to see SGM patients, but were offered limited training in affirmative care. Administrators cited the same concern as providers, emphasizing limited referral possibilities for these youth.

Intervention research with SGM communities. Building on qualitative findings, the PI conducted an open trial study of ABFT within three SGM organizations, one of which is participating in the proposed project (Mazzoni Center). The study included 10 SGM youth (ages 14-25) presenting with severe levels of suicidal ideation. The study included caregivers, including families/caregivers of choice. The qualitative findings described above informed modifications to the treatment and its implementation in LGBTQ organizations. The study had 100% treatment retention and 96% completion of research assessments. Treatment acceptability was evaluated on therapeutic alliance (WAI; Horvath & Greenberg, 1989) and confidence in treatment (OAT; Borkovec & Mathews, 1988). Responses on both measures were consistently high throughout treatment. Treatment outcomes were measured on the Suicidal Ideation Questionnaire (SIQ-JR; Reynolds & Mazza, 1999) and Beck Depression Inventory (BDI II; Beck, et al., 1996). Results showed a significant decrease in suicidal ideation ($\beta = -12.16$, $t(10) = -3.14$, $p < .01$). More than half of the youth (55%) no longer expressed severe levels of suicidal ideation (SIQ ≥ 31) at end-of-treatment. Caregivers reported high levels of program satisfaction and increased parenting capability. The majority of families wanted to continue treatment after the 16-weeks. Providers reported surprise and encouragement that caregivers could be included in the treatment process. Overall, the interviews and intervention research demonstrate this team's ability to successfully carry out suicide prevention work with this high-risk population, in these complex working environments.

3.3 Based on the existing literature, provide the scientific or scholarly rationale for and significance of your research and how will it add to existing knowledge:

C1. Preliminary studies.

Here we demonstrate that the co-investigator has a career focused on conducting suicide prevention and intervention research, including 15 years of work developing and testing the BH-Works program. Given this history, these investigators are well prepared for the planned investigation.

Developing, testing and disseminating the BH-Works program. Reflective of the SBIRT program for drug treatment (SAMHSA, 2012) and the implementation sensitivity of Zero Suicide (Richards et al., 2021), this research team has developed a web-based, comprehensive program for suicide prevention (Diamond et al., 2010, Wintersteen & Diamond, 2013). The BH-

Works program is a systems-level intervention that provides tools and resources to make organization adoption more feasible. It provides several elements that would support the kind of systems-level interventions recommended by Zero Suicide (Richards et al., 2021). The program provides assistance with policy development, staff training, standardized suicide and behavioral health screening, technology-assisted safety planning, patient referral, real time data analytics and support for sustainability (see Table 1). These components are well-developed and have been delivered online for several years. All functions are built into, or supported by, the BH-Works platform and accompanying website (see BH-Works.com; BHLCofPA.com). The platform can deliver many different screening options (e.g., PHQ-9), but we primarily use the Behavioral Health Screen (Diamond et al. 2010).

Table 1. The BH-Works System: Current Functions and Training in the BH-Works Systems

Policy	Staff training	Screening	Engagement	Safety	Referral	Program Evaluation	Sustain-ability
Provide guidance on policy development	Suicide risk managemen t training	Screening with the Behaviora l Health Screen	Training in family and patient engagement	Generate safety plan	Electronic referral systems	Data dash board for real time analytics	Learning Collabor -ative

The system has been used widely in multiple settings, including emergency rooms, primary care, schools, mobile crisis, college health center, and residential treatment settings. The program has been operational in the emergency department of the Children's Hospital of Philadelphia, where we screen nearly 60% of all patients. To date we have screened over 40,000 patients and increased the suicide detection rate from 2% to 5% (Fein et al., 2010). The program is in 47 counties across the state of Pennsylvania and used by over 100 school-based mental health professionals. We have screened over 12,000 students and increased the suicide detection rate from 4% to 15% (Diamond et al., 2021). We are providing an extensive program outcome monitoring system for Newport Academy, an adolescent residential program with 31 sites around the country. In these residential sites, we are screening 2,000 patients a year with repeated assessments during treatment and, then, at 6-month follow-up. We have recently partnered with the Michigan Department of Education who will be offering the screening program to every school across the state. This wide adoption of BH-Works demonstrates our ability to broadly implement this program across settings and make it operational.

4.0 Study Endpoints

*4.1 Describe the primary and secondary **study** endpoints. See links below for discussion of study endpoints and how they may differ from study objectives. These are most common in clinical trials but are sometimes applicable to other types of biomedical research, as well as social, behavioral, or educational research. See link below for a discussion.*

https://docs.google.com/document/d/1Wocz7K7a0hCQJPPO_khh5l1SQQjhGDDGHzcOPRHR5Tw/edit?usp=sharing

Models of the dissemination and implementation of EBTs uniformly emphasize the necessity of involving stakeholders in the program planning, implementation, and evaluation activities of the project (Aarons, et al., 2011; Bernal et al., 2009; Simpson & Flynn, 2007). Therefore, our aims focus on: a) engaging a collaborative stakeholder advisory group; and b) adapting BH-Works manual and training programs.

Engage advisory board and workgroup. A local and national advisory board will serve as project collaborators. This group includes academics, educators, administrators, practicing professionals, and community members who are committed to SGM health. LGBT CenterLink, and our partners at Mazzoni Center and Diversity Camp, Inc., will assist in identifying SGM youth and their caregivers to serve on the board. Our collaboration with CenterLink, the only organizing body for LGBTQ community centers in the world, will have a central role in steering this project. A smaller workgroup will consist of project investigators, leadership from our partnering sites.).

Implementation Strategy. Our implementation strategy focuses on building partnerships and will be started in Years 1 and 2. The overall strategy incorporates three specific strategies: 1) promoting engagement; 2) facilitating professional relationships through learning; and 3) creating sustainable platforms for communication. The first strategy, promoting engagement, involves identifying and connecting professional leaders in LGBTQ organizations and behavioral health settings. For this project, this strategy has already been completed in preparation for this proposal. We have identified LGBTQ organizations (Mazzoni Center and Diversity Camp, Inc.), in two regions of the United States and matched them with local behavioral health partners in child and adolescent psychiatry departments. Leaders of these sites have agreed to participate in collaborative efforts to address suicidality among SGM youth in their localities. In future projects, we will have broader representation of behavioral health organization types.

The second implementation strategy uses the proposed training program as an opportunity to build professional relationships and trust between staff in the different organizations. Our research indicates that staff in LGBTQ organizations are hesitant to refer to behavioral health providers due to concerns about competence in affirmative practice. To address this issue, we invite staff from both organizations to participate in the trainings together. As part of this conjoint training, dialogue and experiential activities offer avenues for these professionals to learn new skills and build trust together. We expect this will increase LGBTQ staff members' confidence in making referrals and increase behavioral health providers' confidence in working with this population. Staff/providers from each organization will also discuss readiness to implement the BH-Works system, using a facility readiness questionnaire as a guide.

Our final implementation strategy focuses on sustainability. At the beginning of Year 3, case consultation sessions will be held with staff from both agencies. This will ensure the highest quality of care for patients and help to maintain the dialogue needed to sustain relationships. In addition, the BH-Works program includes the creation of a learning collaborative website that is

used for documenting program progress and facilitating cross-system collaboration (see BHLCofPA.com for an example of one collaborative we currently facilitate for school-based providers in PA). A monthly Zoom meeting is held to showcase provider progress and convey new information. As more programs join this project in the future, this website will serve as the organizing tool.

Manual Adaptation. Manual adaptation will be steered by the project advisory board and revisions will be developed by the workgroup. Several activities will be conducted. First, we will review the entire BH-Works system, as well as the curricula of the two trainings (suicide risk management and affirmative care).

Second, our advisory board will make recommendations on modification to each of the BH-Works system components and the trainings. These recommendations will be incorporated into the implementation manual. All advisory board meetings will be conducted via video conference (e.g., Zoom), recorded and transcribed. Based on our preliminary studies, we expect the adapted manual to include modifications in terminology, addition of epidemiological information on SGM suicide, new family engagement strategies, and methods for addressing stigma and challenges related to confidentiality. Our revised manual draft (SGM BH-Works) will be reviewed by our advisory board and 10 outside reviewers: directors of LGBTQ organizations identified by CenterLink. This feedback will be reviewed by the advisory board and incorporated into the manual by the workgroup. The final version will be used to guide implementation in our performance sites.

*4.2 Describe any primary or secondary **safety** endpoints. These should be included for all studies that are greater than minimal risk. (Minimal risk: The probability and magnitude of harm or discomfort anticipated in the research that are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.)*:

The procedures conducted in this study mirror those practiced in routine behavioral health and QI studies. The risks to study participants are minimal and include the risks associated with potential a) stress from interview/survey/screening questions, and b) breach of confidentiality.

The BH program has not yet been implemented at Diversity Camp, Inc. or Carilion. Some programs within Mazzoni and Jefferson have been introduced to the BHS in the past. Implementing the BHS into the specific programs of our collaborators will be new. If the research is funded, it is expected that the sites will continue to use the BHS program independent of the research project. Sustainability is a goal of the funder and the purpose of the research is to implement a program that is self-sustaining.

In sum, Previous work by the PI has adapted other suicide treatment procedures in these systems. We have not yet done the adaptation work with BH-Works, suicide risk assessment, referral, and engagement.

5.0 Study Design and Statistical Analysis Plan

5.1 Describe the basic study design/approach (e.g., qualitative study using five focus groups of first year students to describe assimilation into the university community; randomized controlled trial of a behavioral change intervention to increase dietary intake of whole grains; pre- post-test evaluation of new pedagogical techniques to improve adult literacy):

This study will employ an Effectiveness-Implementation Type 2 Hybrid design and utilize a historical, treatment as usual comparison group. The Type 2 Hybrid design is ideal for this study as it guides both the piloting of a clinical intervention and evaluation of implementation strategies (Curran et al., 2013).

For quantitative data, we will conduct descriptive univariate analyses on all study variables. Data will be screened for missing data, violations of normality, and presence of outliers. Because the data will be collected from consumers within screeners/providers, at the two sites, we will use mixed-effects models to accommodate for the nested data structure (Goldstein, 1987; Raudenbush & Bryk, 2002). These mixed models permit missing data and can fit individual trajectories over time even if time points are missing or unevenly spaced. Mixed models can also accommodate varied distributions of the dependent variable (e.g., binary, kurtotic). STATA v14.0 or higher will be used for all analyses. Confidence intervals (95%) and bootstrapped standard error estimates will be reported for statistical precision and effect sizes will be estimated to inform a large more comprehensive trial.

Our approach to quantitative and qualitative data according to hypothesis are described directly below, in section 5.2.

5.2 Describe corresponding data analysis plan/approach (e.g., content analysis of focus group transcripts; descriptive analysis followed by linear regression modeling; nonparametric analysis of pre- and post-test measures):

Analytic approach to each hypothesis:

For Hypothesis #1: All stakeholder partners will approve the adapted manual. This hypothesis will be tested by evaluating the number of stakeholders who approved the manual on our advisory board.

For Hypothesis #2: LGBTQ staff and behavioral health providers will report increased preparedness, likelihood of skill use, and self-efficacy; Hypothesis #3a: LGBTQ staff will report increased confidence referring SGM patients to partnering behavioral health providers;

Hypothesis #3b: Behavioral health providers will report increased confidence working with SGM patient referrals; Hypothesis #4: LGBTQ staff and behavioral health providers will report increased software usability- To test these four hypotheses, we will use a mixed-effects linear model to estimate the pre-training and post-training changes in staff training impact outcomes. Because of the repeated measurements of the dependent variable, we will treat the multiple observations as nested within individuals. We will also cluster the standard errors to account for any differences between the two study sites. An identical approach will be used for analysis of other outcomes such as comparing the trajectories of the outcomes over the consultation time period (three times points of data).

For Hypothesis # 5: The SGM BH-Works program will increase the percentage of identification of SGM adolescents (14-17) and emerging adults (18-19) at-risk for suicide, compared to a historical comparison group; Hypothesis #6: The SGM BH-Works program will increase percentages of successful referrals to behavioral health providers, compared to a historical comparison group- To determine whether participating in the SGM BH-Works program changes these percentages, we will compare the differences in proportions on the outcome variables (proportion identified as at-risk; proportion of successful referrals) based on the phase of the study (i.e., historical control vs. intervention), using a two-sample test of proportions. We will report the z-statistics (Prtest in STATA). We will also compare differences in primary outcomes across sites. If significant differences are found between program sites, then the proportional tests will be conducted separately for both sites.

Hypothesis #7: All participant groups will report satisfaction with SGM BH-Works program elements. We will test this by running descriptive statistics on the AIM for consumer groups. Program satisfaction for staff/providers will be measured using AIM at three time points. Change in program satisfaction over time will be estimated using mixed models. Standard errors will be clustered to account for differences between the two study sites. Interview data will be transcribed verbatim and imported into MAXQDA, qualitative data analysis software. Interview transcripts and staff/provider free responses will be analyzed by two coders using theoretical thematic analysis procedures as outlined by Braun and Clarke (2006). The coding will be guided by the primary research question: What are patient and caregiver perceptions of the SGM BH-Works program?

Hypothesis #8: The SGM BH-Works program will increase the percent of caregivers involved in their child's referral process, compared to a historical comparison group. To explore this mechanism of change, we will compare the percent of caregivers involved in their child's referral process to a historical comparison group, using the two-sample proportional test (Prtest).

Power Calculations. Our previous studies of the BHS have found a significant increase in identification and referral rates (7-8% difference, OR~5 to 6, i.e., medium-large effect size; Chen et al., 2010) after the initiation of the program. Specifically, there was a significant increase in the identification of mental illness or behavioral problems after initiation of the Behavioral Health Screening-Emergency Department (BHS-ED) (10.5% vs. 2.5%, OR = 4.58, 95% CI 3.53, 5.94) and more frequent ED-based behavioral health assessments by social workers or psychiatrists (8.3% vs. 1.7%, OR 5.12, 95% CI 3.80, 6.88). Based on this effect size, we expect

that a sample of 160 youth (i.e., historical comparison group and intervention group) will achieve >80% power to detect a significant difference in identification and referral proportions.

6.0 Setting

6.1 Describe the sites or locations where your research team will conduct the research. Consider each of the items listed below:

- *Identify where your research team will identify and recruit potential subjects.*
- *Identify where the team will perform the research procedures.*
- *Describe the composition and involvement of any community advisory board(s).*
- *For research conducted in other locations, describe:*
  - *Site-specific regulations or customs affecting the research at those locations.*
  - *Local scientific and ethical review structure at those locations. Examples include work in other cultures or ethnic groups (within or outside of the U.S.) and work with churches. The HRPP will provide additional guidance for international research.*

The research operations will be at the Family Therapy Center of Virginia Tech (FTC; Jody Russon, PhD., PI). Personnel at FTC will be responsible for the oversight of all research-related activities and for carrying out most of the tracking procedures. Mdlogix in Baltimore, Maryland will be responsible for maintaining the technological platform for BH-Works. Clinical performance sites include two, LGBTQ youth organizations. The first, Mazzoni Center (Philadelphia, PA), is one of only 12 integrative LGBTQ Health Centers in the country. It is a multi-service, community-based, health and social service provider that aims to advance the health and well-being of SGM communities. Mazzoni is one of the few centers in the City of Philadelphia that provides programming specifically for SGM youth. The second, Diversity Camp, Inc. (Roanoke, VA) is the only LGBTQ organization in the region centered on serving SGM youth. Diversity Camp, Inc. offers an annual summer camp for SGM youth and their families as well as a series of educational, mental health, and community programs all year round. Diversity Camp, Inc. will soon include the Youth Sexual and Gender Alliance (SAGA) group. Youth SAGA was founded 12 years ago in response to the dearth of services for SGM Youth in rural, Southwest Virginia. In addition to these LGBTQ youth organizations, we are partnering with child and adolescent psychiatry programs, in departments of psychiatry at Thomas Jefferson University (Philadelphia, PA) and Carilion Clinic (Roanoke, VA). Both these programs are fully functioning outpatient psychiatry programs providing intakes, crisis services, psychotherapy, and medication management.

7.0 Study Intervention(s)/Investigational Agent(s)

7.1 Describe the study interventions (including behavioral interventions) and/or investigational agents (e.g., drugs or devices) to be used in this study. Consider each of the items listed below:

- *Drug/Device Handling: If the research involves drugs or devices, describe your plans to store, handle, and administer the drugs or devices so that they will be used only on subjects, and only by authorized investigators.*
- *Describe whether any of the following will be used: microwaves, X-rays, DEXA scans, general anesthesia, or sedation*
- *If control of the drugs or devices used in this protocol will be accomplished by following an established, approved organizational SOP (e.g., Research Pharmacy SOP for the Control of Investigational Drugs, etc.), please reference the SOP in this section.*

Interventions. Several interventions will be piloted over the course of this project. These interventions include: a) trainings (suicide risk management and affirmative care); screening with the BHS; and c) use of the electronic referral system. These intervention components are packaged within the BH-Works structure.

Please see appended document for BH-Works implementation guide that will be used for the sites participating in this study.

BH-Works is a systems-level, multicomponent suicide prevention program designed for youth populations. The program includes two primary components, comprehensive web-based behavioral health screening (BHS), and an electronic referral system. The BHS component was developed by our research team. The BHS utilizes screening software developed by Medical Decision Logic, Inc. (mdlogix). This mdlogix technology allows for all screening data and referral information to be collected in the BH-Works platform. This gives staff and providers the ability to register patients, keep track of their data, and link information with local EMR platforms. The BH-Works platform allows patients to complete the screening tool on electronic devices, including smart phones. The electronic referral system component of BH-Works is a major innovation and strength of the program. BH-Works is cloud-based and offers a software informatics platform for collecting program data and facilitating referrals. This system enables staff and providers to write reports at the level of patients, provider, county, and state. Because the platform integrates with any site's local EMR, it can share data and reports back and forth between systems. The BH-Works platform pulls registration data from the EMR and, then, will deliver all the screening and tracking data. The platform instantly generates a report for review.

The BH-Works program is a suicide prevention program has been successfully used in schools, primary care, emergency rooms, college counseling centers, and mental health facilities (Diamond et al., 2017; Diamond et al., 2021; Fein et al., 2010). This project will adapt and import this program into LGBTQ organizations. This project builds upon robust partnerships with two diverse LGBTQ organizations (Mazzoni Center, in Philadelphia, Pennsylvania and Diversity Camp Inc., in rural Roanoke, Virginia) and their behavioral health partners (Thomas Jefferson psychiatry, in Philadelphia and Carilion Clinic psychiatry, in Roanoke).

This study will serve to adapt the BH-works program to LGBTQ+ youth organizations and their behavioral health partners. Therefore, the program will differ based on this adaptation from the historical implementation of BH-works.

Implementation Strategy. Our implementation strategy focuses on building partnerships and will be started in Years 1 and 2. The overall strategy incorporates three specific strategies: 1) promoting engagement; 2) facilitating professional relationships through learning; and 3) creating *sustainable* platforms for communication. The first strategy, ***promoting engagement***, involves identifying and connecting professional leaders in LGBTQ organizations and behavioral health settings. For this project, this strategy has already been completed in preparation for this proposal. We have identified LGBTQ organizations (Mazzoni Center and Diversity Camp, Inc.), in two regions of the United States and matched them with local behavioral health partners in child and adolescent psychiatry departments. Leaders of these sites have agreed to participate in collaborative efforts to address suicidality among SGM youth in their localities. In future projects, we will have broader representation of behavioral health organization types.

The second implementation strategy uses the proposed training program as an opportunity to **build professional relationships** and trust between staff in the different organizations. Our research indicates that staff in LGBTQ organizations are hesitant to refer to behavioral health providers due to concerns about competence in affirmative practice. To address this issue, we invite staff from both organizations to participate in the trainings together. As part of this conjoint training, dialogue and experiential activities offer avenues for these professionals to learn new skills and build trust together. We expect this will increase LGBTQ staff members' confidence in making referrals and increase behavioral health providers' confidence in working with this population. Staff/providers from each organization will also discuss readiness to implement the BH-Works system, using a facility readiness questionnaire as a guide.

Our final implementation strategy focuses on ***sustainability***. At the beginning of Year 3, case consultation sessions will be held with staff from both agencies. This will ensure the highest quality of care for patients and help to maintain the dialogue needed to sustain relationships. In addition, the BH-Works program includes the creation of a learning collaborative website that is used for documenting program progress and facilitating cross-system collaboration (see BHLCofPA.com for an example of one collaborative we currently facilitate for school-based providers in PA). A monthly *Zoom* meeting is held to showcase provider progress and convey new information. As more programs join this project in the future, this website will serve as the organizing tool.

Trainings. Two training curricula will be delivered in this project. Suicide Risk Management training is a day-long, online synchronous workshop. It provides an introduction to empirically-supported clinical strategies for professionals who manage suicide crises among youth populations. The training has three parts: risk assessment, safety planning, and family engagement. The training includes lecture, discussion, experiential exercises, and training videos of patient care. Follow-up consultations are offered to organizations who require assistance in

implementing these strategies. The training is used widely in several states to meet annual suicide awareness continuing education requirements for mental health providers. Participants consistently report an increase in knowledge, preparedness, and self-efficacy as a result of participation. Paired Sample T-Test was used to examine whether participants' scores differ from baseline to post intervention. A Bonferroni correction was applied, and all significance levels were set to .0167 to correct for Type I errors. Results indicate there was a statistical significant improvement in total score for suicide assessment $t(114) = -8.468$, $p < .001$, safety planning $t(96) = -9.862$, $p < .001$, and family engagement $t(78) = -6.151$, $p < .001$ from baseline to post-intervention. Our advisory board will review the material and help us modify this program for SGM youth.

Mazzoni Center's Affirmative Care training helps professionals learn LGBTQ-affirmative care techniques. The Education and Professional Development branch of Mazzoni Center offers tailored affirmative care training packages to a range of providers and educators serving SGM youth. These training programs offer organized workshops and consultations and have been tailored to medical professionals, educators, administrators, and behavioral health providers. The training curriculum starts with a half-day, online synchronous workshop and includes activities aimed to assist providers in noticing and navigating implicit bias in their healthcare settings. The training also helps providers consider health disparities in treatment, and understand stressors experienced by SGM patients. Like the Suicide Management curriculum, follow up consultations involve assessing and addressing specific gaps, barriers, and needs. All consultations are focused on creating safer environments for SGM patients in the context of consumer programs. Mazzoni Center has been providing education to professionals in Philadelphia and surrounding communities for over 40 years. Their training packages have been delivered in hundreds of organizations and are well-received by provider communities.

DCI-FTC partnership:

For the Diversity Camp, Inc. site only, a partnership with the Family Therapy Center of Virginia Tech will facilitate implementation of the BH-Works program. Instead of Diversity Camp, Inc. carrying out the BH-Works mental health screening and referral process independently, they will be partnering with the Family Therapy Center of Virginia Tech to do these activities. Further, as Diversity Camp, Inc. does not have the staffing to provide youth with monitoring and support in the time between mental health screen and first appointment, Family Therapy Center will be providing bridge services (for up to two weeks) to youth who endorse ANY risk on the highlighted items in the appended Behavioral health Screen Demo participant file, titled "Behavioral Heath Screen_DEMO (highlighted items). Youth who are at risk for suicide will be referred to the study's behavioral health partners at Carilion Clinic. Youth who endorse the highlighted items, but are not at risk for suicide, will be referred to community services. Youth who are in need of mental health support, but do not endorse highlighted items, will receive a follow-up call from Diversity Camp, Inc. to discuss their screening results and/or receive supportive resources (as needed).

The FTC will house the BHS platform (bhworks) and will consent youth to services and research activities at the time of screen. Those youth who will receive follow-up from DCI will be referred to DCI immediately following the screen (and FTC bridge service appointments will not

ensue) whereas youth who endorse critical items will have their bridge service sessions/contacts documented in their chart at the FTC. The bridge services to be provided by the FTC will follow the policies and procedures outlined for practice at this site. Mental health specialists are doctoral student family therapists under supervision of clinical faculty. All FTC specialists on this project not only will have received training in FTC policy and procedures, but will have also completed the Affirmative, Family-Based Youth Suicide Prevention training described in this protocol. The frequency of bridge services sessions provided by FTC therapists will depend on the unique needs of each case. Sessions will include continued suicide assessment and monitoring using the BHS and CSSRS, as clinically indicated. Assessment data and session content (FTC notes) will be analyzed for the purposes of bridge service program evaluation.

Because the FTC allowing minors (ages 14 and older) to consent to their own treatment, the research team has consulted with Virginia Tech legal about clinical policies and procedures to support participation. Recommendations from legal have been obtained and documented. Participating minors can consent to their own treatment without permission from parents/guardians. Further, healthcare providers may withhold records from parents/guardians if documentation in the chart indicates that giving access to these parents/guardians would cause harm to the youth. As such, at the time of screen, a determination will be made whether such documentation is indicated.

7.2 List the name of all drugs (including any vitamins, supplements, herbs, or nicotine) to be used in the study. Indicate whether they have FDA approval, and list any limitations for their use:

N/A

7.3 List all devices, how they will be used, their purpose in the study, and if they will be used in a manner consistent with their approved uses. If they will be used in ways that are not yet FDA approved, indicate whether they need an IDE or a determination that they are exempt from the IDE Determination. If a determination of significant risk or non-significant risk is needed for any of the devices, include the researcher's recommendation for each of those devices:

N/A

7.4 If the drug is investigational (has an IND) or the device has an IDE or a claim of abbreviated IDE (non-significant risk device), include the following information:

- *Identify the holder of the IND/IDE/abbreviated IDE.*

- *Explain procedures followed to comply with sponsor requirements for FDA regulated research for the following:*

	Applicable to:		
FDA Regulation	***IND Studies***	***IDE studies***	***Abbreviated IDE studies***
21 CFR 11	***X***	***X***	
21 CFR 54	***X***	***X***	
21 CFR 210	***X***		
21 CFR 211	***X***		
21 CFR 312	***X***		
21 CFR 812		***X***	***X***
21 CFR 820		***X***	

N/A

8.0 Procedures Involved

8.1 Describe and explain the study design:

This study will employ an Effectiveness-Implementation Type 2 Hybrid design and utilize a historical, treatment as usual comparison group. The Type 2 Hybrid design is ideal for this study as it guides both the piloting of a clinical intervention and evaluation of implementation strategies (Curran et al., 2013). After program adaptation, this project will implement and evaluate SGM BH-Works. We will evaluate primary program outcomes (increased suicide identification and successful referrals), secondary outcomes (program acceptability, software usability), and exploratory program mechanisms (training impact, partnership development, and caregiver involvement). We will implement the program in two LGBTQ organizations and their partnering psychiatry departments in Philadelphia, PA and rural Roanoke, VA. These two sites will allow us to explore cultural differences between these geographic locations.

Control group data will be collected from months 5-24, while we do manual and program adaptation (Aim #1). At the end of year 2, we will conduct the trainings with LGBTQ organizations and behavioral health site staff. We will initiate the screening tool for a month. Then, we will gather initial feedback on the program and make final adaptations to the manual. In years 3 and 4, we will run the program and collect satisfaction (patient), feasibility, acceptability, and preliminary effectiveness data. At the end of year 4, we will do closing focus groups with staff, administrators, caregivers, and patients at all sites. We will write up manuscripts and an R01 to test the SGM BH-Works program on a larger scale.

8.2 Provide a description of:

- *All research procedures being performed*
- *If the study has more than one procedure, session, and/or subject population, describe each procedure, session, and/or study population separately. For complex studies, you are encouraged to include a figure or chart.*

Aim #1: Engage LGBTQ organization staff and partnering behavioral health providers. This aim focuses on: a) engaging a stakeholder advisory group, and b) initiating our implementation strategy.

Administrative stakeholder participants have already agreed to participate in this research an serve as Co-Is on the project (a core tenant of CEnR). LGBTQ staff/behavioral health provider participants will be recruited by leadership to participate in this project. We expect to include 4-8 staff/providers at each site. Consenting processes will occur immediately before the first training begins. Each agency reports having at least 4 to 6 intake workers and all will be trained in the program. These staff members will complete assessments at the beginning of the study and then five times over the course of years 3 and 4. They will participate in a final interview after the one month pilot period and at the end of the study.

Engage advisory board and workgroup. A local and national advisory board will serve as project collaborators. This group includes academics, educators, administrators, practicing professionals, and community members who are committed to SGM health (see letters of support and commitment). LGBT CenterLink, and our partners at Mazzoni Center and Diversity Camp, Inc., will assist in identifying SGM youth and their caregivers to serve on the board. Our collaboration with CenterLink, the *only* organizing body for LGBTQ community centers in the world, will have a central role in steering this project. A smaller workgroup will consist of project investigators, leadership from our partnering sites, and our consultants (Willging, Diamond). The advisory board meets periodically throughout the project.

Aim #2: Adapt and pilot the BH-Works Program for LGBTQ organizations and partnering behavioral health sites. The adapted BH-Works Program will be implemented into LGBTQ organizations' workflow for a one-month open trial. Qualitative and quantitative data will be collected to evaluate initial feasibility and acceptability as well as to explore barriers and facilitators to usability in urban and rural organizations. The manual will undergo revisions.

Adaptation process. We will employ Lau's (2006) framework for the cultural adaptations of EBTs. Lau recommends that adaptation of EBTs is necessary when contextual processes (e.g. discrimination, caregiver support, mistrust of health systems) contribute to unique vulnerabilities in specific populations, such as SGM youth (particularly those living in rural contexts where fewer specialized LGBTQ services exist). In this project we focus on Lau's Enhancing Engagement trajectory of adaptation work. As such, our workgroup will focus on generating BH-Works program adaptations that will increase social validity, a potential target for increasing engagement. The role of the workgroup is essential in the adaptation process. We expect this group will increase the social validity of the program by helping us adapt the screening language

to be more affirmative, better manage matters of pronoun use, and address concerns about discrimination in standard operating procedures.

Adolescent, emerging adult, and caregiver participation in the pilot process mirrors what is described below in Aim #3. Following the Aim #2 pilot of the BH-Works program, organization staff, patients and caregivers will be invited to participate in a focus group to discuss features of the BH-Works program that they find appealing and unappealing, as well as suggestions for improvement. Responses will be consolidated across group and location type (urban vs. rural).

Aim #3: Test the feasibility, acceptability, and preliminary effectiveness of the SGM BH-Works Program compared to a historical control group. This quasi-experimental design will test the relationships between targets (training impact, partnership development, software usability) and outcomes (successful referral, program satisfaction, caregiver involvement, suicide identification). The proposed research responds to the growing national need to identify and refer vulnerable youth at risk for suicide.

Adolescent consent will begin at the point of screening. The BH-Works screening tool will be included in the standard of care procedures. However, our IRB has approved a brief consent at the beginning of the screen asking permission to use de-identified screening data for research; 90% of patients agree to participate. At the end of the BHS, participants complete a brief satisfaction measure about their experience with the screening tool. This is included as part of the screening process for ongoing QI purposes. In our past studies, if patients endorse any level of current suicidal ideation, a consent form is automatically presented at the end of the screening asking permission to follow up with the adolescent in one week and one month to see if services were recommended and obtained. However, in this study, the LGBTQ agencies already do a standard of care follow up call to see if patients went to services. As such, they will ask if the research team can call to follow up with them about participating in an interview about seeking services. Consent for participation in this follow-up assessment will occur in the first part of the meeting. In both PA and VA, youth, ages 14 and older, can seek their own mental health services without parental consent. At our partnering LGBTQ organizations, many adolescents do not want their parents involved. These youth can still participate in this project without involving their parent, even though caregiver engagement will be encouraged.

Caregivers will be recruited in a similar fashion as adolescent patients. After receiving family engagement training, it is expected that staff will be able to engage approximately 50-60% patients' caregivers in the referral process. If caregivers have been engaged, staff will ask if the research team can contact them about participating in a follow up research assessment about seeking help. As with patient participants, caregivers will be contacted to set up a 60-minute meeting a week after their child was screened and referred. Caregivers will provide consent at the beginning of the meeting. We will not exclude caregivers from participation if their adolescent chooses not to participate (and vice versa). It is likely these individual participants can offer important perspectives on screening and referral processes.

Historical comparison group. Treatment as usual data will be collected from month 5-24 using the procedures outlined above. Data will be collected on the number of patients who were a)

assessed for suicide, b) identified as at risk for suicide, and c) referred for behavioral health services. As part of standard care procedures, staff currently conduct a one week follow up call on any patient refereed for services, asking if they attended and about their experience. To facilitate comparison with the intervention group, we will ask LGTBQ staff members to include 4-item Acceptability of Intervention Measure (Weiner et al., 2017) for participants to report on their experience with a) the referral process, and b) their first behavioral health appointment (see measures section). De-identified QI data is shared with the research team via procedures outlined in the data safety plan (see appended). For some Diversity Camp summer programming in 2024, agency staff will be asked to share information with the research team via a questionpro survey. The survey (see appended)

8.3 Describe:

- *Procedures or safeguards intended to reduce the probability and magnitude of risks. (For example: Reducing the risk of injury in a virtual reality study either by having the subjects sit during the study or by providing an obstacle-free space for walking.)*
- *Be sure to describe all drugs and devices used in the research, when they will be administered or used, and their purpose.*
- *Methods used to collect data about subjects. Please upload all data collection forms to Protocol Management. Some common examples are:*
  - *Screening questionnaires*
  - *Survey(s), including online surveys*
  - *Demographic questionnaire(s)*
  - *Interview guide(s), e.g., questions or pool of questions for semi-structured interviews*
  - *Focus group guide(s)*
  - *Other documents used to collect data*

As is recommended in adaptation and implementation science, we have involved multiple constituent groups in the design of this project. As such, we are conducting three studies with different populations:

Administrator/Staff/Provider Training and BH-Works Program Acceptability.
LGBTQ staff/behavioral health provider participants will be recruited by site leadership to participate in this project. They will complete surveys over the period (beginning of study, pre-training and post-training as well as at baseline, midpoint and endpoint of the effectiveness pilot). Staff will be interviewed at the beginning prior to training (for those administrators/staff/providers engaged with creating and providing feedback on policy and procedures for suicide prevention at their site),, after the one-month pilot period, and at the end of the study (at all four sites).

Staff/provider surveys will be based on their experience of the BH-Works program, training activities they receive, and the follow-up consultations they receive (approximately every other month) over the course of theproject period. LGBTQ staff and behavioral health providers will be trained to work with SGM youth with suicidal thoughts and behavior. This will involve

delivering a) conjoint suicide risk management training to LGBTQ staff and behavioral health providers, b) affirmative care training to behavioral health providers, and c) conjoint follow-up consultations with trainers, site leadership, and staff/providers. Training attendance will be encouraged for all staff/providers in the organization; however, those who plan to interact with the BH-Works program will be included in the research. Staff/providers may participate in the trainings without choosing to participate in the research. Training slides are appended to this protocol.

BH-Works Program Effectiveness and Acceptability for SGM Adolescents and Emerging Adults.

Youth ages 14 and older can seek their own treatment and, therefore, can participate in healthcare systems independently of parental consent. As many youth entering LGBTQ organizations are not out to their parents, including those adolescents (14 years and above) in this study allows us to fully engage this population.

Adolescents (14-17 years old) and emerging adults (18-19) will engage in several activities to support the evaluation of SGM BH-Works program outcomes. We will first collect control group data in the first period of the project. Data will be collected by staff in LGBTQ organizations as part of a QI investigation. As part of standard care procedures, staff at regularly follow-up with youth referred to behavioral health. As part of this follow-up procedure, staff will contact patients and involved caregivers a week after referral. During this follow-up call, adolescents (14-17) and emerging adults (18-19) will be asked if they attended a first appointment and if a caregiver facilitated attendance at the first appointment. To obtain a comparison group to evaluate BH-Works program acceptability, staff will also ask consumers to complete the 4-item AIM measure on their experience with a) the referral process, and b) their first behavioral health appointment (see measures section). De-identified data on each of the outcomes will be provided to the research team to use as a historical comparison group before the intervention is implemented.

Then, after the launch of SGM BH-Works in Year 3, and after a one month pilot, we will collect data from on program effectiveness, acceptability, and mechanisms. Adolescent (14-17) and emerging adult (18-19) patient participants will enter the study through routine channels within each LGBTQ organization. During the SGM BH-Works pilot, we expect to screen over 160 SGM adolescents (14-17) and emerging adults (18-19) and conduct referral follow-up calls for between 60 and 80 of these patients. As part of routine care/programming, patients will complete the Behavioral Health Screen (BHS) under the supervision of a staff screener. At the beginning of the BHS, participants will complete a consent form requesting access to data for research purposes. At the end of the BHS, participants will complete a brief acceptability measure about their experience with the screening. Using standardized information on risk indicators, screeners will initiate the SGM BH-Works referral system. If referrals are made, the screener will inquire whether patients agree to have a researcher follow up with them via phone or Zoom within a month. If the patient agrees, a research team member will contact the patient and schedule a time for a 60-minute meeting to collect survey and qualitative information.

Procedural differences across sites:

For the Mazzoni Center site, consent for participation in this follow-up will occur in the first part of the scheduled 60-minute meeting. For patients who do not agree to be contacted for research follow-up, a staff screener will call to inquire about the success of the referral and document the response for internal, QI purposes. The research team will then request de-identified access to this QI data. For the DCI site, caregivers will be consented using the procedures outlined for the Mazzoni Center; however, youth participants will be consented at the time of BHS screen (see section 7.0 above).

BH-Works Program Effectiveness and Acceptability for Caregivers of SGM Youth. Caregiver activities are similar to those of adolescent (14-17) and emerging adult (18-19) participants. If they were engaged in their child's referral process, caregivers will be contacted for follow-up by LGBTQ organization staff (for the control group) and asked to complete a brief, 5-minute survey for QI purposes. For the pilot in Year 3, caregivers will be asked to participate in the study if they were involved in their child's referral process. We expect a higher percentage of caregivers to be involved in Year 3 (approximately 50-60%). After receiving family engagement training in in year 2, it is expected that staff will be able to engage approximately more patients' caregivers in the referral process (approximately 40-50). If caregivers have been engaged in their child's referral process, screeners will ask them if they agree to be contacted for research follow-up. As with patient participants, caregivers will be contacted to set up a 60-minute meeting a week after their child was screened and referred. Caregivers will provide consent at the beginning of the meeting. We will not exclude caregivers from participation if their adolescent chooses not to participate (and vice versa). It is likely these individual participants can offer important perspectives on screening and referral processes.

Materials and Potential Risks.

Participants in this project will provide self-report and interview data in addition to BHS-works usage data. Administrators/staff/providers will complete 30-45-minute questionnaires, six times over their participation period. They will also complete 2-3 interviews at the beginning of the project period (for those administrators/staff/providers engaged with creating and providing feedback on policy and procedures for suicide prevention at their site), after the pilot period, and at the end of the study (all four sites). These questionnaires and interview questions focus on preparedness, likelihood of using new skills, self-efficacy, knowledge and awareness related to the training content. They will also be asked several questions about their confidence making and receiving SGM youth referrals. Finally, they will be asked about their satisfaction of the BH-Works program.

Adolescents (14-17) and emerging adults (18-19) will complete the 10-15 minute BHS measure as part of their routine care in LGBTQ organizations. The BHS is psychometrically sound and screens broadly across psychosocial domains. The BHS is currently being widely used in emergency rooms, primary care, health centers and schools. Adolescents (14-17) and emerging adults (18-19) will complete a brief satisfaction survey after completing the BHS. As part of follow-up calls, adolescents (14-17), emerging adult participants (18-19) and participating caregivers will complete brief surveys about a) their referral experience with the LGBTQ

organization, and b) the first appointment with their behavioral health provider. They will then participate in individual interviews (approximately 30-60 minutes) which will inquire about perceptions of the experiences with regards to screening, referral, and the first appointment (e.g., "What was your first appointment with your counselor like?" and "Did you feel welcome at their office?"). If caregivers were involved, researchers will inquire about how they assisted with the process (e.g., "Did your caregiver help you attend your first appointment? If so, how?"). Interview protocols will be developed in collaboration with our advisory board and will support the solicitation of illustrative examples as well as recommendations for program improvements. No conjoint meetings will occur with adolescent participants and caregivers.

Potential Risks

The procedures conducted in this study mirror those practiced in routine behavioral health and QI studies. The risks to study participants are minimal and include the risks associated with potential a) stress from interview/survey/screening questions, and b) breach of confidentiality.

For youth and caregivers, private, identifiable data will be collected by the agencies over the course of the control group data collection QI study in years 1 and 2. De-identified data will be provided by the research team via the methods outlined on the data safety plan (appended). For data collection in years 3 and 4, data with identifiers will be collected by the research team. The purpose of collecting private information is to track participants for follow-up. All data from this study will be collected through electronic platforms. The BH-Works program will house BHS data. The BH-Works program is HIPAA compliant and designed for use in medical systems. Satisfaction reports related to the BHS can be housed in the same system. Interviews will be conducted using the HIPAA compliant Zoom web conferencing system or via phone. Electronic audio recordings of the interviews will be collected using the Zoom platform (or digital voice recorders, if participating by phone) and transferred to an encrypted Virginia Tech computer by following stringent guidelines established by the university. Audio will be stored on OneDrive (HIPAA compliant) and will be transferred only by flash drive or portable hard drive, CD ROM, or Secure FTP. Any flash drives or removable media will be encrypted. Our teams at Virginia Tech has a data safety plan and confidentiality policy. This policy has been approved by Virginia Tech's IRB and information security specialists. When scheduling the interviews, participating directors will be provided with an ID number to use during the research process. A separate document matching IDs with names and contact information will be stored in an encrypted excel file. Before the interview, participants will be asked to complete brief questionnaires via QuestionPro (a secure, web-based survey system). No identifying information will be recorded on QuestionPro. Instead, directors will be asked to enter their ID numbers on the QuestionPro survey. All audio data and QuestionPro files will be labeled with participating directors' ID numbers. The same process will be used to collect survey information from staff/provider participants.

Surveys administered to staff and providers will be similar to those many providers complete for CE credits after a training. One risk to staff/providers is the breaking of confidentiality, which would lead to others in their organization knowing their information as it relates to completing the program and administering the elements of the BH-Works screening and referral program.

The risks to participants and caregivers are minimally different from those associated with participating in a wellness or mental health program, but are related to a) participating in behavioral health screening (participants only), b) completing the evaluations of care, and c) breaking of confidentiality. The major risk for participating in the screening program is the related to the discomfort of revealing personal information. This risk is offset by the fact that the BHS has been tested and used successfully with diverse youth populations. In addition, staff administering the screen will be trained thoroughly by the research as part of their involvement in this study. These staff screeners will give more professional attention to suicide risk management than in typical outpatient settings.

Adequacy of Protection Against Risk

Consenting procedures vary based on study period and participant group. Consenting and assenting procedures are described for each study below.

Consenting procedures will be conducted at the beginning of the staff/provider training activities. The consenting process will occur as a group, though participants' involvement will remain confidential. At the beginning of the meeting, the researcher will ask that those who meet inclusion criteria consider taking part in the research study. The researcher will explain the purpose of the study and what it would mean to take part (see appended consents). The group will then be encouraged to ask questions verbally in the group, privately through the Zoom chat feature (or both). Once questions are answered, the researcher will send out a link to the QuestionPro consent form and first survey through the chat feature of zoom. The researcher will tell participants they can turn off their cameras and take time to review the consent and complete the survey. The researcher will be available on camera and via chat to answer questions during this time. The researcher will instruct those in the group not interested in participating to take a break instead of filling out the consent form and completing the first survey.

Adolescents (14-17) and emerging adults (18-19) will complete the BHS as part of routine services. They will receive a permission form at the beginning of the screen inquiring whether their de-identified data can be used for research. If they indicate they had thoughts of suicide on the survey, they will be asked automatically if they can be contacted for follow-up. Templates of these forms are included in the appendices and will be adapted for this study. In addition, adolescents (14-17) and emerging adults (18-19) who are provided with referrals from LGBTQ staff (and any involved caregivers) will be asked verbally if the research team can follow up with them. When the researcher meets with participants for the follow-up, they provide consent/assent to participate (see appendices for drafts of these consent/assent forms). The consenting/assenting process will occur over Zoom or by phone. The researcher will send the participant a link to the consent form via QuestionPro and review it with them. The purpose of the study will be explained along with confidentiality issues, and the possible risks and benefits. Participants will be invited to review the consent/assent form and ask any questions regarding study participation. For participants who have difficulty reading the informed consent/assent form, the research staff will read the form to them. Those who are willing to participate will sign the informed consent form (via QuestionPro) for the research interviews, surveys, and audiotaping.

All procedures will be approved by sIRB described in this application.

Protections Against Risk

The community engagement approaches used in the design of the study will increase the acceptability of study procedures, surveys and interviews. The content of the program (and many of the data collection instruments) will be adapted in Years 1 and 2 in accordance with feedback from our advisory board. Using well-trained interviewers, screeners and research personnel will help minimize discomforts that may arise as a result of revealing personal information and information about experiences with the BH-Works program. Efforts will be made to protect all participants' confidentiality using the strategies outlined in paragraph two of the Potential Risks Section above.
As a result of our extensive work with depressed and suicidal patients, our team has developed a wealth of experience in dealing with high-risk patients. We intend to pass this knowledge along in our trainings to staff/providers working with the BH-Works program. Staff/providers as well as study personnel will be able to access project leadership 24 hours a day for support.

Vulnerable Subjects

Children (between the ages of 14 and 17) will be involved in current research procedures. This study poses no greater than minimal risk to participating children. Study activities involve routine procedures offered in behavioral health settings. In this study, parental or guardian permission is not a reasonable requirement to protect adolescent participants. We will work closely with our sIRB to make sure all adequate protections are put in place in study procedures.

See section 7.0 above for plans to engage children in treatment without parental permission.

Potential benefits of the Proposed Research

The potential benefits of this study for all participants will be the increased monitoring of suicidal thoughts and behaviors and increased access to referrals. The potential benefit to society is substantial. Successful outcome would mean that the BH-Works Suicide Prevention program can be adapted for settings serving SGM youth and is effective in identifying youth at risk and increasing rates of successful behavioral health referrals. With appropriate precautions taken, the benefits to both individuals and society will, in our view, far outweigh the risks of the study.

Importance of the Knowledge to be Gained

The primary knowledge gained will be demonstrating that the BH-Works Suicide Prevention program can be adapted for and implemented into LGBTQ organizations. We will also determine whether the program is effective in identifying SGM youth at-risk for suicide and increasing successful referrals. Finally, we will be assessing program components (mechanism) that may be responsible for these outcomes (training, partnerships, and caregiver involvement).

8.4 What data will you collect during the study and how you will obtain them? Please include descriptions of electronic data collection, database matching, and app-based data collection:

Please see appended data collection materials. If materials may revised over the course of the study and amendments will be submitted accordingly. We will submit new and adapted measures to the IRB before use.

The following is a description of all measures as well as a table mapping measures onto study outcomes:

Training impact. Impact of training on staff/providers will be measured using our modified version of the Gatekeeper Behavior Scale (Albright et al., 2016).

This scale was developed and validated on a sample of over 8,000 educators. It consists of 11 items making up three subscales. The preparedness scale first assesses gatekeepers' knowledge about suicide risk behaviors and warning signs (e.g., recognizing when an adolescent appears to have psychological distress). Preparedness also measures gatekeepers' skills in assessment and their capacity to refer an adolescent for help (e.g., motivating them to seek counseling). The Likelihood scale assesses if the gatekeeper thinks would follow through with suicide prevention behavior (e.g. referring an adolescent). The Self-Efficacy scale measures how confident the gatekeeper feels about carrying out the assessment and behavior. Factor loading showed all items correlated highly with theoretical constructs of planned behavior ($r > .84$, $p < .001$). Construct validity, criterion validity, and convergent validity were also strong. Regression analysis also showed that all three scales predicted gatekeepers' reports of actually employing behavioral techniques with an adolescent (e.g., talking with them about suicide/depression or referring them for services). Scale adaptions have also been made. This scale is based on the theory of learned behavior (Bandura, 1977) and items can be easily applied to any training. To this end, we have created version for pre-training, post-training and follow-up evaluations for the safety planning and family engagement elements of the suicide risk management training curriculum. We have used these adapted versions extensively with over 1,000 providers from over 10 trainings. The adapted scale has demonstrated strong psychometrics. For this proposed study, we will also adapt this scale to measure the impact the affirmative care training curriculum. At the end of training, we will evaluate whether behavioral health providers feel more prepared, confident and capable (self-efficacious) in working with this high risk population. Modifications of this tool will be reviewed with our advisory board in Years 1 and 2.

Partnership development. Partnership development will be measured by a brief questionnaire (to be developed in collaboration with our advisory board). For LGBTQ staff, we will ask questions about partnerships with behavioral health partners (e.g., to what extent do you feel confident behavioral health partners can work with LGBTQ youth?). This measure will be administered several times over the course of the pilot period.

Suicide identification. Data from the BHS suicide scale will determine whether a patient is at-risk for suicide. Validated clinical cutoffs indicating risk levels (see Diamond et al., 2010) are used in the BH-Works system to "flag" patients. The number of flagged patients will yield a total

count of patients at-risk. For our pilot period, we will divide the total number of patients screened by those flagged to yield a percentage of patients identified.

Successful referrals. Researchers will ask patients and/or their caregivers if they attended a first session with a behavioral health provider. The response will indicate whether or not there was a successful referral. The total number of patients receiving behavioral health referrals will be divided by the number of those who report attending a first session, yielding a percentage of successful referrals.

Program satisfaction. Staff/providers and consumers will complete the Acceptability of Intervention Measure (AIM; Weiner et al., 2017). The AIM is a brief, four-item measure of key leading indicators of implementation success (Proctor et al., 2011). The AIM was developed to be used with a wide range of stakeholders and has demonstrated strong psychometric properties (see Weiner et al., 2017). Participants will also be provided a free response question in order to provide more detailed feedback. Satisfaction will be collected at several time points during the screening and referral process from staff, providers, and consumers.

When given permission, we will conduct a qualitative interview with consumers about their experience of the screening and referral process. (e.g., What was your first appointment with your counselor like? and Did you feel welcome at their office?). If caregivers were involved, researchers will inquire about how they assisted with the process (e.g., Did your caregiver help you attend your first appointment? If so, how?). Interview protocols will be developed in collaboration with our advisory board and submitted to IRB before use.

Software Usability. The Software Usability Measurement Interview (SUMI) will be used to measure usability (Coleman, 1993; McSweeney, 1992) for staff/providers. It has 50 Likert-scale items and takes about 5 minutes. It addresses a standard set of usability factors consisting of: Affect, Control, Helpfulness, Learnability, and Efficiency. The quantitative goal is for each factor to achieve a score of at least 80% of the maximum possible score. Progress over the course of the pilot period meeting these goals will be tracked by the successive usability scores. Once modified, this measure will be submitted to IRB for approval.

Caregiver involvement. Caregivers involved in patients' referral processes will be identified by staff screeners at LGBTQ organizations. Staff screeners will record which caregivers were asked to participate in a follow-up call with the study team (see recruitment and enrollment). In addition, during follow-up calls, both patients and caregivers will be asked if their caregiver/they helped attend a first appointment with a behavioral health provider. At least one affirmative answer from LGBTQ staff, patient, or caregiver will indicate caregiver involvement for that case. The total number of patients referred will be divided by those with caregiver involvement, yielding a percentage of cases with caregiver involvement.

Objective measures. The research team will also use more objective measures of our primary outcomes by drawing data from our web-based screening program and from the EMRs. Given that the BH-works platform sets up the ability for providers to communicate across systems, we can document the communication process, including arrival at the first session. Partnering behavioral sites will have a BH-Works license and ability to use the BHS screening tool. The

system can also document attendance at the learning collaborative, frequency of screening tool use, sending of screening reports between sites, and the providers' frequency of opening sent reports.

NIMH Resource Sharing Measures.

For data sharing purposes with the NIMH Data Archive, NIMH requested that specific measures on their database (public domain) be used in this study:
https://grants.nih.gov/grants/guide/notice-files/NOT-MH-20-067.html

These measures are described below and can be accessed using the link above.

Summary of data to be shared

For Aim #3 of this project, demographic and clinical screening data will be acquired from 160-200 adolescent patients. We expect to refer between 60 and 80 of these patients to behavioral health providers due to suicidal ideation and/or behavior. All these 60-80 youth participants will agree to the sharing of data results with the NIMH Data Archive (NDA). All data will be de-identified prior to receipt by the repository, but the information needed to generate a GUID will be collected for each participant. The proposed research will also involve collecting data from approximately 50-60% of caregivers whose adolescents participate in the research. Demographic information from these participating caregivers will be shared using the procedures described for adolescent participants above. As the focus of the study is on adolescent patient populations, no clinical assessment will be collected for caregivers. Caregivers will be asked to provide parent/caregiver reports on adolescents' health. This information will be shared with the NDA.

The proposed research also acquires data from administrators and clinical staff at collaborating organizations, however, no clinical assessments will be collected from these participants.

Standards/Data Dictionaries to be Used

Adolescent Patient Participants

For this study, an empirically-supported screening tool will be implemented into routine care at LGBTQ organizations. The demographic information and screening results from this standardized tool will be shared with the NDA. In addition, for those 60-80 patient participants, who endorse suicidal ideation and/or behavior (and agree to participate in the research), patient age, sex (assigned at birth), ethnicity, height, weight, socioeconomic status, and other demographic data will be collected using the following instruments as defined in NDA:

1) Research Subject and Pedigree (ndar_subject01)
2) Demographics Short Form (demsf01)
3) Ethnic Group Questionnaire (ethgrp01)
4) Height and Weight (height_weight01)
5) Hollingshead Socioeconomic Rating Scale (ses01)

In compliance with NOT-MH-20-067, the following data will be collected from the 60-80 aforementioned adolescent participants to facilitate aggregation of this data set with other data sets:

1) Age (ndar_subject01)
2) Sex at Birth (ndar_subject01)
3) DSM Crosscutting for Youth (dsm5crossch01)
4) RCADS-25 (rcads2501)

In compliance with NOT-MH-20-067, the following parent/guardian report data will be collected from any participating caregivers to facilitate aggregation of this data set with other data sets:

1) DSM Crosscutting Parent/Guardian Report (dsm5crosspg01)
2) RCADS-25 Parent/Guardian Report (cde_rcads01)

The clinical screening assessment data to be collected for all adolescent patients participating in this study are listed below. All participants screened will be asked if they are willing to share their data with the researchers (and, therefore, with the NIMH NDA).

1) Behavioral Health Screen (doi:10.1542/peds.2009-3272; new data dictionary will be defined in NDA)

Caregiver Participants

For this study, it is expected that 50-60% of the caregivers of adolescents screened will agree to participate in the research. As the purpose of the study is focused on youth patients, no clinical assessments will be collected from caregivers. Caregiver age, sex (assigned at birth), ethnicity, height, weight, socioeconomic status, and other demographic data will be collected using the following instruments as defined in NDA:

1) Research Subject and Pedigree (ndar_subject01)
2) Demographics Short Form (demsf01)
3) Ethnic Group Questionnaire (ethgrp01)
4) Height and Weight (height_weight01)
5) Hollingshead Socioeconomic Rating Scale (ses01)

Validation Schedule

If funded, within 6 months of the Notice of Award date we will submit a Data Submission Agreement signed by the principal investigator and an institutional business official, as well as define and complete the Data Expected section of this project. Uploads of all initial demographic and clinical data will be completed by the next submission cycle deadline following the initiation of data collection of clinical assessments outlined in the timeline for this project. Clinical data collection, therefore, will occur when the pilot phase begins, at the beginning of year 3 (Fall 2024), of the project. The next submission cycle deadline following would be January 15th,

2025. Subsequent data uploads will be harmonized, validated, and submitted biannually on the standard January 15th and July 15th submission deadlines.

We also plan to use the NDA validation tool as a quality control measure in between formal submissions to the data archive. The data manager in charge of submitting data to NDA will help researchers in the group validate their data once a month.

Table. Summary of study measures related to **core hypotheses** (zero suicide measure not included in this table as they supplement core hypotheses)

Measure	Primary Variable	Stakeholder Respondents	CFIR Framework Domain
Gatekeeper Behavior Scale (appended)	Training impact	S	Staff characteristics
Partnership Questionnaire (appended)	Partnership development	S	Inner setting
Software Usability Measurement Interview (appended)	Usability	S	Inner setting, Implementation processes
BHS Suicide Scale (appended)	Endorsement of current thoughts of suicide.	P	Intervention characteristics
Reported First Session Attendance	Successful Referral	P, C	Intervention characteristics
Acceptability of Intervention Measure (AIM) (appended)	Program Satisfaction	S, P, C	Staff characteristics
Reported Caregiver Engagement	Caregiver Involvement	S, P, C	Intervention characteristics

*Key for constituent abbreviations: S= Staff/providers; P= Patients; C= Caregivers

8.5 Who will transcribe or code audio and/or video recordings?:

The investigators and members of the research team listed on the IRB will work with the data. In addition, we will use the Virginia Tech approved software, "TranscribeMe!" to transcribe de-identified transcripts.

8.6 Include a description of any deception to be used in the study. Include justification for the use of deception (why the deception is necessary), describe the debriefing process, and describe how the study meets <u>all</u> the following criteria for alteration of consent (deception is considered an alteration of informed consent):

- *The research involves no more than minimal risk to the subjects*
- *The alteration will not adversely affect the rights and welfare of the subjects*
- *The research could not practicably be carried out without the alteration/deception*
- *(Optional but encouraged in most cases) Subjects will be provided with additional pertinent information after participation (i.e., debriefing for studies involving deception)*

N/A

8.7 If the study involves long-term follow-up (once all research related procedures are complete), describe what data will be collected during the follow up period and when it will occur:

N/A

9.0 Data and Specimen Long Term Storage and Use

9.1 If you will store data or specimens for future use, describe where you will store the data or specimens, how long they will be stored, and how and by whom the data or specimens will be accessed:

The present study includes a documented plan for the collection, storage, protection and analysis of research data. The key components of this plan include restriction from unauthorized access to identifiable participant data, storage of data to protect against inadvertent loss, and use of appropriate database software tools to maintain integrity of data for subsequent analyses. All research files are coded using a study identification number. Participant identifying information (name, address, etc.) is stored separately from other data collected for this study, and is only accessible by those investigators or staff who have a need to know this information for the purpose of conducting the study. All data are stored in locked cabinets and locked offices or in password-encrypted files or HIPAA-compliant data storage clouds. Access to these files is limited to investigators and support personnel with the need to enter or analyze data.

All research information obtained is kept confidential unless the participant is an immediate danger to themselves or to others. (Note, clinically relevant, but not life-threatening information may be shared with outside personnel with participant permission). If a crisis situation occurs, this clinical information may be provided to others in order to facilitate appropriate treatment and minimize the risks of self-harm or harm to others.

Please see appended data safety Data Safety and Monitoring Plan document as well as the Virginia Tech Research Team's Data Safety Plan (Russon Data Safety Plan_2021). These plans have been reviewed and approved by Virginia Tech's HIPAA compliance officer, Mary Potter.

9.2 For specimens, list the data to be stored or associated with each specimen:

N/A

9.3 Describe the procedures to release data or specimens outside of the research team, including the process to request a release, approvals required for release, who can obtain data or specimens, and what data will be provided with specimens:

The information we collect will be on file for 7 years after the study.

Data from this study will be submitted to the National Institute of Mental Health Data Archive (NDA) at the National Institutes of Health (NIH).

During and after the study, the study researchers will send deidentified study data about participants' health and behavior to the NDA.

Participants may decide now or later that do not want their study data to be added to NDA. Participants can still participate in this research study even if they decide that do not want their data to be added to NDA.

Participants that decide any time that do not want their data to be added to NDA, call or email the study staff who conducted this study, and they will tell NDA to stop sharing their study data.

9.4 Describe the identifiers to be included with stored data or specimens, as well as any key or code that could be used to make them identifiable. Describe where the code will be stored, who will have access to it, and when it will be destroyed:

Participant names, contact information and other identifiers will be kept confidential and only available to the PI, Co-Is and research assistants at approved study site locations. In order to participate in the study, interested participants will be provided with an ID number to complete

all research materials. All data will be labeled with an ID instead of identifying information. At the end of the data collection period, documents linking participant names/contact information and IDs will be destroyed. During data collection, this document will be stored on a secure server, OneDrive.

Data with identifiers will be stored on encrypted external hard drives or kept on OneDrive, which is only accessible once research team members are approved and invited by the PI/Co-I to access.

Data will be locked and stored 7 years, including at least 3 years beyond the completion of all study activities, including publication and presentation of results, per federal regulations.

Please see appended data safety Data Safety and Monitoring Plan document as well as the Virginia Tech Research Team's Data Safety Plan (Russon Data Safety Plan_2021).

9.5 Please select the identifiers you will obtain (whether directly from participants or from another source), including but not limited to:

☒	*Name*
☒	*Geographical subdivisions smaller than a state, including street address, city, county, precinct, zip code, and equivalent geocodes (note, the initial three digits of a zip code are not considered identifiable)*
☒	*Elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death, and single year of age over 89 and all elements of dates (including year) indicative of such age (note, such ages and elements may be aggregated into a single category of age 90+)*
☒	*Phone numbers*
☐	*Fax numbers*
☒	*Electronic mail addresses (e-mail)*
☐	*Social Security numbers*
☒	*Medical record numbers*
☐	*Health plan beneficiary numbers*
☐	*Account numbers*
☐	*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 voice prints (audio recording)*

☐	*Full face photographic images and any comparable images (including video recording)*
☐	*Student record number or identification number*
☐	*User name for online or computer accounts*
☒	*Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code the data)**:*** Audio recordings

10.0 Sharing of Results with Subjects

10.1 Describe whether you will share results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) with subjects or others (e.g., the subject's primary care physician). If so, describe how you will share the results and include this information as part of the consent document. Upload materials you will use to explain the results to subjects:

The revised BH-Works manual, which will incorporate feedback from LGBTQ organization leaders, SGM youth and their caregivers, will support the sustainability of the screening and the referral processes tested in this study. The involvement of stakeholder and consumers in the adaptation process is intended to help increase participant retention. In addition, the suicide risk management and affirmative care trainings provided to participating sites delivering the program, is intended to support participant engagement.

In addition, findings and/or de-identified may be published on participating organizations websites such as the Mental Health Data Archive (NDA) and the National Institutes of Health (NIH).

All data will be de-identified prior to being shared.

11.0 Study Timelines

11.1 Describe:

- *The duration of an individual subject's participation in the study (for example, 1 hour, 2-4 weeks, 3-5 years).*
- *The amount of time expected to enroll all study subjects (weeks, months, years, etc.)*
- *The amount of time expected for the investigators to complete this study including primary data analyses.*

Control group data will be collected from month 5-24, while we do manual and program adaptation (Aim #1). At the end of Year 2, we will conduct the trainings with LGBTQ organizations and behavioral health site staff. We will initiate the screening tool for a month. Then, we will gather initial feedback on the program and make final adaptations to the manual. In years 3 and 4, we will run the program and collect satisfaction (patient), feasibility, acceptability, and preliminary effectiveness data. At the end of year 4, we will do closing focus

groups with staff, administrators, caregivers, and patients at all sites. We will write up manuscripts and an R01 to test the SGM BH-Works program on a larger scale.

12.0 Inclusion and Exclusion Criteria

12.1 Describe how you will screen individuals for eligibility. When will screening occur and what procedures will you use? Upload any screening scripts or surveys to Protocol Management:

Participants in this study include administrators/staff/providers, adolescent (14-17) and emerging adult (18-19) patients and their caregivers presenting in LGBTQ organizations.

Sample Size. In the SGM BH-Works pilot period, we expect to screen over 160 SGM adolescents and refer between 60 and 80 of them. In her letters of commitment, one agency director (Mazzoni) reports they see approximately 60 SGM youth referrals per year. The other director (Diversity Camp) sees over 100 SGM youth each year. We, therefore, expect our partnering organizations to have over 210 youth to screen.Epidemiological studies suggest that SGM youth are 5-7 times more likely to experience suicidal ideation than their heterosexual and cisgender peers (Almeida et al., 2009; Taliaferro & Muehlenkamp, 2017). It is also estimated that between 30-50% of transgender and gender non-conforming youth attempt suicide during their adolescence (Toomey, et al., 2018). Our community partners have stated that the majority of SGM youth they serve have endorsed current or past suicidal ideation. Therefore, we estimate to identify a total of at least 160 youth at risk for suicide over the course of the pilot. We believe that half of these youth will have engaged caregivers in the referral process and research. We expect a total of 50-100 caregivers will participate in the control data collection phase and the intervention phase.

4-8 administrators/providers/staff from each collaborating site will be identified by their supervisors and invited to participate. Providers/staff who are recruited will be invited to participate by the PI, who does not work at the sites. The PI will maintain confidentiality and will also handle all study-related matters.

12.2 Describe the eligibility criteria that define who will be included and who will be excluded from enrollment for each procedure of your study. Include any geographic criteria (e.g., Virginia Tech undergraduate students, a national sample of adults with engineering degrees, minors aged 8-12 in the New River Valley, university faculty in Virginia and Paris, France):

Adolescent and Emerging Adult Inclusion and Exclusion Criteria. Inclusion criteria for adolescents include: a) self-identification as a sexual (lesbian, gay, bisexual, questioning, queer, etc.) or gender (e.g., transgender, non-binary, gender queer, bigender, etc.) minority; b) being between the ages of 14 and 17. (Including emerging adults ages 18 and 19).; and c) endorse current suicidal ideation on the BHS. These youth must be seeking services at the participating LGBTQ organizations. Adolescents and emerging adults will be excluded if they meet the

following criteria: a) lack enough English-language proficiency to complete the BH-Works program, or b) are not capable of understanding the requirements for study participation.

Parent Inclusion and Exclusion Criteria. Caregivers will be invited to take part in the study if they are involved in their child's referral process. If they are not, providers will consider engaging them if it is appropriate and safe. As part of the project, however, we aim to increase LGBTQ staff appreciation of the importance of caregiver involvement. In SGM communities, families of choice may also be involved. Caregivers will be broadly defined as any adult who the adolescent or emerging adult identifies as having a caregiving role in their lives. Exclusion criteria for caregivers are the same as for patients.

Staff/Provider Inclusion and Exclusion Criteria. All professionals at our four partnering sites (LGBTQ organizations and psychiatry departments) will be invited to attend all trainings. However, study participants will be those involved in the assessment and referral process.

12.3 Indicate specifically whether you will include or exclude each of the following special populations: (You may not include members of these populations as subjects in your research unless you indicate them in the description of your subject population.)

- *Minors, as defined by state law where the study is performed (infants, children, teenagers)*
- *Pregnant women (can be included in minimal risk studies by mentioning in section 13.1)*
- *Prisoners (including all incarcerated individuals)*
- *Adults not capable to consent on their own behalf*

Children (between the ages of 14 and 17) will be involved in current research procedures. This study poses no greater than minimal risk to participating children. Study activities involve routine procedures offered in behavioral health settings. In this study, parental or guardian permission is not a reasonable requirement to protect adolescent participants. We will work closely with our IRB to make sure all adequate protections are put in place in study procedures.

This study is considered greater than minimal risk given that subjects endorse suicidality, the inclusion of marginalized minors, and the inclusion of an adapted prevention intervention protocol.

13.0 Vulnerable Populations

13.1 If the research involves individuals who are vulnerable to coercion or undue influence, please describe additional safeguards you will include to protect their rights and welfare. Consider the applicable items listed below:

- *If the research involves Virginia Tech students, indicate whether these are students of any of the investigators. If so, describe whether the activities will*

take place during class time as part of the curriculum and the steps you will take to reduce the possibility that students feel obliged to participate in order to improve their course grade. The HRPP can provide further guidance as needed. Describe whether you will request access to student records (e.g., SAT, GPA, GRE scores).

- *If the research involves employees of Virginia Tech or the research sponsor, describe steps you will take to ensure that the employees are freely participating and describe how their data will be protected from inspection by their supervisors.*
- *If the research involves Virginia Tech NCAA athletes, you must obtain approval from the athletic department.*
- *For research involving Montgomery County Public Schools, you must obtain county approval (after obtaining contingent Virginia Tech approval). Other locales have different requirements; please check on these and describe here. Approval is typically granted by the superintendent, principal, and classroom teacher (in that order). Approval by an individual teacher is insufficient. School approval, in the form of a letter or a memorandum should be uploaded as a supporting document.*
- *If the research involves pregnant women, review "CHECKLIST: Pregnant Women (HRP-412)" to ensure that you have provided sufficient information in this protocol.*
- *If the research involves prisoners, review "CHECKLIST: Prisoners (HRP-415)" to ensure that you have provided sufficient information in this protocol.*
- *If the research involves persons who have not attained the legal age for consent to treatments or procedures involved in the research (minors), review the "CHECKLIST: Minors (HRP-416)" to ensure that you have provided sufficient information in this protocol.*
- *If the research involves cognitively impaired adults, review "CHECKLIST: Cognitively Impaired Adults (HRP-417)" to ensure that you have provided sufficient information in this protocol.*

Minors will be involved in the study. Minors will include those adolescents and who attend and/or seek services at partnering LGBTQ+ community centers.

Given that pregnant adolescents, young adults, and caregivers access mental health services at our partnering organizations and may be in need of suicide risk management services, they will also be invited to participate in the study.

HRP-412 and 416 have been completed and appended in supporting documents.

Those supporting the intervention will be the community center organization's staff on site in collaboration with the research team.

Study procedures will occur in the context of centers and behavioral health systems familiar with confidentiality practices. Procedures outlined in this study are routine in these systems. The majority of personnel on this study have degrees and are licensed to provide health care to children. They will be trained to collect informed consent/assent for this project.

14.0 Number of Subjects

14.1 Indicate the total number of subjects to be enrolled and how this number was determined (e.g., sample size calculation [show], number of available subjects in a finite pool, number of tests funding award would allow):

The number of subjects we plan to enroll depends on the constituent group (e.g., adolescents vs. staff) and the specific aim of the project. The breakdowns are as follows:

Staff and administrator recruitment (7/15/24-8/15/26): 24 (for all project aims)

Youth recruitment (8/15/24-8/15/26): 160-200 (for all project aims)

Caregiver recruitment (8/15/24-8/15/26): 50-90 (for all project aims)

For Aim 3: our RMR record on file with NIMH includes recruitment targets for caregivers of youth participating in the feasibility, acceptability, and preliminary effectiveness trial as well as the pilot study and closing interviews. For the effectiveness trial, we expect to engage 160 youth participants in the screening and we expect half (80) to endorse current suicidal ideation and/or behavior. We expect that 50% of the caregivers of these youth (with current suicidal ideation and/or behavior will participate). Therefore, we expect approximately 40 caregivers (total from Diversity Camp and Mazzoni sites) will participate in the referral follow-up portion of the effectiveness trial. This number is reflected in the total number of caregiver participants we aim to enroll in all parts of the study. In her letters of commitment, one agency director (Mazzoni) reports they see approximately 60 SGM youth referrals per year. The other director (Diversity Camp) sees over 100 SGM youth each year. We, therefore, expect our partnering organizations to have over 200 youth to screen in the 18-month period, although our recruitment goal remains at 160.

The recruitment goal was also informed by the power calculations as follows:
Our previous studies of the BHS have found a significant increases in identification and referral rates (7-8% difference, OR~5 to 6, i.e., medium-large effect size; Chen et al., 2010) after the initiation of the program. Specifically, there was a significant increase in the identification of mental illness or behavioral problems after initiation of the Behavioral Health Screening-Emergency Department (BHS-ED) (10.5% vs. 2.5%, OR = 4.58, 95% CI 3.53, 5.94) and more frequent ED-based behavioral health assessments by social workers or psychiatrists (8.3% vs. 1.7%, OR 5.12, 95% CI 3.80, 6.88). Based on this effect size, we expect that a sample of 160 youth (historical comparison group and intervention group) will achieve >80% power to detect a significant difference in identification and referral proportions.

14.2 If this is a multi-site study, indicate the number of subjects to be enrolled at this site and the total to be enrolled from all sites:

During the 18-month SGM BH-Works data collection period in years 3 and 4, we expect to screen over 160 SGM adolescents (14-17) and emerging adults (18-19) and refer between 60 and 80 of these patients to behavioral health providers due to suicidal ideation and/or behavior (30-40 at each site).

LGBTQ staff/behavioral health provider participants will be recruited by leadership to participate in this project. We expect to include 4-6 staff/providers/administrators at each site.

Caregivers will be recruited in a similar fashion as patients.

In her letters of commitment, one agency director (Mazzoni) reports they see approximately 60 SGM youth referrals per year. The other director (Diversity Camp) sees over 100 SGM youth each year. We, therefore, expect our partnering organizations to have over 200 youth to screen in the 18-month period, although our recruitment goal remains at 160.

Click here to provide a response.

14.3 If applicable, indicate the number of potential subjects you expect to screen for enrollment, and the number of subjects you will need to complete the research procedures:

Based on historical referrals to the partner sites, we expect to have approximately 200 youth to screen for enrollment.

14.4 If the study has more than one procedure, indicate the total number of subjects to undergo each procedure separately:

We anticipate to screen 160-200 youth for enrollment. We anticipate referring 60-80 total (30-40 from each site) youth to behavioral health providers.

We will also include providers at each site in the program. We anticipate 4-6 staff/administrators at each site (24 total).

15.0 Recruitment Methods

15.1 Describe when, where, and how you will recruit potential subjects:

As is recommended in adaptation and implementation science, we have involved multiple stakeholder groups in the design of this project. As such, we are conducting three studies with different populations who will be recruited as follows:

Staff/Provider Training and BH-Works Program Acceptability
LGBTQ staff/behavioral health provider participants from the programs will be recruited by site leadership to participate in this project at the beginning of the study. Staff/providers may participate in trainings without choosing to participate in the research. We expect to include 4-6 staff/providers/administrators at each of our four participating sites (two LGBTQ organizations and two partnering psychiatry departments). Consenting processes will occur immediately before the first training begins.

BH-Works Program Effectiveness and Acceptability for SGM Adolescents
Adolescents (14-17 years old) and emerging adults (18-19) will engage in several activities to support the evaluation of SGM BH-Works program outcomes. These individuals will be recruited from the LGBTQ organizations. Individuals will be recruited for the SGM BH-Works program. Adolescent (14-17) and emerging adult (18-19) patient participants will enter the study through routine channels within each LGBTQ organization. As part of routine care/programming, patients will complete the Behavioral Health Screen (BHS) under the supervision of a staff screener. At the beginning of the BHS, participants will complete a consent form requesting access to data for research purposes.

Youth ages 14 and older can seek their own treatment and, therefore, can participate in healthcare systems independently of parental consent. As many youth entering LGBTQ organizations are not out to their parents, including those adolescents (14 years and above) in this study allows us to fully engage this population.

BH-Works Program Effectiveness and Acceptability for Caregivers of SGM Youth.
Caregiver activities are similar to those of adolescent (14-17) and emerging adult (18-19) participants. If they were engaged in their child's referral process, caregivers will be contacted for follow-up by LGBTQ organization staff in control group data collection phase and asked to complete a brief, 5-minute survey for QI purposes. For the intervention data collection phase, caregivers will be asked to participate in the study if they were involved in their child's referral process. We expect a higher percentage of caregivers to be involved during the second phase (approximately 50-60%). After receiving family engagement training, it is expected that staff will be able to engage approximately more patients' caregivers in the referral process (approximately 50-60 in the intervention data collection phase).

15.2 Describe the source of subjects (for example, clinic patients with specific conditions, students in the library, community members at a gathering, or members of a local gym):

There will be three groups of participants:

1. LGBTQ staff/providers/administrators who will be recruited from each of our four participating sites (two LGBTQ organizations and two partnering psychiatry departments).

2. Youth (adolescents (14-17 years old) and emerging adults (18-19)) who engage with the partnered LGBTQ organizations.

3. Caregivers of youth who engage with the partnered LGBTQ organizations.

All participants who are recruited will engage in this research as part of routine clinical/programmatic practices and participant will be voluntary

15.3 Describe the methods that you will use to identify potential subjects:

Participants will be identified based on recruitment from participating sites. This includes staff/provider/administrators participants, youth, and caregivers. The BH-Works intervention will be implemented at the agencird. Each individual using the program will be asked if they would like to participate in the research.

15.4 Describe materials that you will be use to recruit subjects. Attach copies of these documents with this protocol in Protocol Management and be sure to include the IRB protocol number on each document.

- *For flyers, attach the final copy of printed flyers.*
- *For Virginia Tech News, Facebook postings and ads, newspaper ads, websites, MTurk/SONA/online survey systems, etc., attach the final wording and graphics to be used.*
- *For email recruitments, please include the subject line.*
- *For advertisements meant for audio broadcast, please submit the wording of the advertisement prior to taping (to avoid having to re-record with approved language) and submit the final recorded version for IRB review before use.*
- *Describe any compensation to subjects. Separate compensation into appropriate categories, such as: reimbursement for expenses, time and effort, and additional incentives for study participation. For each category, specify the amount (including any pro-rated amount), schedule, and method of payment.*

Any recruitment materials used in the context of the study will be submitted to IRB as an amendment before use. There are currently no recruitment materials to be used as the procedures are embedded in routine care.

Youth participants will be compensated $20.00 for participating in a follow up assessment.

Caregivers will be compensated $20.00 for participating in a follow up assessment.

Staff/providers will be compensated $20.00 for participating in each quantitative assessment point or qualitative interview. However, the following notice has been included in the consents given that different sites have diverse policies around compensation:
Depending on your site, you may be given work time for completion of research questionnaires and interviews. Unless prohibited by your union or workplace policy, administrators/staff will be paid $20.00 for the completion of each assessment and interview. Compensation will be paid in the form of an electronic Amazon gift card sent via email, within two weeks following participation. Participants will have 30 days to redeem (i.e., click to add the funds to their Amazon account). If the gift card is not redeemed within 30 days, it will no longer be available.

Compensation will be in the form of gift cards and will be either mailed or emailed to participants within two weeks following participation.

16.0 Withdrawal of Subjects

16.1 Describe circumstances under which you anticipate subjects could be withdrawn from the research without their consent:

If a participant is demonstrating notable distress while participating in the research, activities will immediately cease and the research team will proceed with risk management activities outlined earlier in this protocol.

Please see data safety and monitoring document appended.

16.2 If applicable, describe any procedures for orderly termination (e.g., discontinuation of a study drug or debriefing after a behavioral intervention):

If a participant is demonstrating distress, then the activities related to BH-Works, activities will immediately cease and the team will implement risk management activities. These risk management activities will align with the aforementioned suicide risk management training.

16.3 Describe procedures that you will follow when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection (e.g., participant declines to continue with regular blood draws, but continues with periodic behavioral questionnaires):

If a participant is removed from the research due to distress, partial responses will not be retained without written permission from the participant. These permission forms will be documented. In instances where a participant withdraws or is removed, the participant will receive full compensation for the activity started, but not completed.

17.0 Risks to Subjects

17.1 List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects' participation in the research. Include for the IRB's consideration a description of the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, privacy, and economic risks. Do not indicate "No risk" or "N/A." Instead, for studies with very low risk (e.g., anonymous online questionnaire on a mundane topic) indicate "The investigators are not aware of any risks from participation in this study." or "No more than risks than are found in everyday life." The example consent form presents a tabular method for risk information, which you can also use here. Common risk types include:

- *Physical (e.g., potential for pain, discomfort, infection)*
- *Psychological (e.g., potential for stress, discomfort, and/or embarrassment)*
- *Social (e.g., potential for discrimination or stigmatization and disruption of personal and family relationships)*
- *Legal (e.g., potential for disclosure of illegal activity, negligence)*
- *Privacy (e.g., potential for personal information being accessed, used, or disclosed without the subjects' knowledge or consent, breach of confidentiality/security)*
- *Economic (e.g., potential for individuals to lose access to economic services, employment, insurability)*

The risks to participants are considered more than minimal due to the vulnerable population under study. Risks associated with study procedures include potential stress from the interview/survey/screening questions and the potential for a breach of confidentiality. More specifically the risks are as follows:

Physical: No more risks that are found in everyday life.

Psychological: Discomfort related to revealing personal information

Social: Potential for a breach of confidentiality.

Legal: No more risks than are found in everyday life.

Privacy: Potential for a breach of confidentiality.

Economic: No more risks than are found in everyday life.

Clear consenting procedures allow for participants to understand the risks associated with participation in the study. Further, the community engagement approach utilized in the design of this study will increase the acceptability of procedures, surveys, and interviews. In addition, the research personnel will be well-trained as interviewers. Therefore, they will help to minimize the discomforts associated with revealing personal information. The teams who are a part of the research have extensive experience in dealing with high-risk patients.

17.2 Indicate the measures you will use to minimize risks and monitor subjects for safety. (e.g., asking a subject at regular intervals to rate how they are feeling from 1 to 10, or to slowly crouch in order to check their balance.) Indicate the measures you will use to minimize risks and monitor subjects for safety. (e.g., asking a subject at regular intervals to rate how they are feeling from 1 to 10, or to slowly crouch in order to check their balance.)

Participants risk will be minimized and we will monitor participants for safety based on the following procedures and the suicide risk management training.

Administrators/Staff/Providers: The researcher will explain the purpose of the study and what it would mean to take part (see appended consents). The group will then be encouraged to ask questions verbally in the group, privately through the Zoom chat feature (or both). Once questions are answered, the researcher will send out a link to the QuestionPro consent form and first survey through the chat feature of zoom. The researcher will tell participants they can turn off their cameras and take time to review the consent and complete the survey. The researcher will be available on camera and via chat to answer questions during this time. The researcher will instruct those in the group not interested in participating to take a break instead of filling out the consent form and completing the first survey.

Youth/Caregivers: Adolescents (14-17) and emerging adults (18-19) will complete the BHS as part of routine services. They will receive a permission form at the beginning of the screen inquiring whether their de-identified data can be used for research. If they indicate they had thoughts of suicide on the survey, they will be asked automatically if they can be contacted for follow-up. Templates of these forms are included in the appendices and will be adapted for this study. In addition, adolescents (14-17) and emerging adults (18-19) who are provided with referrals from LGBTQ staff (and any involved caregivers) will be asked verbally if the research team can follow up with them. When the researcher meets with participants for the follow-up, they provide consent/assent to participate (see appendices for drafts of these consent/assent forms). The consenting/assenting process will occur over Zoom or by phone for youth and caregivers. The researcher will send the participant a link to the consent form via QuestionPro and review it with them. The purpose of the study will be explained along with confidentiality issues, and the possible risks and benefits. Participants will be invited to review the consent/assent form and ask any questions regarding study participation. For participants who have difficulty reading the informed consent/assent form, the research staff will read the form to them. Those who are willing to participate will sign the informed consent form (via QuestionPro) for the research interviews, surveys, and audiotaping.

Protections Against Risk

The community engagement approaches used in the design of the study will increase the acceptability of study procedures, surveys and interviews. The content of the program (and many of the data collection instruments) will be adapted in Years 1 and 2 in accordance with feedback from our advisory board. Using well-trained interviewers, screeners and research personnel will help minimize discomforts that may arise as a result of revealing personal information and information about experiences with the BH-Works program. Efforts will be made to protect all

participants' confidentiality using the strategies outlined in paragraph two of the Potential Risks Section above.

As a result of our extensive work with depressed and suicidal patients, our team has developed a wealth of experience in dealing with high-risk patients. We intend to pass this knowledge along in our trainings to staff/providers working with the BH-Works program. Staff/providers as well as study personnel will be able to access project leadership 24 hours a day for support.

Vulnerable Subjects
Children (between the ages of 14 and 17) will be involved in current research procedures Study activities involve routine procedures offered in behavioral health settings. In this study, parental or guardian permission is not a reasonable requirement to protect adolescent participants (see description of study 2 above). We will work closely with our sIRB to make sure all adequate protections are put in place in study procedures.

The investigators on the project will share coverage of the 24-hour emergency phone line. Calls will be documented and discussed at regular investigator meetings. The PI will be available for consultation should co-investigators need support during coverage. We have provided this service for 10 years at our research clinic.

17.3 If applicable, indicate which procedures might have risks to the subjects that are currently unforeseeable. This will be rare, and usually applicable when testing a new drug or device or a new use of an existing drug or device:

N/A

17.4 If applicable, indicate which procedures might have risks to an embryo or fetus should the subject be or become pregnant:

N/A

17.5 If applicable, describe risks to others who are not subjects (e.g., collection of sensitive health data that might affect sexual partners if disclosed, mandatory reporting of abuse, DNA testing that might affect family members or relationships):

As data is collected in the context of social and health services, state laws regarding the reporting of child and elder abuse is required. Study personnel will follow state guidelines for reporting and adhere to the policies outlined in their organizations.

18.0 Potential Benefits to Subjects

18.1 Describe the potential benefits that individual subjects might experience from participating in the research. Include the probability, magnitude, and duration of the potential benefits, as this will be useful to the IRB's risk:benefit analysis. Do not include benefits to society or others. Do not list monetary or non-monetary compensation for participation, as this is not a benefit These should be included in section 2 or 3 of this document:

A potential benefit of this study is increased monitoring of suicidal thoughts and behaviors and increased access to referrals. For staff/provider participants, training opportunities to increase the quality of treatment will be offered.

18.2 If applicable, specify that there are no anticipated direct benefits for participants:

N/A

19.0 Data Management and Confidentiality

19.1 Describe procedures that you will use for quality control to ensure validity of collected data:

Data will be handled per a detailed data safety and monitoring plan. The data safety and monitoring plan requires strict adherence to human subject protection policies, timely monitoring, feedback, and reporting of potential ethical issues, careful attention to the potential for adverse events, close communication with the IRB, and careful data monitoring to ensure patient confidentiality.
The data safety plan outlines potential adverse events and serious adverse events and various procedures related to attending to these adverse events, such as reporting procedures. Further, the team will carefully attend to confidentiality and acknowledges potential limitations as well the precautions that may be taken. These limitations include utilizing ID numbers instead of identifiable data. Any identifiable data will be stored separately from the other data collected and will only be accessible by approved study personnel. Further, all data will be stores in locked cabinets and offices, password-encrypted files, and/or HIPAA-compliant data storage clouds. Limitations to confidentiality (including the potential for danger to self or other) will be attended to as necessitated by legal and ethical guidelines.

A DSMB has been obtained for this study as requested by NIMH. More information regarding data management and confidentiality, including detailed plans, are included in the data safety and monitoring plan. For the full plan, see appended Data Safety and Monitoring plan as well as Russon's (PI) Data Safety document.

19.2 Describe any existing data or biospecimens you will obtain as part of this study. Include:

- *Variables or samples to be obtained*
- *Source of the data or specimens*
- *Your authorization to access or receive the data or biospecimens*
- *Whether the data or biospecimens are publicly available*
- *Whether the data or specimens you receive will contain identifiers*

N/A

19.3 Describe the steps that you will take to handle and secure study data during data collection, storage, use, and transmission. Include information about training of study staff, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, separation of identifiers and data, etc.:

The present study includes a documented plan for the collection, storage, protection and analysis of research data. The key components of this plan include restriction from unauthorized access to identifiable participant data, storage of data to protect against inadvertent loss, and use of appropriate database software tools to maintain integrity of data for subsequent analyses. All research files are coded using a study identification number. Participant identifying information (name, address, etc.) is stored separately from other data collected for this study, and is only accessible by those investigators or staff who have a need to know this information for the purpose of conducting the study. All data are stored in locked cabinets and locked offices or in password-encrypted files or HIPAA-compliant data storage clouds. Access to these files is limited to investigators and support personnel with the need to enter or analyze data.

All research information obtained is kept confidential unless the participant is an immediate danger to themselves or to others. (Note, clinically relevant, but not life-threatening information may be shared with outside personnel with participant permission). If a crisis situation occurs, this clinical information may be provided to others in order to facilitate appropriate treatment and minimize the risks of self-harm or harm to others.

See appended Data Safety and Monitoring plan as well as Russon's (PI) Data Safety document.

19.4 For multi-site studies, describe how data or specimens will be handled and secured for each site (e.g., central or disseminated data storage, data coordinating center):

Virginia Tech will be responsible for the long-term storage of collected data. Data will be stored in locked cabinets and locked offices. Additionally, it will be stored in password-encrypted files or HIPPA-compliant data storage clouds. Data access will be limited to only those with the need to access data.

See appended Data Safety and Monitoring plan as well as Russon's (PI) Data Safety document. This plan has been reviewed and approved by Virginia Tech's HIPAA compliance officer.

19.5 Describe the plan for data disposition following the conclusion of the study (e.g., long term maintenance of data, data destruction methods).

- *What information will be included in the long term storage of data or specimens?*
- *How long will the data or specimens be stored?*
- *Where and how data or specimens will be stored?*
- *Who will have access to the data or specimens during long term storage?*
- *Who is responsible for receipt or transmission of the data or specimens?*
- *How will data or specimens be shared or transported?*
- *When and how will personal identifiers be destroyed?*

- The complete data set will be stored in long-term storage. However, identifier keys will be retained until the end of the 3-year study period and then destroyed (permanently deleted).
- Data will be locked and stored 7 years, including at least 3 years beyond the completion of all study activities, including publication and presentation of results, per federal regulations.
- Data specimens will be stored at Virginia Tech in locked cabinets and locked offices. Additionally, it will be stored in password-encrypted files or HIPAA-compliant data storage clouds.
- Data access will be limited to only those with the need to access data.
- Data receipt and/or transmission will be managed by approved members of the research team.
- Identifier keys will be retained until the end of the 3-year study period and then destroyed (permanently deleted).

20.0 Provisions to Protect the Privacy Interests of Subjects

20.1 Describe the steps that you will take to protect subjects' privacy interests. "Privacy interest" refers to a person's desire to place limits on with whom they interact or to whom they provide personal information (e.g., collecting the

minimal amount of private information required to complete the study, protecting the data once it is obtained):

The community engagement approaches used in the design of the study will increase the acceptability of study procedures, surveys and interviews. The procedures of this study are designed so that they fit within the context of community-based case. The content of the program (and many of the data collection instruments) will be adapted in Years 1 and 2 in accordance with feedback from our advisory board. Using well-trained interviewers, screeners and research personnel will help minimize discomforts that may arise as a result of revealing personal information and information about experiences with the BH-Works program. Efforts will be made to protect all participants' confidentiality using the strategies outlined in paragraph two of the Potential Risks Section above.

As a result of our extensive work with depressed and suicidal patients, our team has developed a wealth of experience in dealing with high-risk patients. We intend to pass this knowledge along in our trainings to Admins/staff/providers working with the BH-Works program. Staff/providers as well as study personnel will be able to access project leadership 24 hours a day for support.

The oversight by the appointed DSMB will provide additional protection to the human subjects participating in this study.

20.2 Describe steps that you will take to make subjects feel at ease with the research situation in terms of the questions being asked and the procedures being performed. "At ease" does not refer to physical discomfort, but the sense of intrusiveness a subject might experience in response to questions, examinations, and procedures (e.g., use of a same gender investigator to place sensors on the torso, a private changing area if clothing must be changed, sensitivity when discussing pregnancy testing with subjects, making it clear on surveys that participants can discontinue at any time, not asking questions about private or sensitive issues unless necessary for the research):

These research activities are being conducted in the context of standard programs and services. Most staff/providers engaging with participants have degrees/licenses to provide services. Research assistants will have at least a master's degree in the health professions and will be trained in this study protocol. Virginia Tech research assistants conducting interviews and follow-up calls will receive training from the PI. Using well-trained interviewers will help minimize discomforts that may arise as a result of revealing personal information. Interviewers will make sure that adolescents are in a confidential location before continuing the interview.

In order to address the potential for breach of confidentiality among adolescents, researchers will ask adolescents the best method for contacting them and which devices/numbers offer confidential voicemail/access. If adolescents choose not to involve their parents, the researcher will document the best way to reach the adolescent and what to do if someone else answers the

phone. This is routine practice in health care settings that are bound by HIPAA and standards of confidentiality.

Participants will have access to the PI team's contact information if questions or concerns arise.

20.3 Describe how you plan to access existing sources of information about the subjects (e.g., medical records, grades) and how you will protect participant privacy through the data security plan:

In the control group data collection phase of the study, staff will begin to collect QI data from those who participate in their services in years 1 and 2. This data will be managed internally, de-identified and then shared with the investigators (if participants agree to have their de-identified data shared at the time of data collection in years 1 and 2).

20.4 Describe any required reporting that might occur as a result of your research questions, study populations, and data collection methods. Examples for Virginia and Virginia Tech include:

- ***Any*** *suspicions (e.g., circumstantial, disclosed) of child abuse (physical, emotional, sexual) and neglect*
- *Sexual discrimination and/or sexual violence that involves a student*
- *Disclosure or signs of intention to harm oneself (i.e., suicidal ideation and/or plan)*
- *Disclosure or signs of desire to harm others (i.e., homicidal ideation and/or plan)*
- *Suspected abuse, neglect or exploitation of vulnerable adults (e.g., individuals with a disability, elderly persons)*

As data is collected in the context of social and health services, state laws regarding the reporting of child and elder abuse is required. Study personnel will follow state guidelines for reporting and adhere to the policies outlined in their organizations.

Our team includes a statement in every study consent/assent form indicating limits to confidentiality. The team members obtaining consent are trained to explicitly review this statement while consenting all participants. Below is how these limits to confidentiality are disclosed on our consent forms:

As per Virginia and Pennsylvania state law, research team members are legally required to report suspected child and elder abuse disclosed in the context of our research programs. Of note, this includes suspected abuse of individuals discussed by the participant that may or may not be directly related to participant. Additionally, if you are a university student participating

in this research, research team members are required by your university to report title IX issues, such as assault or harassment on campus. If a participant is at risk of harming themselves or others, this information must also be disclosed for safety purposes.

21.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

Safety monitoring is <u>required</u> when research involves greater than minimal risk and is sometimes appropriate for other studies.

21.1 Describe:

- *The plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe (e.g., periodic reporting to the IRB, establishing a data monitoring committee, reporting data monitoring committee findings to the IRB and the sponsor).*
- *What data you will review, including safety data, unexpected events, and data that show the ability to produce the intended results.*
- *How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with subjects).*
- *The frequency of data collection, including when safety data collection starts.*
- *Who will review the safety data and with what frequency.*
- *The statistical tests for analyzing the safety data to determine whether harm is occurring.*
- *Any conditions that will trigger an immediate suspension of the research (e.g., a serious adverse event).*

<u>The following is the data safety and monitoring plan (also appended in supporting documents) that will be used in this study:</u>

Consistent with NIMH policy (http://www.nimh.nih.gov/research/safetymonitoring.cfm), the purpose of the Data and Safety Monitoring Plan (DSMP) is to specify the procedures and rationales of the current study to ensure the safety of participants and the validity and integrity of the data. This specifies who will look at the data and any adverse events, how often, and what they are authorized to do. A detailed Data Safety Monitoring Plan will be submitted to our IRB. The PI and study investigators (study team) will be responsible for internal data and safety monitoring in collaboration with the IRB (a sIRB will be managed by the PI's institution, Virginia Tech, for this study). A data safety and monitoring board will provide external oversight.

The specific internal procedures will be developed by the study team in collaboration with our consultant (Willging) during project start-up. These procedures will be submitted for approval by the IRB. The study team and consultant will meet quarterly via *Zoom* videoconferencing to review the study protocol and plans for data and safety monitoring (including the reporting of

adverse events to the IRB) and consumer confidentiality prior to the start of the BH-Works pilot period. After the initiation of the pilot period, the study team will continue meeting quarterly to discuss participant recruitment and retention, risks versus benefits to participants, and new developments that are relevant to the participants' safety or the ethics of the study. Prior to each meeting, the PI will provide the team members with current data on participant recruitment, adverse events (on a group basis), serious adverse events (on an individual basis), and the reasons for study discontinuations. Minutes from meetings will be submitted to the IRB for review.

The following are specific internal responsibilities and actions of the study team:

1. Review and approve, disapprove, or suggest modifications to the study protocols and/or consent documents to assure both scientific integrity and adherence to human subject protection policies.

2. Monitor, provide feedback, and report on scientific and ethical issues related to study implementation for the protection of human subjects, and advise on ethical issues related to adverse events. The team will monitor adverse event reports for purposes of determining whether their nature, frequency and severity are consistent with expectations.

3. The team will report to the IRB any unanticipated problems involving risks to subjects. If considered related to the study, unanticipated adverse events involving risks to subjects or others must be reported. The IRB can recommend remedies or other appropriate actions, such as introducing new monitoring protocols, altering inclusion or exclusion criteria, or recommending changes in the informed consent documents.

4. Monitor data management activities and ensure that the study protocol maintains participants' confidentiality in a manner that is appropriately balanced against issues of clinical care and safety.

Potential Adverse Events

The study team and IRB will be kept apprised of all serious adverse events on an ongoing basis and will serve as the final arbiters of whether individual participants should be removed from the protocol. Although our study screeners and research personnel are empowered to take whatever immediate action is necessary to safeguard the welfare of individual participants, the study team and IRB will be called upon whenever possible to render judgments in the advent of a serious adverse event. We acknowledge that there may be the rare instances where some emergent situation occurs that was unanticipated regarding the welfare of the participant. In these situations, IRB may be contacted to help resolve the situation.

Protocols for Addressing Adverse Events

All study participants will have access to the study 24-hour emergency phone. *Strategy for reporting adverse events:*

1. The screener/study personnel will immediately notify the PI.

2. The PI will notify the IRB and DSMB (see below) about adverse events.

3. If the adverse event is serious, NIMH will be informed.

Adverse Events (AEs) and Serious Adverse Events (SAEs)

The reporting of adverse events is another key element in ensuring the careful monitoring of the study by appropriate regulatory bodies. The following rules describe the relevant IRB definitions and procedures for adverse events. According to our Office of Regulatory Affairs, an adverse event (AE) is any noxious, pathological, or unintended change in anatomical, physiologic, or metabolic functions as indicated by physical signs, symptoms or laboratory changes occurring in any stage of the study of any degree of severity that may or may not be attributed to the study.

- AEs are reported to the sponsor, using the study's Case Report Form (CRF).

- AEs are reported regardless of whether they are considered study related.

- AEs may include an exacerbation of a pre-existing condition, intercurrent illness, drug overdose, failure of expected action or significant worsening of the disease under study.

- AEs will be elicited by non-leading questions such as, "Have you felt any different since our last contact?"

The date and time of onset and outcome, course, intensity, action taken, and causality to study activities will be assessed. The PI has the final decision regarding what is to be reported on the adverse event form. The PI has the option to reclassify an AE as a serious adverse event. In general, a serious adverse event (SAE) is an event where a relationship between the research study cannot be ruled out and the event is:

- Life threatening/results in death OR

- Disabling/incapacitating OR

- Requires or prolongs hospitalization OR

- Involves an overdose OR

- Was otherwise unanticipated, related to the study procedures or could lead to one of the other serious event conditions.

In case of an SAE

The date and time of onset and outcome, course, intensity, action taken, and relationship to study activities will be assessed. SAEs will be reported to NIMH, DSMB and IRB according to the timelines described below. Given that the present study recruits and enrolls participants who are a high risk for suicide attempts and completed suicide, we expect that a small portion of the participants may make a subsequent suicide attempt. If the study team becomes aware of a subsequent suicide attempt, will be evaluated with respect to its relationship to the research study. Any suicide attempt in which a relationship to the study cannot be ruled out will be classified as a SAE.

Confidentiality- Limits and Precautions

The present study includes a documented plan for the collection, storage, protection and analysis of research data. The key components of this plan include restriction from unauthorized access to identifiable participant data, storage of data to protect against inadvertent loss, and use of appropriate database software tools to maintain integrity of data for subsequent analyses. All research files are coded using a study identification number. Participant identifying information (name, address, etc.) is stored separately from other data collected for this study, and is only

accessible by those investigators or staff who have a need to know this information for the purpose of conducting the study. All data are stored in locked cabinets and locked offices or in password-encrypted files or HIPAA-compliant data storage clouds. Access to these files is limited to investigators and support personnel with the need to enter or analyze data.

All research information obtained is kept confidential unless the participant is an immediate danger to themselves or to others. (Note, clinically relevant, but not life-threatening information may be shared with outside personnel with participant permission). If a crisis situation occurs, this clinical information may be provided to others in order to facilitate appropriate treatment and minimize the risks of self-harm or harm to others.

Data Safety Monitoring Board

In addition to the internal activities specified in the sections above, this multi-site trial will be monitored by a data safety monitoring board (DSMB). Given the life and death nature of suicidal behavior, ensuring the highest quality of data gathering and monitoring procedures is essential and enhanced by the monitoring of the study by outside personnel. Enhanced monitoring can also address other safety aspects of treatment trials with persons at high risk for suicidal behavior, including intervention side effects, lack of intervention response, or an increase in related symptoms.

Mission

Consistent with NIMH policy (https://www.nimh.nih.gov/funding/clinical-research/nimh-policy-governing-the-monitoring-of-clinical-trials), this DSMP includes a Data Safety Monitory Board (DSMB) that is charged with reviewing protocols and consent documents for this trial, monitoring safety issues throughout the study, monitoring the quality of the accumulating data, providing guidance on interim analyses and stopping rules, and serving as a liaison among the study investigators, the National Institute of Mental Health (NIMH), and Virginia Tech's Office of Human Research Protections.

Membership

The DSMB for this project includes members who are independent from any professional or financial conflict of interest with the research project and the principal investigator. Board nominees consist of three members, including content-related experts (Russell, McGeorge, Olson-Kennedy), and a biostatistician (Russell). The following are brief biographies for proposed DSMB members:

Stephen Russell, Ph.D. is a Priscilla Pond Flawn Regents' Professor in Child Development, Chair of the Department of Human Development and Family Science, and the Director of the School of Human Ecology at University of Texas at Austin. He was an elected board member of the National Council on Family Relations (NCFR) (2005-2008) and past-president of the Society for Research on Adolescence.

Christi McGeorge, Ph.D. is a professor in the Department of Human Development and Family Science at North Dakota State. She is a past chair for the NCFR Family Therapy Section and was an elected member of the NCFR Inclusion and Diversity Committee.

Johanna Olson-Kennedy, M.D. is an associate professor of clinical pediatrics with Keck School of Medicine of University of Southern California. She is also the medical director of the Center for Transyouth Health and Development at the Children's Hospital of Los Angeles.

Meetings

Board members will review the DSMP and study protocol prior to the enrollment of the first participant to establish a charter that clearly outlines which data points will be monitored, how the data will be monitored, and the monitoring schedule.

The DSMB will meet once per year starting in year 2 (in-person or via teleconference) and will review reports submitted by the PI twice per year starting in year 3. Board members will be familiar with the protocol and study procedures. The DSMB will review the study protocol and plans for data and safety monitoring (including the reporting of adverse events to the IRB, and NIMH as described below) and consumer confidentiality prior to the start of data collection. After the initiation of the study, the DSMB will be responsible for evaluating the progress of the trial, including periodic assessments of participant recruitment and retention, risks versus benefits to participants, and new developments that are relevant to the participants' safety or the ethics of the study. In addition, the DSMB will be responsible for providing feedback and suggestions to the PI about these issues, and for recommending whether the study should be continued or terminated. The DSMB and PI will decide upon the format of the meetings. Additional open or closed meetings or telephone conferences will be held if it is recommended to do so by the DSMB. Board members and the PI will determine meeting logistics based upon clinical urgency and the availability of DSMB members.

Prior to each DSMB meeting or report review, the PI will provide the Board members with current data on participant recruitment and retention, adverse events, serious adverse events (on an individual basis), and the reasons for subjects' discontinuations. The Board will also have the option of reviewing individual participants' materials if indicated. Minutes of the DSMB must be sent to NIMH and to the investigators. The PI will submit minutes to the IRB.

DSMB Responsibilities and Actions

1. Review and approve, disapprove, or suggest modifications to the trial protocols and/or consent documents to assure both scientific integrity and adherence to human subject protection policies.

2. Monitor, provide feedback, and report on scientific and ethical issues related to study implementation for the protection of human subjects, and advise on ethical issues related to adverse events. The DSMB will monitor adverse event reports for purposes of determining whether their nature, frequency and severity are consistent with expectations.

   The DSMB, in coordination with the PI, will report to the NIMH any unanticipated problems involving risks to subjects. If considered related to the

trial, unanticipated adverse events involving risks to subjects or others must be reported by the PI and/or DSMB to Virginia Tech's IRB.

Along with the IRB and NIMH staff, the DSMB can recommend remedies or other appropriate actions such as introducing new monitoring protocols, altering inclusion or exclusion criteria, or recommending changes in the informed consent documents.

3. Ensure that the study protocol maintains subjects' confidentiality in a manner that is appropriately balanced against issues of clinical care and safety.

4. Monitor data regarding effectiveness. The DSMB will review data for outcome events. When differences in results between historical control and experimental groups appear to be clinically significant, the DSMB will decide whether the trial should continue with or without further enrollment of new subjects. The DSMB has the authority to halt the trial as needed.

5. Monitor data management activities. The DSMB may ask to review data relevant to quality control. The DSMB will review requests for interim analyses and approve, disapprove, require additional information, or defer decisions.

Data Reporting to DSMB

The study investigators will submit statistical reports to the DSMB one week prior to scheduled meetings or report review dates. These reports will include all reported data up to and including 14 days prior to the reporting deadline (except for Serious Adverse Experiences, which are to be reported within 24 hours of the event). For each meeting at which the study is to be considered or monitored, the PI will present an overall progress statement. This brief statement should contain the assurance that the PI has considered the trial's progress and that there is/is not evidence of safety issues that should be addressed by the DSMB.

Interim analyses will be conducted at each of these reviews to determine whether the emerging pattern of findings with respect to initial response or subsequent recurrence alters the risk-benefit ratio to the point that the study needs to be discontinued. Interim analyses will be planned in order to detect whether there are problems in recruitment, operational problems affecting the integrity of the study, and stronger treatment effects than anticipated that may lead to deliberation of ending the trial early.

Potential Adverse Events

The DSMB will be kept apprised of all SAEs on an ongoing basis and will serve as the final arbiters of whether individual subjects should be removed from the protocol. Although our collaborating clinical staff are empowered to take whatever immediate action is necessary to safeguard the welfare of individual subjects, the DSMB will be called upon whenever possible to render judgments in the advent of a SAE. We acknowledge that there may be the rare instances where some emergent situation

occurs that was unanticipated regarding the welfare of the participant. In these situations, the Virginia Tech or the DSMB may be contacted to help resolve the situation.

Timeline for Reporting Events

The PI, DSMB and Virginia Tech IRB all have responsibilities for reporting as described above. The following is the timetable for event reporting in accordane with NIMH policy (https://www.nimh.nih.gov/funding/clinical-research/nimh-reportable-events-policy):

1. Suspensions/Terminations from regulatory organizations will be reported to NIMH, by the PI and DSMB, within three business days.

2. Deaths related to study participation will be reported immediately (or no later than five business days), by the PI, to NIMH, DSMB, and Virginia Tech IRB.

3. Unexpected SAEs related to study participation will be reported to NIMH, by the PI, within 10 business days.

4. Unanticipated problems involving risks to subjects will be reported to NIMH, DSMB, and Virginia Tech IRB, by the PI, within 10 business days.

5. Noncompliance will be reported to NIMH, by Virginia Tech's IRB, within 10 business days.

6. SAEs and AEs (expected and/or unrelated to the study) as well as protocol violations will be submitted with DSMB reports, by the PI. NIMH will be made aware of these events in the annual progress report.

22.0 Compensation for Research Related Injury

22.1 If the research involves more than minimal risk to subjects, describe the available compensation in the event of research-related injury, if any:

N/A

22.2 Provide a copy of contract language, if any, relevant to compensation for research-related injury. At Virginia Tech, this is most common for sponsored research:

N/A

23.0 Economic Burden to Subjects

23.1 Describe any costs that subjects might be responsible for because of participation in the research, including any uncompensated costs for items such as transportation, missed work, and childcare:

N/A- Data will be collected as part of routine care and services. Compensation for Follow-up interviews will be provided. Follow-up interviews will be conducted remotely via HIPAA-compliant zoom web-conferencing (see appended Russon Data Safety Protocol) or via phone.

24.0 Consent Process

24.1 Indicate the process by which you will obtain consent for study participation. Please upload all consent, parental permission, and assent forms, documents, and scripts referenced in this section to Protocol Management.

Describe the following:

- *Where the consent process will take place (e.g., clinic waiting area, classroom, online)*
- *The time interval between sharing the consent information with the prospective subject and obtaining consent. For lab, interview, and focus group studies, the Virginia Tech IRB prefers that subjects have at least 24 hours to review the consent form and study information before the appointment where consent will be obtained. For simple online survey studies, you can typically present the consent information immediately before subjects begin participation.*
- *If applicable, processes to ensure ongoing consent or assent (e.g., for multiple sessions; for research in which a minor will turn 18 during the study; for longitudinal research with minors who will later be asked to provide or affirm their assent).*
- *Please review "SOP: Informed Consent Process for Research (HRP-090)" for recommended procedure. Describe your process, being sure to include:*
  - *The name and role of all study personnel who will be trained and certified by the PI to conduct the consent process*
  - *The time that will be devoted to the consent discussion*
  - *Steps that you will take to minimize the possibility of coercion or undue influence*
  - *Steps that you will take to gauge or ensure the subjects' understanding*

All consent and assent documents are appended. The appended screening tool (BHS) has a consent form embedded in the program.

Consenting procedures vary based on study period and participant group. Consenting and assenting procedures are described for each study below.

Administrator/Staff/Provider: Consenting procedures will be conducted at the beginning of the staff/provider training activities. The consenting process will occur as a group, though participants' involvement will remain confidential. At the beginning of the meeting, the researcher will ask that those who meet inclusion criteria consider taking part in the research study. The researcher will explain the purpose of the study and what it would mean to take part (see appended consents). The group will then be encouraged to ask questions verbally in the

group, privately through the Zoom chat feature (or both). Once questions are answered, the researcher will send out a link to the QuestionPro consent form and first survey through the chat feature of zoom. The researcher will tell participants they can turn off their cameras and take time to review the consent and complete the survey. The researcher will be available on camera and via chat to answer questions during this time. The researcher will instruct those in the group not interested in participating to take a break instead of filling out the consent form and completing the first survey.

Note: administrators will only be consented to complete interviews.

Youth/caregiver: Adolescents (14-17) and emerging adults (18-19) will complete the BHS as part of routine services. They will receive an information form (will be submitted to the IRB before use) at the beginning of the screen inquiring whether their de-identified data can be used for research. If they indicate they had thoughts of suicide on the survey, they will be asked automatically if they can be contacted for follow-up. Templates of these forms are included in the appendices and will be adapted for this study. In addition, adolescents (14-17) and emerging adults (18-19) who are provided with referrals from LGBTQ staff (and any involved caregivers) will be asked verbally if the research team can follow up with them.

When the researcher meets with participants for the follow-up, they provide consent/assent to participate (see appendices for drafts of these consent/assent forms). The consenting/assenting process will occur over Zoom or by phone. The researcher will send the participant a link to the consent form via QuestionPro and review it with them. The purpose of the study will be explained along with confidentiality issues, and the possible risks and benefits. Participants will be invited to review the consent/assent form and ask any questions regarding study participation. For participants who have difficulty reading the informed consent/assent form, the research staff will read the form to them. Those who are willing to participate will sign the informed consent form (via QuestionPro) for the research interviews, surveys, and audiotaping.

Steps to minimize the possibility of coercion or undue influence:

The research conducted as part of routine services. Participants will be able to choose whether or not they would like to participate in the research. Consenting staff will be trained to emphasize that participants can choose whether or not they would like to participate in the research and that they can continue to receive services in the program regardless of whether they choose to participate or allow for the research team to access their data.

Steps to gauge or ensure subject's understanding:

Consenting staff will be trained to review each component of the form with the participant. This training will include watching for indicators of understanding and misunderstanding. The staff will be trained to stop after each section of the form to ask the participant to reflect back what they heard to confirm understanding.

Non-English Speaking Subjects

- *Indicate what language(s) other than English are understood by prospective subjects or representatives.*
- *If non-English speakers will be recruited, describe the process you will use to ensure that the oral and/or written consent information provided will be in a language that they understand.*
- *If you translate consent forms and study materials, please provide a certified translation of the form as well as the certification document.*
- *Indicate the spoken language that study personnel obtaining consent will use. Describe how you will assess fluency of personnel obtaining consent to ensure that the translation is accurate.*

N/A

Waiver or Alteration of Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception)

- *Review the "CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)" to ensure you have provided sufficient information for the IRB to make these determinations (i.e., that it meets the criteria for a waiver or alteration of the consent process).*

A waiver of parental consent is requested for minor participants. HRP 410 and 411 forms have been completed.

Subjects who are not yet adults (minors: infants, children, teenagers)

- *Describe the criteria that you will use to determine legal age for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted (e.g., in Virginia, individuals under the age of 18 years).*
  - *For research conducted in Virginia, review "SOP: Legally Authorized Representatives, Minors, and Guardians (HRP-013)" to determine which individuals in the state meet the definition of "minor."*
  - *For research conducted outside of the state, please describe the legal requirements for the definition of "minor."*
- *Describe the process for obtaining parental permission.*
  - *Permission from one parent is acceptable for studies that involve no greater than minimal risk OR involve greater than minimal risk but present the prospect of direct benefit to the minor subject.*
  - *Permission from both parents is required in all other cases (unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the minor).*

- *Describe whether you will obtain permission from individuals other than parents or Legally Authorized Representatives, and if so, who will be allowed to provide permission. Describe the process you will use to determine these individuals' authority to consent to the minor's general medical care.*
- *Indicate whether you will obtain assent from all, some, or none of the minors. If you will obtain assent from some minors, indicate which minors will be required to assent. Consider chronological age and intellectual capacity when determining who will be required to provide assent (e.g., infants are unable to assent. However, teenagers are likely able to read and sign an assent form).*
- *When assent of minors is obtained, describe whether and how you will document it. Will minors sign an assent form or give verbal assent?*
- *Attach parental permission and minor assent forms or scripts in Protocol Management.*

- Given the nature of the project, the research team is requesting that adolescents 14-17 years of age will be able to agree to part in the study without parental permission. Many LGBTQ youths go to community agencies, such as Mazzoni Center and Diversity Camp, Inc., as a refuge from parental rejection, community discrimination and, for some, to avoid the stressors of homelessness. Because of these wider issues, many youth decide not to tell their parents and families about their involvement in LGBTQ-specific programs and medical services. Indeed, some of these youths do not have regular contact with their parents. Requiring parental permission for these youths to participate, will thoroughly limit their capacity to be involved. This project is being conducted in the context of community services.

- The criteria to determine the legal age for consent: In PA youth, ages 14 and older, are able to consent to mental services without parental permission. In VA, a minor is deemed an adult for the purpose of medical or health services needed in the case of outpatient care, treatment or rehabilitation for mental illness or emotional disturbance.
-

- As in other projects where parents are either not accessible or not legally authorized to receive their adolescent's health information, we are requesting a waiver for parent consent for adolescents 14-17 years old to participate in this research at our collaborating sites. If participation causes any distress, the PIs and Co-Is (all clinicians) can provide professional assistance.

- Written assent will be obtained from all participating minors. The assent form is appended.

- HRP-411 and 416 forms have been completed and appended in the supporting documents.

Subjects who are not yet adults (minors: infants, children, teenagers)

- *Describe the criteria that you will use to determine legal age for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted (e.g., in Virginia, individuals under the age of 18 years).*
  - *For research conducted in Virginia, review "SOP: Legally Authorized Representatives, Minors, and Guardians (HRP-013)" to determine which individuals in the state meet the definition of "minor."*
  - *For research conducted outside of the state, please describe the legal requirements for the definition of "minor."*
- *Describe the process for obtaining parental permission.*
  - *Permission from one parent is acceptable for studies that involve no greater than minimal risk OR involve greater than minimal risk but present the prospect of direct benefit to the minor subject.*
  - *Permission from both parents is required in all other cases (unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the minor).*
- *Describe whether you will obtain permission from individuals other than parents or Legally Authorized Representatives, and if so, who will be allowed to provide permission. Describe the process you will use to determine these individuals' authority to consent to the minor's general medical care.*
- *Indicate whether you will obtain assent from all, some, or none of the minors. If you will obtain assent from some minors, indicate which minors will be required to assent. Consider chronological age and intellectual capacity when determining who will be required to provide assent (e.g., infants are unable to assent. However, teenagers are likely able to read and sign an assent form).*
- *When assent of minors is obtained, describe whether and how you will document it. Will minors sign an assent form or give verbal assent?*

Attach parental permission and minor assent forms or scripts in Protocol Management.
The research team is requesting that adolescents 14-17 years of age will be able to agree to part in the study without parental permission. Many LGBTQ youths go to community agencies, such as Mazzoni Center and Diversity Camp, Inc., as a refuge from parental rejection, community discrimination and, for some, to avoid the stressors of homelessness. Because of these wider issues, many youth decide not to tell their parents and families about their involvement in LGBTQ-specific programs and medical services. Indeed, some of these youths do not have regular contact with their parents. Requiring parental permission for these youths to participate in our discussion group, will thoroughly limit their capacity to be involved. This project is being conducted in the context of community services.

Adults Unable to Consent

- *Describe the process you will use to determine whether an individual adult is capable of consent.*
- *List the individuals from whom you will obtain permission in order of priority (e.g., durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and non-minor child).*
    - *For research conducted in the Virginia, review "SOP: Legally Authorized Representatives, Minors, and Guardians (HRP-013)" to determine which individuals in the state meet the definition of "legally authorized representative."*
    - *For research conducted outside of Virginia, please describe the legal requirements for obtaining permission from a legally authorized representative in the state where the research will occur.*
- *Describe the process for assent of the subjects.*
    - *Indicate whether you will require assent from all, some, or none of the subjects. If some, indicate which subjects will be required to assent and which will not.*
    - *If you will not obtain assent from some or all subjects, please provide justification for not obtaining assent.*
    - *Describe whether and how you will document assent.*

N/A

25.0 Process to Document Consent in Writing

25.1 Consult "SOP: Written Documentation of Consent (HRP-091)" for recommended procedures, and describe whether and how consent of the subject will be documented in writing:

The research team will obtain written consent/assent from participants via electronic means if they will participate in referral and follow-up procedures. QuestionPro will be used as a platform to obtain consent. The BH-Works platform also has a consent page (appended). Participants will be shown the consent page before the BH-Works or QuestionPro systems allow them to continue. Consent will be obtained using the methods outlined in this protocol. All forms will be saved as a PDF according to Virginia Tech's data safety protocol.

25.2 If the research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context, you can request that the IRB waive the requirement to obtain written documentation of consent (e.g., consent to participate is indicated by pressing a button for an online questionnaire – after the consent information is presented and before the questionnaire begins):

We are requesting that consent is waived for the screening portion (see appended BHS information form). Screening is part of the everyday practice procedures. Participants can elect

to not participate in the research but because the screening process is part of the everyday clinic practices, all individuals will still be screened. This form is embedded in the BH-Works program. The information sheet will be submitted via an amendment.

25.3 If you will document consent in writing, attach a consent document with places for signatures. If you will obtain consent, but not document consent in writing, please attach the consent script or text. Review "CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)" to ensure that you have provided sufficient information. You should use "TEMPLATE CONSENT DOCUMENT (HRP-502)"to create the consent document or script:

Please see appended consent/assent/information documents.

26.0 Resources Available

26.1 Describe the resources available to conduct the research. For example, as appropriate:

- *Describe the PI's availability to supervise the research.*
- *Justify the feasibility of recruiting the required number of suitable subjects within the agreed recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?*
- *Describe the time that you will devote to conducting and completing the research.*
- *Describe your facilities.*
- *Describe the availability of medical or psychological resources that subjects might need as a result of an anticipated or unanticipated consequence of participation in the research.*
- *Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions (e.g., training plans, detailed study notebooks).*

The PI will be available to supervise the research as described in the data safety and monitoring plan.

The PI has been allotted 22-23% effort in each year of the project to oversee operations. Co-Investigators, research assistants, and staff at all sites will facilitate oversight.

Please see attached facilities and equipment descriptions for the project.

These research activities are being conducted in the context of standard programs and services. Most staff/providers engaging with participants have degrees/licenses to provide services. Research assistants will have at least a master's degree (obtained or in process) in the health professions and will be trained in this study protocol. Those Virginia Tech research assistants conducting interviews and follow-up calls will receive training from the PI. Using well-trained

interviewers will help minimize discomforts that may arise as a result of revealing personal information.

Training staff/providers at our collaborating sites is part of the BH-Works program.

Our RMR record on file with NIMH includes recruitment targets for caregivers of youth participating in the feasibility, acceptability, and preliminary effectiveness trial as well as the pilot study and closing interviews. For the effectiveness trial (Aim 3), we expect to engage 160 youth participants in the screening and we expect half (80) to endorse current suicidal ideation and/or behavior. We expect that 50% of the caregivers of these youth (with current suicidal ideation and/or behavior will participate). Therefore, we expect approximately 40 caregivers (total from Diversity Camp and Mazzoni sites) will participate in the referral follow-up portion of the effectiveness trial. This number is reflected in the total number of caregiver participants we aim to enroll in all parts of the study. In her letters of commitment, one agency director (Mazzoni) reports they see approximately 60 SGM youth referrals per year. The other director (Diversity Camp) sees over 100 SGM youth each year. We, therefore, expect our partnering organizations to have over 200 youth to screen in the 18-month period, although our recruitment goal remains at 160.

Participants will have access to the PI team's contact information if questions or concerns arise.

27.0 Multi-Site Research

Contact the HRPP for multi-site research (involving multiple institutions) and the details required for this section will be provided. Otherwise, indicate N/A.

This is a multi-site research project with an sIRB.

Study-Wide Recruitment Methods: While sites may advertise their use of the BH-Works program, we do not anticipate using advertisements for the study. When the organizations adopt the BH-Works program in year, clients do not need to participate in the study in order to benefit from the program. Participants will be recruited from the study at collaborating LGBTQ community organizations (Mazzoni and Diversity Camp, Inc.). All youth coming in to receive services will be invited to complete the behavioral health screen. For the Mazzoni site, once the youth complete their screen, they will be asked whether they are willing to share their data with the research team and participate in the follow-up portions of the study. Those who endorse any current suicidal ideation will be invited to participate in the study (as long as inclusion criteria is met). Diversity Camp, Inc. will follow the procedures outlined in section 7.0 above.

Any scripts needed at Diversity Camp, Inc. and Mazzoni Center to engage participants in the BHS will be submitted to the IRB before use. These scripts will be developed in collaboration with these LGBTQ community organizations.

Appendix:

Statistical Analysis Plan

For Aim #2, hypotheses will be tested using a mixed-effects linear model to estimate the pre-training and post-training changes in staff training impact outcomes. Because of the repeated measurements of the dependent variable, we will treat the multiple observations as nested within individuals. Standard errors will be clustered to account for any differences between the two study sites. An identical approach will be used for analysis of other outcomes, such as comparing the trajectories of the outcomes over the follow-up consultation time period.

For Aim #3 both qualitative and quantitative data sources will be analyzed. To determine whether participating in the SGM BH-Works program leads to changes in risk identification and referral, we will compare proportions of at-risk identifications and successful referrals between groups (service as usual vs. intervention), using a two-sample test of proportions (z-test; prtest in STATA). We will also compare differences in primary outcomes across sites. If significant differences are found between program sites, then the proportional tests will be conducted separately for both sites.

To analyze participant satisfaction, we will begin by running descriptive statistics on the AIM for all participant groups. Program satisfaction for youth and caregivers will be measured after they complete BH-Works, whereas program satisfaction for staff/providers will be measured using AIM at three time points over the 18-month intervention period. Change in staff/provider satisfaction over time will be estimated using mixed models with site-clustered standard errors. Qualitative interview data on program satisfaction will be transcribed verbatim and imported into MAXQDA 22 (Verbi, 2021), qualitative data analysis software. Interview transcripts will be analyzed by two coders using theoretical thematic analysis procedures as outlined by Braun and Clarke (2006). The coding will be guided by the primary research question: What are participant perceptions of the SGM BH-Works program? Finally, to examine caregiver involvement, we will compare the percent of caregivers involved in their child's referral process to a historical comparison group using the two-sample proportional test (prtest).

Power Calculations. Previous studies have demonstrated meaningful improvements in risk identification following the implementation of the BHS, with observed differences of 7-8% (OR~5 to 6), indicating a medium-to-large effect size (Chen et al., 2010). For example, after initiation of the BHS in an emergency department setting (BHS-ED), the proportion of youth identified with mental illness or behavioral problems increased from 2.5% to 10.5% (OR = 4.58, 95% CI [3.53, 5.94]) and assessments by social workers or psychiatrists rose from 1.7% to 8.3% (OR 5.12, 95% CI [3.80, 6.88]). Although we are applying the BHS in a different setting, based on these effect sizes, we expect that a sample of 160 youth (i.e., historical comparison group and intervention group) will achieve >80% power to detect a significant difference in identification and referral proportions.