Efficacy of a Multi-level School Intervention for LGBTQ Youth
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Study Protocol

Study Title: Efficacy of a Multi-level School Intervention for LGBTQ Youth

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Study Procedures

Background

Sexual and gender minority (SGM; e.g., lesbian, gay, bisexual, transgender, queer) adolescents experience victimization in schools at much higher rates than their peers. Studies, including meta-analyses, have found that gay and lesbian students are 8 to 10 times more likely to be victimized in school than heterosexuals, with rates even higher among transgender youth. Victimization comes from not only other students but also teachers and administrators. This bias-based victimization, part of what is commonly known as minority stress, has been associated with poor behavioral health outcomes for SGM adolescents. This includes disparate rates of depression, anxiety, self-harm, and suicidal ideation and attempt in sexual minority adolescents, with even stronger disparities found among gender minority adolescents. Even compared to similarly victimized non-SGM peers, victimized SGM adolescents report significantly higher rates of suicidality.

Studies also indicate that SGM victimization is more common in schools that lack protective policies and resources such as gender/sexuality alliances (GSAs), SGM-specific antibullying policies, teacher/staff training, and openly supportive allies. When schools lack SGM bullying policies, SGM students are more likely to report suicidality than peers in schools with these policies. We assert that any intervention for SGM youth must simultaneously (a) help SGM youth cope with minority stress and (b) work to reduce the likelihood of future victimization by addressing school-level factors. Thus, it is concerning that a recent review found there are no determinative studies, such as RCTs, of the efficacy of school-based interventions for SGM youth.

Objectives

To fill this gap, we have developed a first-of-its-kind school-based intervention for SGM youth, *Proud & Empowered!* (P&E). The multi-level program was developed over the last 9 years through (a) psychometric, developmental, and acceptability studies funded by the NIH, foundations (Zumberge), and intramural sources; (b) a collaboration with three SGM youth drop-in centers, more than 100 SGM youth, and a dozen academic and clinical experts; and (c) an exploratory study (R21MD013971) to assess the feasibility and preliminary efficacy of the intervention. Given encouraging findings, we now propose to employ a large-scale randomized controlled trial (RCT) with 24 schools in Los Angeles to establish program efficacy. At intervention sites (n = 12), after the 10-session small group portion of the intervention with SGM youth is completed, peer allies (who are identified through a popular opinion leader model) are invited to participate in 4-session leadership program focused on changing SGM-related school climate. This is followed by student-led implementation of environmental change strategies at the school level focused on key domains of school climate described by Thapa et al. (2013): safety, relationships, teaching and learning, and institutional environment. At the SGM student

level, analysis will focus on the hypothesized mechanism of change (minority stress) and key behavioral health outcomes (depression, anxiety, PTSD, suicidality, substance use).

Change in school climate will also be assessed qualitatively using content analysis and observational methods in the intervention and post-intervention years. Our specific aims are to: 1) Determine participant-level efficacy of the intervention in an RCT with 24 schools, 2) Determine the schoolwide intervention effects on (a) reporting of minority stress and behavioral health outcomes among all SGM students and (b) perceptions of school climate (norms, attitudes, beliefs, bullying behaviors toward SGM youth, policies) among all students, and 3) Examine factors that may affect intervention success (e.g., fidelity of implementation, barriers or facilitators to implementation, school or student characteristics) to prepare the intervention for future dissemination.

Participants

1. Inclusion Criteria:

    a) P&E Intervention Participants will be eligible to participate if they: 1) are students at the selected schools, 2) self-identify as lesbian, gay, bisexual, transgender, or any other non-heterosexual/cisgender identity, 3) speak English, and 4) are able and willing to provide assent/consent.

    b) POL Allies/Make Space Participants will be eligible to participate if they: 1) are selected by P&E intervention participants as a popular opinion leader (i.e. students who others look up to and consider good leaders), 2) are willing to be an ally to the LGBTQ community, and 3) are able and willing to provide assent/consent.

2. Exclusion Criteria: not meeting the inclusion criteria above

3. Special Population:

    a) Minors: a waiver of parental permission for youth participation has been granted as there is concern that an IRB requirement of parental permission will put some sexual minority youth at risk regarding disclosure of their sexual orientation to their parents. This may then place these youth at risk for parental harassment, abuse, or expulsion from the parental home.

    b) Pregnant Women: There is no risk to pregnant individuals due to participation. Therefore, we will allow those who are pregnant to participate in the study.

4. Limitations:

    a) Although our feasibility trial had one school with 17 youth participating in the Proud groups, we found that this group was too large to manage effectively, and so we will limit the individual-level intervention group size to 12.

    b) Given that this is a Los Angeles-based study with a limited budget and that the majority of schools in the Greater Los Angeles Area are English speaking, we will be restricting enrollment those who speak English.

Recruitment

LGBTQ Cohort: Recruitment flyers (Recruitment Flyer for P&E.docx) will be distributed by school counselors to students in participating schools. Flyers will not be posted in any non-public area, rather they will be handed out to school clubs (i.e. Gay/Straight Alliance, Rainbow Club, etc) and to students directly by student counselors. Flyer contains information about the study and contact information for student counselors in their school. Students who endorse interest will have private and confidential meetings with their counselor regarding participating in this study. In week four of the school year, we will randomly select 12 names at each school from the LGBTQ+ youth identified via these recruitment methods to be invited to participate in the LGBTQ+ youth cohort portion of the study. These youth will be invited to a first P&E session, where they will be provided the link to the Proud & Empowered e-consent (or consent if they are 18+) form (P&E Assent Consent WUSTL 9.22.22.rtf), also hosted on RedCap and accessible via phone or school assigned tablet/computer.

Make Space Allies: To identify POL allies, P&E facilitator (Carey) will introduce the Make Space program, student advocacy and discuss the meaning of LGBTQ+ allies with our P&E students during session 4: Peers and Relationships. Students will then discuss allies whom they feel would benefit the Make Space project. Students will then begin nominating individuals who can serve as a popular opinion leader (POL) for the Make Space project. Students will select potential POL allies in session 6. School counselors/liaisons will then meet with these identified students and assess for the student's willingness to operate as an effective LGBTQ ally (e.g., willingness to provide visible support for SGM students), and students who are not interested, for any reason (related to topic or otherwise), will not be asked to participate. After screening each POL for interest in participation, Study Coordinator will then randomly select ten of the students identified to participate in the Make Space intervention portion of the study. Students who report interest and are chosen for participation will provide e-assent (or consent if they are 18+), similar to the process described for LGBTQ+ youth (on RedCap using phones or tablets). See "Make Space Intervention Procedures" below for more information on the Make Space assent/consent process.

Waiver of Parental Consent

All willing participants will be assented or, if over the age of 18, consented into the study. All data collected in this study, including the P&E Survey and Make Space survey, are covered in these assent/consent processes.

We request a waiver of parental consent for this study. There is concern that an IRB requirement of parental permission will put some sexual minority youth at risk regarding disclosure of their sexual orientation to their parents. This may then place these youth at risk for parental harassment, abuse, or expulsion from the parental home. There is also concern that this requirement may decrease the participation rate because some youth will fear that they may be "outed"- that is, revealed that they are gay as a result of their participation. This is particularly relevant in the current study since we will be sampling youth with varying disclosure and may be

out to very few individuals and thus they will have varying degrees of acceptance by their parents and family members.

Lastly, in accord with national policy recommendations from the Society for Adolescent Medicine, we believe requiring parental permission for the proposed study would have a number of possible negative effects, including: (1) reducing the validity of the findings by effectively eliminating potential participants unwilling to share permission forms with their parents/guardians; (2) increasing risk to some youth whose parents have a negative response to the material in the permission forms that would (correctly) suggest their child has a minority or alternative sexual orientation; and (3) adding little in the way of actual subject protection, given the minimal risk of participation in a study and anonymity of data collected.

Waiver of Documentation of Consent:

The assent/consent form is the only document in this study which would capture participant names and connect them to being LGBTQ. Given our concerns, noted above in our request for the waiver of parental consent, for participant privacy and the unique risks faced by sexual and gender minority youth, we ask for a waiver of required signature for consent. Instead, participants will be prompted to check a box indicating their agreement (or not) to participate in the study.

Methods

Proud & Empowered! Intervention: The proposed study is intended to rigorously test the efficacy of Proud & Empowered! (P&E) program in a large-scale RCT with 24 high schools across the Greater Los Angeles Area. Schools will be randomly assigned to an intervention or control condition. Schools assigned to the intervention condition will be further randomized to receive either just the P&E direct intervention or both P&E and Make Space. Detailed information on each program (Proud & Empowered! and Make Space) can be found in sections below. LGBTQ participants in the intervention schools will participate in P&E, whereas those attending control schools will complete only study survey measures during the study on the same timeline (all three time points) as the intervention schools.

LGBTQ Youth Procedures: For LGBTQ P&E participants, measures (information on measures can be found in the *Instrumentation* section below) will be obtained at three time points: the beginning of the P&E intervention (September), after the intervention period (November), and at the conclusion of the school year (May). LGBTQ+ student participant survey can be found in the attachments section as “Y2 P&E Survey.docx”. LGBTQ+ youth participants will create a Unique ID, which the study team will use to link measures taken over time. Detailed information on recruitment of LGBTQ youth participants can be found in the *Recruitment* section above. School counselor will ensure there is a time and space available for each student to meet for a 45-minute intervention session once per week for 10 weeks. The study activities will occur at the school during school hours and the school counselor will ensure students can discreetly participate in the intervention sessions by either 1) grouping participating youth into the same homeroom/advisory period where the intervention will administered by Study Facilitator/Study Coordinator, or 2) providing students with a counseling slip, allowing them to miss a class to

participate in the intervention session. Schools will choose what works best for them. If option 2 is selected, intervention sessions will be staggered and run during a different class period each week so that participating youth do not miss the same class every week. Study staff (Carey) will present adolescents with information sheets/assent, or informed consent from those aged 18 or older, and obtain assent/consent in order to keep as little identifying information about LGBTQ+ participants as possible. Next, each LGBTQ participant will create a unique identification code that will be used in the participant's survey entries to link successive data points. Surveys will be self-administered on tablets, laptops, or cell phones. The data manager and study facilitator at the study site will track participant names and unique identifiers to keep track of the number of sessions attended by students (dosage). School staff will not have access to participant data from surveys. Youth who turn 18 during the study will complete an informed consent.

10-week P&E Intervention Procedures: A PDF of the Proud & Empowered intervention program can be found in the attachments section of this IRB application as "Proud & Empowered.pdf". The 10-week protocol includes an introductory and data collection session, then sessions on Stress and Coping, Disclosure, Families, Peers and Friendship, School-related Stress, Spirituality/Religion, Social Justice, Health and Wellness, and a final Celebration and data collection session. Each session runs about 45 minutes and will be Facilitated by MSW-level study staff. We have formalized the process for tracking fidelity and other outcomes after each session via a post-session facilitator feedback form. This form (uploaded to "attachments" section as "Post-Session Data Collection.docx) will be completed by the intervention facilitator (Carey) immediately after each session. Data to collect includes attendance (dosage), intervention location, and information on participant engagement and collaboration.

School Policy Scan

Content analysis. Schools will provide the research team with access to current copies of the student handbook and internal policy documents that relate to LGBTQ students (including non-discrimination, curricular inclusion, name and pronoun policies, student data privacy protocols, gender-neutral facilities, bullying interventions, and suicide prevention policies). Schools will also provide the research team with recent copies of history, social science, and health education curriculum. The research team will conduct qualitative content analysis of provided materials, the result of which will compose part of a pre-Making Space intervention "policy scan" of the school. This process will be conducted in the year that the school participates and will be repeated in the same schools in the year following participation to allow for assessment of changes in policy over the intervention year.

Observational site visits. The research team (Carey) will conduct an on-site visit of the school during the intervention year and in the following year. To prepare for observational site visits, schools will be asked to provide a campus map, a list of student groups, and the meeting room for any LGBTQ-focused student group (such as Gender and Sexuality Alliances). During observational site visits, the research team members will walk around the school campus and take notes and photographs of campus facilities, such as classrooms and gender-specific facilities like restrooms and locker rooms. Notes and photographs will focus on the availability, accessibility, acceptability, and quality (AAAQ) of LGBTQ-specific or -relevant campus facilities, such as the classroom where an LGBTQ student group meets or the relative accessibility of gender-neutral restrooms vs gender-segregated restrooms. Photographs will only

be used as reference material to compare change from year to year and will not include any images of students, school staff, or school names or branding (i.e. the school mascot in the background). Photographs will be labeled in records using the date and time of the site visit, such that schools will not be associated with photographs by name.

Make Space Intervention Procedures: There will be two sets of youth participating in the Make Space intervention portion of this study: 1) LGBTQ+ youth who also participated in P&E and; 2) Allies to the LGBTQ community who were nominated by the LGBTQ P&E students. Set 1 will be referred to as "LGBTQ Make Space participants" and set 2 will be referred to as "Make Space Allies."

There are 2 different assent/consent documents for the Make Space portion of the study. Consent 1 (Y2 Make Space LGBTQ Assent Consent.rtf) is for the "LGBTQ Make Space participants" who will not complete any survey associated with Make Space because they are already completing the surveys associated with Proud & Empowered and will receive compensation for each survey they complete. Consent 2 (Y2 Make Space ALLIES Assent Consent.rft) is for the "Make Space Allies" who in addition to participating in the Make Space intervention will complete 2 surveys and receive compensation for each survey. For Make Space Allies, measures will be obtained at two time points: once after the P&E intervention period (November), and again at the conclusion of the school year (May). Make Space Allies will create a Unique ID which the study team will use to link measures taken over time. The survey for Make Space allies can be found in the attachments section as "Y2 Make Space Survey.docx".

Detailed information on recruitment of Make Space Ally participants and LGBTQ Make Space participants can be found in the *Recruitment* section above. Students who report interest and are chosen for participation will provide assent (or consent if they are 18+), similar to the process described for LGBTQ youth. LGBTQ youth participants who participate in Proud & Empowered will be invited to participate in Make Space intervention alongside the Make Space Allies who they nominate.

A PDF of the Make Space intervention program can be found in the attachments section of this IRB application as "Make Space Curriculum.docx". The Make Space intervention is a student leadership and advocacy intervention training program. The training will be facilitated by MSW-level staff and is completed over four, 45-minute sessions, similar to how the P&E intervention sessions will be run. The Make Space intervention includes modules on: Team Building, Exploring LGBTQ+ Issues, Capacity Building, and Youth Activism. LGBTQ youth who are part of the P&E intervention will take part in this training, as will the Make Space Allies who were nominated by the P&E intervention participants. After the training, ongoing intervention planning and organizing sessions will be facilitated by MSW-level study staff focused on planning the school climate project chosen during the Make Space training. To support youth in identifying a school climate project for their school, WUSTL study staff will provide participating youth with their schools' results of the policy scan. Youth will work with the WUSTL study staff as frequently as is needed to implement the chosen activities. Similar to the P&E Intervention implementation plan, study activities will occur at the school during school hours and the school counselor will ensure students can discreetly participate in the intervention sessions by either 1) grouping participating youth into the same homeroom/advisory period

where the intervention will administered by Study Facilitator/Study Coordinator, or 2) providing students with a counseling slip, allowing them to miss a class to participate in the intervention session. Schools will choose what works best for them. If option 2 is selected, Make Space sessions will be staggered and run during a different class period each week so that participating youth do not miss the same class every week. We have formalized the process for tracking fidelity and other outcomes after each session via a post-session facilitator feedback form. This form (uploaded to "attachments" section as "Post-Session Data Collection.docx) will be completed by the intervention facilitator (Carey) immediately after each session. Data to collect includes attendance (dosage), intervention location, and information on participant engagement and collaboration.

Instrumentation

All measures are valid and reliable psychometric tests. As this is a quantitative study, all measures are closed-ended and survey-based. Information on each specific measure is as follows:

Sexual Minority Adolescent Stress Inventory: 54-item survey across 10 domains of minority stress. Assesses experiences of minority stress among adolescents. Each statement reflects past-30-day thoughts, feelings, and situations a person may have experienced.

Beck Anxiety Inventory: 21-item self-report assessment of anxiety symptoms.

PTSD Checklist for DSM-5 (PCL-5): 20-item self-report assessment of post-traumatic stress disorder (PTSD) symptoms which addresses all 20 DSM-5 symptoms of PTSD.

Beck Depression Inventory: 21-item self-report assessment of depression symptoms and severity of depression.

Adapted CSSRS Suicide Questions (Columbia Suicide Severity Rating Scale): Six items assessing current suicidality that were adapted from the longer, treatment-based Columbia Suicide Severity Rating Scale

Youth Risk Behavior Survey Substance Use Questions: Measures individual's usage of various substances in their lifetime and within the past 30 days as well as the ways in which individuals have used marijuana, tobacco, or nicotine in the past 30 days.

Coping Strategies Inventory: 16-item assessment measuring specific coping strategies people use in response to stressful events with each item assessing components of Problem Solving, Cognitive Restructuring, Social Support, Expressed Emotions, Problem Avoidance, Wishful Thinking, and Social Withdrawal.

LGBTQ+ Coping: 20-item assessment measuring ways individuals cope with stressors that are specifically related to being LGBTQ+ over the past 3 months.

California Healthy Kids Survey General Bullying and Gender Identity/Sexual Orientation-Based Harassment Module: Assesses students' perceptions of harassment experiences on school campus among the general student population in addition to bullying and harassment experiences on school campus specific of students who identify as, or are perceived to be, lesbian, gay, bisexual, transgender, questioning, or gender nonconforming.

Civic Measurement Models: Measures competency for civic action, political efficacy and participatory citizen to assess young people's perceived ability to engage in civic action (e.g., organize a meeting), express their political voice (e.g., sign a petition), and critically analyze political messages.

Data Analysis

A series of analyses will be conducted to thoroughly investigate the program effects and its fidelity on outcomes of interest. First, a cluster-randomized repeated measures ANOVA will be used to examine the intervention effects on minority stress, behavioral health outcomes, and coping skills among the cohort of SGM adolescents who participate in the small group intervention and their control-school counterparts. Second, qualitative content and observational analysis by study staff will be used to conduct a baseline policy scan in the intervention year, inform Make Space participant activities, and evaluate change in policies over the course of the year.

Data Protection

All survey data will be coded using a unique code selected by each participant. Coded data will be held separately from all identifying data, such as recruitment information. Assent/consent will be collected in a separate survey though RedCap in order to keep as little identifying information about LGBTQ+ participants and POL participants as possible. All contact information used for recruitment be destroyed at the conclusion of the study. Downloaded data will be stored on dual-authentication and password-protected computers. Only the PI and authorized study staff will have access to survey data.

Dissemination of Findings

The proposed study plans to consistently disseminate findings from study data and – if warranted – to provide broad access to the final intervention program. The dissemination plan aims to inform research on minority health, risk and protective factors among SGM youth. Research findings will also be disseminated through peer-reviewed journals, national conferences, and relevant compendiums of intervention research if possible (e.g., Cochrane).

Data Safety Monitoring Board (DSMB)

The DSMB will meet quarterly during the first year of the project and annually thereafter and is composed of recognized experts in SGM clinical (Ashley Austin, PhD) and adolescent research (Shelley Craig, PhD; Traci Schwinn, PhD) with no direct involvement in the study. The DSMB will be charged with ensuring the highest standards for participant safety and data

quality. Initially, the board will review the study design, instruments and methods, recruitment criteria, intervention plan, and data analytic plan. It will provide recommendations to safely achieve our goals. Subsequent meetings will focus on monitoring study participant enrollment, safety, and protocol adherence (*see DSMB and Letters of Support)*.

Although the impetus for P&E is to *reduce* victimization and bullying experiences, increased visibility due to participation could result in increased targeting. This may not only occur for SGM-identified participants, but also for POL allies, who may be targeted by association. Given this, our recruitment and consent processes for both SGM and POL students will discuss this potential risk of participation. As part of our study intake procedures, we educate participants on existing policies and what procedures are in place to protect them, including whom they should contact and what kinds of support they can expect. During the intervention, facilitators check in weekly with participants about safety concerns and refer to school-based supports, as necessary, following existing school protocols. Youth may also discontinue participation, if desired, at any time. Finally, our DSMB will meet regularly to review all procedures, including potentially trial stopping factors such as increased victimization. These protocols allow us to monitor student experiences regardless of whether victimization experiences are related to study participation or other extraneous factors.

Suicide and Emergency Standards of Procedure

Potential Emergencies:

For purposes of monitoring and reporting adverse events, the following NIH definitions will be used:

Adverse Event (AE): any untoward medical occurrence that may present itself during treatment or administration of an intervention, and which may or may not have a causal relationship with the treatment. Adverse events could arise from the study (e.g., breach of confidentiality) or could arise due to the population under study (e.g., a participant becomes upset answering sensitive questions).

Serious Adverse Event (SAE): Any medical occurrence that results in death; is life-threatening; requires inpatient hospitalization or prolongation of existing hospitalizations; creates persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Such an event could include suicidal ideation or attempted drug overdose or withdrawal, etc.

There are five possible sources of AE which we can foresee based on our prior work with sexual minority adolescents:

1. Emotional distress due to discomfort with the survey questions. Although rare, we recognize that some youth may find personal questions distressing to answer.
2. Accidental disclosure of confidential material. It is possible that despite our carefully constructed privacy safeguards that there could be accidental disclosure of confidential information.
3. Imminent threat to self. It is possible that youth will express suicidal intent. **See detailed notes at the end of this document for specific suicide protocols for study surveys.**

4. Imminent threat to others. It is possible that youth will express the intention to harm someone else or someone else's property.
5. Detection of previously undisclosed child or elder abuse. It is possible that youth may disclose abuse to our research staff during the surveys or intervention.

If a participant discloses possible self-harm, suicidal ideation, homicidal ideation, or the sexual or physical abuse of a minor or elder during the intervention or research study, research staff will immediately contact the PI (Dr. Goldbach) for consultation in appropriately handling the potential emergency. In our prior experience, fewer than 1% of interviews required enacting the emergency protocol.

The study staff will assess the situation and, if need be, inform and consult Connor Carey (research manager) about the case. Connor Carey is an experienced clinical Master of Social Work and has overseen fieldwork and handled emergency situations in clinical settings. The study staff facilitating the training will also be a licensed and/or masters-level mental health clinician (LCSW, LPCC, LMFT) with experience in working with LGBTQ+ youth. Project administrator and/or study facilitator will immediately notify the PI (Dr. Goldbach) of any adverse or serious adverse event

All study team members will complete emergency procedures training prior to contact with study participants. In the event of an emergency situation, a debrief with all of the research staff will occur to discuss what happened, what worked well, and what to know for next time. All study team members will be instructed on how to implement emergency procedures in situations without alarming the subjects (e.g., by teaching study staff to remain calm and to proceed with the emergency procedures in the same calm and forthright manner that they have been conducting the rest of the study). Study staff will also be trained in the following emergency response protocol that includes:

(i) Staff will be taught to stay with the subject for as long as it takes for them to have made contact with the manager and to be directed as to what the next step needs to be. If the staff is directed to call the psychiatric emergency services for a 5150 evaluation or for other emergency or police services, they will stay with the participant until the emergency team arrives.

(ii) There will be a 15-minute maximum wait for the Project Administrator to respond to the study staff; after 15 minutes, the study staff will then call the site coordinator or school counselor.

(iii) During the waiting period, study staff will be trained to provide a simple explanation to the participant that they need to contact a supervisor team member to make a plan to provide referrals for the participant and to ensure a safety plan. They will be trained to provide reassurance and support for the participant, letting them know that they will remain with the participant until they are able to make a good plan for how to address the emergency issue. They should also answer any questions the participant may have in a simple and straightforward fashion. If they are uncertain about a response, they should state that the first step is for both of them to get more information from the supervisor about

what would be helpful to make sure the participant's needs are met. Since they have already conducted the identified safety screening algorithm, and determined that a consultation with a supervisor is appropriate, the staff will be trained to not continue an assessment of the emergency issue (such as suicidality) until the information is reviewed with the PI, project administrator, and/or study facilitator.

(iv) Study staff will remain with the participant, explaining the procedure to consult with the Project Administrator and PI in situations when a participant is distressed and/or if there is a concern about safety issues. If there is a waiting period, the staff will provide reassurance and support to the participant in order to reduce any potential distress or concern. In the rare situation in which a participant may be highly agitated, raising an immediate safety concern for the participant, study staff, or other individuals, study staff will call 911 and request emergency services.

(v) As noted above, the study protocol provides a back-up list of emergency supervisors for the study team to contact. If for any reason study staff is unable to reach a supervisor or back up supervisor, they will be trained to contact the emergency service team and/or police directly for an evaluation request.

(vi) In addition, most recruitment and all study interaction will occur at schools, where school counselors will be available to assist in any emergency situation.

It is highly unlikely that participation in the study will cause an AE or SAE, as outlined above. Should an AE occur, project administrator and PI will be immediately contacted and will keep a log of all AE and SAEs. We will also work closely with the chair of the HSP subcommittees that will be assigned to this project. These individuals will be more immediately accessible to the project than the full committees and will review AEs and consult with the PIs and Co-Is. In consultation with the subcommittee chairs, we will determine if an AE is related to the research project and will file an immediate written report to the HSPC and NIH Project Officer, whether the event relates to the project or not. The log will also be used to provide information about adverse events in annual progress reports to the HSPC and NIH. Outcomes for AEs will be monitored by the PI, and outcome information will be entered into a log for inclusion in reports to the HSPC and NIH.

Additional protocol for identifying suicidality in survey participants: Because the intervention participant surveys assess for recent suicidal ideation, intent, plans, and attempts, we will implement protocols to immediately identify youth who report suicidal risk and connect them to the school counselor. The participant survey will be programmed in Qualtrics and the final screen for all youth will instruct them to: "Let the research team know you've finished the survey to receive your gift card. Code: complete." This will allow the team to verify survey completion and give the student their gift card. The Qualtrics survey will be programmed to include the youth's score on the suicide measures with the "Code: complete" message, such that students with no risk will get "Code: complete 1" and those with highest risk will get "Code: complete 5." This code is designed to not catch the attention of the student, but still allow the research staff to note the student's risk level, and then confidentially connect the student to the school counselor for further help outside of the intervention session.

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