STUDY DESIGN STUDY PROTOCOL AND STATISTICAL ANALYSIS PLAN

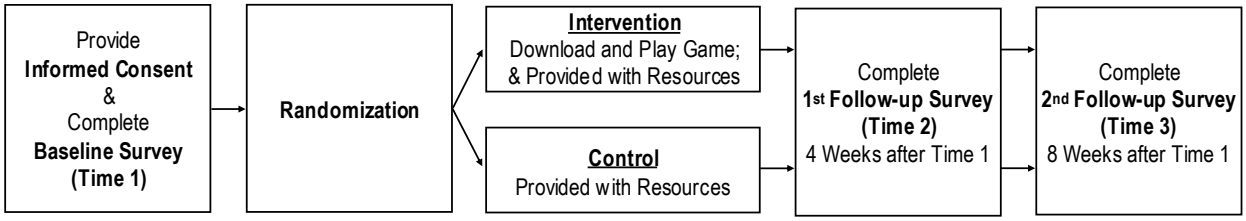
Evaluation of an Online Intervention to Help LGBTQ Youth Cope With Bullying

NCT: NCT03501264
IRB ID: PRO17060347

Most Recent Renewal: 10/25/2018

STUDY DESIGN

PARTICIPANT TIMELINE



DESCRIPTION OF PARTICIPANT FLOW

1. Advertisements direct potential participants to Screener survey
2. Participants complete screener (in REDCap)
3. If eligible, participants complete informed assent/consent (in REDCap)
    - If ineligible, participants are thanked for their time and no more contact is made with them.
4. If consent is provided, participants are emailed/texted a link to the baseline survey (T1) to complete (in REDCap)
    - Incentive: $10 when T1 survey is completed
5. Researchers then randomize participants to intervention or control (in REDCap)
6. All participants (both intervention and control groups) receive a list of website resources related to study outcomes.
7. Intervention group receives Intervention Download Instructions (via Redcap)
    - Until participants download the game, email reminders (5 maximum) will be emailed to participants every 3 days (automatically performed in REDCap). If participants also provided a phone number where we can text them, we will remind them via text message to complete the REDCap survey.
8. Participants complete first follow-up survey (T2) (in REDCap)
    - Incentive: $25 when T2 survey is completed
    - Survey will activate 4 weeks after T1 survey completion
    - Survey will be open until 7 weeks after T1 survey completion
    - All participants will complete survey similar to baseline survey (minus demographics and potential confounder variables)
    - Intervention group will also complete questions about satisfaction with the game.
    - Until participants complete the survey, email reminders (5 maximum) will be emailed to participants every 4 days (automatically performed in REDCap). If participants also provided a phone number where we can text them, we will remind them via text message to complete the REDCap survey.
9. Participants complete second/final follow-up survey (T3) (in REDCap)
    - Incentive: $50 when T3 survey is completed
    - Survey will activate 8 weeks after T1 survey completion
    - Survey will be open until 11 weeks after T1 survey completion

- Until participants complete the survey, email reminders (5 maximum) will be emailed to participants every 4 days (automatically performed in REDCap). If participants also provided a phone number where we can text them, we will remind them via text message to complete the REDCap survey.

MAIN OUTCOMES

The primary outcomes of this study are related to feasibility. This includes the domains of acceptability, demand, implementation, practicality, integration, adaptation, expansion, and preliminary efficacy testing (based on Bowen, et al., 2009, Am J Prev Med). Below, we present each of the feasibility domains, how they will be measured, and corresponding hypotheses (in parentheses).

ACCEPTABILITY
- Measured using the Gaming Experience Questionnaire (average ≥2 in each domain)
- Would you recommend that your friends play this game? (≥75%)
- How likely would you be to tell your friends about this game? (≥80%)

DEMAND
- The number of hours the game was played (≥75% who played for ≥1 hour)
- Intervention group's self-reported use of the game in hours (≥75% who played for ≥1 hour)

IMPLEMENTATION
- How many participants in in the intervention arm downloaded the game? (≥80%)
- How many people played the game? (≥80%)
- How many people completed surveys at T1, T2, T3? (≥80% each survey wave)
- How many people completed ALL surveys? (≥75%)
- How many people completed at least 2 surveys? (≥85%)
- How many reminders before people completed the surveys? (exploratory)
- How well they did in the game? Did they meet the milestones in the game? (exploratory)
- How many times texted before they completed survey? (exploratory)
- How many times contacted? (exploratory)
- Percent of people who consented post screening (80%)
- How long does it take to get 240 people to enroll in the study? (exploratory)
- Did randomization work? (yes, we hypothesize no group differences in demographics at baseline)
- How many got randomized? (240 participants)
- How many people recruited from which venue? (exploratory)

PRACTICALITY
- How many people have PC or Mac computers in our screening procedures (exploratory)
- Screening based on having an email address (exploratory)
- How easily was the game downloaded without contacting our research coordinator? (exploratory)
- Feelings of safety with regards to password protection? (exploratory)
- Feelings of safety with regards to having other people see the game? (exploratory)
- Did the game interfere with other activities? (exploratory)

INTEGRATION
- How could this better fit into the youth's life? (exploratory)
- How well does this fit into youth's life now? (exploratory)
- How could the game be improved? (exploratory)

ADAPTATION
- Would you want to be able to play this game on your phone (an app)? (exploratory)
- Did you like this game on the computer? (exploratory)
- This game may not be appropriate for older kids. (how much do they agree with this? Exploratory)
- We will examine the Gaming Experience Questionnaire scores by gender, sexual orientation, race/ethnicity, age (exploratory)

EXPANSION
- How could the game be improved? (exploratory)
- What would you like to be added to the game? (exploratory)
- What would you like removed from the game? (exploratory)

PRELIMINARY EFFICACY TESTING
We hypothesize that the intervention group (versus control group) will have greater levels of change over time in the following outcomes:
1. Increased help-seeking self-efficacy, intentions, and behaviors
2. Increased coping strategies and coping flexibility
3. Increased knowledge and use of online resources
4. Decreased bullying and cyberbullying victimization
5. Decreased loneliness
6. Decreased mental health problems (anxiety, depression, suicidality)
7. Decreased substance use (alcohol, tobacco, and other drugs)
8. Decreased internalized sexual and gender minority stigma

STATISTICAL ANALYSIS

For the measures of acceptability, demand, implementation, practicality, integration, adaptation, and expansion, we will report results using descriptive statistics (i.e., percentages and frequencies for categorical variables, or means and standard deviations for continuous variables).

For the preliminary efficacy testing outcomes, we will use repeated measures (i.e., multilevel) statistical models using logistic or linear regression, depending on the distribution of the outcomes. To examine whether there were greater improvements over time in the intervention group versus control group, we will test the interaction term of time by group. While we are powered to find medium effects (based on Cohen), our primary interest is in estimating the effect size and confidence interval width, which will help us power a future, larger randomized controlled trial.

IRB PROTOCOL

University of Pittsburgh **OSIRIS**

Section: Triage

[reviewer notes¬]

Provide a short title for this study (200 characters or less)**:**

RCT of Help-Seeking Intervention

T1.0

Select the type of application:
New Research Study

T2.0

Is the proposed research study limited to the inclusion of deceased individuals?
* No

T2.1

Are any research activities being conducted at the VA Pittsburgh Healthcare System or with VA funds?

* No

Section: Triage

[reviewer notes¬]

T3.0 What is the anticipated risk to the research participants?

Minimal Risk

T3.1 Why do you feel that all aspects of this research study, including screening and follow-up, involve no more than minimal risk to the research subjects?

The probability and magnitude of harm or discomfort anticipated in our research study are not greater in and of themselves than those ordinarily encountered in daily life (i.e., of the general population).

Asking sexual and gender minority (SGM) youth questions about help-seeking behaviors, bullying experiences, mental health, substance use experiences, and their experience with the game intervention should be regarded as minimal risk. The probability and magnitude of harm or discomfort anticipated in our research study are not greater in and of themselves than those ordinarily encountered in daily life (i.e., of the general population).

The survey questions to be asked are questions and discussions that youth normally have. Additionally, these survey questions are routinely as part of the Youth Risk Behavioral Surveillance Survey (YRBSS) throughout the United States as part of their high-school experience.

It should also be mentioned that the confidential nature of the surveys greatly reduces risk to participant.

T4.0

Does the proposed study qualify for 'exempt' IRB review or for a determination of either 'not research' or 'no human subject' involvement?

* No

T5.0

Does the proposed research study qualify for 'expedited' IRB review status?

* Yes

Section: Cover Sheet

[reviewer notes¬]

CS1.0 What is the reason for this submission?

New Research Protocol Submission

CS1.1

Has this research study been approved previously by the University of Pittsburgh IRB?

* No

CS1.1.1

Has this research study (or a substantially similar research study) been previously disapproved by the University of Pittsburgh IRB or, to your knowledge, by any other IRB?

* No

[reviewer notes¬]

CS2.0

Title of Research Study:

Pilot Randomized Controlled Trial of a Help-Seeking Intervention Game for Sexual and Gender Minority Adolescents

CS2.0.1

Requested approval letter wording:

CS2.1 Research Protocol Abstract:

The purpose of this research study is to conduct a pilot randomized controlled trial of a game-based intervention is able to increase help-seeking-related knowledge, attitudes, and behaviors, reduce health risk factors/behaviors, and increase resiliencies among sexual and gender minority (SGM) youth. The goals of the proposed study are to: (1) Test the feasibility and acceptability of a game-based intervention to increase help-seeking-related knowledge, attitudes, and behaviors among SGM youth; and (2) Using a randomized controlled trial, test the efficacy of a game-based intervention to increase help-seeking-related knowledge, attitudes, and behaviors, reduce health risk factors/behaviors, and increase resiliencies among SGM youth.

CS2.2

Select the category that best describes your research:
Social, behavioral, educational, and/or public policy research

[reviewer notes¬]

CS3.0 Name of the Principal Investigator:

James Egan

Note: Adjunct faculty of the University, including lecturers and instructors, are not permitted to serve as a PI or Faculty Mentor but may serve as co-investigators. Refer to Chapter 4 on the HRPO website for more information.

Section: Cover Sheet

CS3.1 Affiliation of Principal Investigator:

UPitt faculty member

If you chose any of the **Pitt options**, please indicate the specific campus:
Main Campus - Pittsburgh

If you chose the UPitt faculty member option, provide the PI's **University Faculty Title**:
Assistant Professor

CS3.2 Address of Principal Investigator:

4138 Parran Hall
130 De Soto Street
Pittsburgh, PA 15261

CS3.3 Recorded Primary Affiliation of the Principal Investigator:

U of Pgh | Graduate School of Public Health | Behavioral and Community Health Sciences

CS3.4 Identify the School, Department, Division or Center which is responsible for oversight of this research study:

U of Pgh | Graduate School of Public Health

CS3.5 Telephone Number of Principal Investigator:

412-624-2255

CS3.6 Recorded Current E-mail Address of Principal Investigator to which all notifications will be sent:

JEE48@pitt.edu

CS3.7 Fax Number:

CS3.8 Does this study include any personnel from Carnegie Mellon University, and/or use any CMU resources or facilities (e.g., Scientific Imaging and Brain Research Center (SIBR)?

* No

CS3.9 Is this your first submission, as PI, to the Pitt IRB?

* No

Section: Cover Sheet

[reviewer notes¬]

CS4.0

List of Co-Investigators:

Last	First	Organization
Coulter	Robert	U of Pgh | Graduate School of Public Health | Behavioral and Community Health Sciences

[reviewer notes¬]

CS5.0 **Name of Primary Research Coordinator:**

Robert Coulter

CS5.1

Address of Primary Research Coordinator:

Children's Hospital Office Building (CHOB)
Children's Hospital of Pittsburgh, UPMC
3414 Fifth Avenue, Room 101

CS5.2

Telephone Number of Primary Research Coordinator:

7165238564

CS6.0

Name of Secondary Research Coordinator:

Jordan Sang

CS6.1 **Address of Secondary Research Coordinator:**

4138 Parran Hall
130 DeSoto St
Pittsburgh PA 15261

CS6.2 **Telephone Number of Secondary Research Coordinator:**

9176368446

CS6.3 **Key Personnel/Support Staff (Only list those individuals who require access to OSIRIS):**

Last First Organization

There are no items to display

[reviewer notes¬]

CS7.0 **Will this research study use any Clinical and Translational Research Center (CTRC) resources?**

No

Section: Cover Sheet

[reviewer notes¬]

CS8.0 Select the entity responsible for scientific review.

Department Review - (a dean, department chair, division chief, or center head)
Note: **DoD funded studies** require departmental review

CS8.1

Select the school, department or division which is responsible for scientific review of this submission.

U of Pgh | Graduate School of Public Health | Behavioral and Community Health Sciences

[reviewer notes¬]

CS9.0 Does this research study involve the administration of an investigational drug or an FDA-approved drug that will be used for research purposes?

* No

CS10.0 Is this research study being conducted under a University of Pittsburgh-based, sponsor-investigator IND or IDE application?

* No

If YES, you are required to submit the IND or IDE application and all subsequent FDA correspondence through the Office for Investigator-Sponsored IND and IDE Support (O3IS). Refer to applicable University policies posted on the O3IS website (www.O3IS.pitt.edu).

[reviewer notes¬]

CS11.0

Use the 'Add' button to upload one or more of the following:

- **the sponsor protocol (including investigator initiated studies) and/or other brochures**
- **the multi-center protocol and consent form template, *if applicable***

Name Modified Date

Is this research study supported in whole or in part by industry? This includes the provision of products (drugs or devices).

* No

Is this a multi-centered study?

* No

Section: Cover Sheet

[reviewer notes¬]

CS12.0 **Does your research protocol involve the evaluation or use of procedures that emit ionizing radiation?**

* No

CS13.0 **Does this research study involve the deliberate transfer of recombinant or synthetic nucleic acid molecules into human subjects?**

* No

Upload Appendix M of NIH Guidelines:
Name Modified Date

CS14.0 **Are you using UPMC facilities and/or UPMC patients during the conduct of your research study?**

* No

If Yes, upload completed Research Fiscal Review Form:
Name Modified Date

Section: Cover Sheet

[reviewer notes¬]

CS15.0

Indicate the sites where research activities will be performed and/or private information will be obtained.

Choose all sites that apply and/or use **Other** to include sites not listed:

Sites:
University of Pittsburgh

University of Pittsburgh
Campus:
Main Campus - Pittsburgh

List university owned off-campus research sites if applicable:

If you selected **School**, **International** or **Other**, list the sites:

***For research being conducted at non Pitt or UPMC sites, upload a site permission letter granting the researcher permission to conduct their research at each external site:**
Name Modified Date

CS15.1 **Have you, James Egan , verified that all members of the research team have the appropriate expertise, credentials, and if applicable, hospital privileges to perform those research procedures that are their responsibility as outlined in the IRB protocol?**

* Yes

CS15.2

Describe the availability of resources and the adequacy of the facilities to conduct this study:

* Dr. Egan's office in the Graduate School of Public Health has locked filing cabinets, secure password protected computers, printers, fax machines and photocopiers with work space for each team member. Dr. Egan and his team have up-to-date computer equipment with relevant statistical software and access to large secure servers for managing data. Dr. Egan's computer support is more than adequate to carry out the proposed research plan. The computer networking is supported 24/7 by highly trained computer staff.

Section: Cover Sheet

[reviewer notes¬]

CS16.0 Special Research Subject Populations:

Categories

Children (age < 18 years old)

[reviewer notes¬]

CS17.0 Does your research involve the experimental use of any type of human stem cell?

* No

[reviewer notes¬]

NIH Definition of a Clinical Trial

A research study[1] in which one or more human subjects[2] are prospectively assigned[3] to one or more interventions[4] (which may include placebo or other control) to evaluate the effects of those interventions on health related biomedical or behavioral outcomes.[5]

[1] See Common Rule definition of research at 45 CFR 46.102(d) .

[2] See Common Rule definition of human subject at 45 CFR 46.102(f) .

[3] The term "prospectively assigned" refers to a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial.

[4] An intervention is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies.

[5] Health-related biomedical or behavioral outcome is defined as the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects' biomedical or behavioral status or quality of life. Examples include: positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and /or information retention); positive or negative changes to disease processes; positive or negative changes to health-related behaviors; and, positive or negative changes to quality of life.

CS18.0 * Based on the above information, does this study meet the NIH definition of a clinical trial?

(●) **Yes** ( ) No

If Yes, click Save and then Click Here For Study Team's CITI Training Records . Please ensure all personnel's training is up to date

	Section: Section 1 - Objective, Aims, Background and Significance

[reviewer notes¬]

1.1 Objective: What is the overall purpose of this research study? (Limit response to 1-2 sentences.)

The purpose of this research study is to assess the feasibility, acceptability, and preliminary efficacy of a randomized controlled trial of a game-based intervention is able to increase help-seeking-related knowledge, attitudes, and behaviors, reduce health risk factors/behaviors, and increase resiliencies among sexual and gender minority (SGM) youth.

1.2 Specific Aims: List the goals of the proposed study (e.g., describe the relevant hypotheses or the specific problems or issues that will be addressed by the study).

The goals of the proposed study are to:

1) Test the feasibility and acceptability of a game-based intervention to increase help-seeking-related knowledge, attitudes, and behaviors among sexual and gender minority (SGM) youth; and

2) Using a randomized controlled trial, test the preliminary efficacy of a game-based intervention to increase help-seeking-related knowledge, attitudes, and behaviors, reduce health risk factors/behaviors, and increase resiliencies among SGM youth.

1.3 Background: Briefly describe previous findings or observations that provide the background leading to this proposal.

Sexual and gender minority (SGM) youth experience high rates of bullying. Based on 28 school-based studies of randomly selected youth, Friedman et al., 61 found that 44.4% of lesbian, 39.9% of bisexual female, 43.2% of gay male, and 50.2% of bisexual male teenagers reported physical assault by a peer at school (prior year), rates that far exceeded those of heterosexual youth. SGM youth also disproportionately experience negative health outcomes. Meta-analyses by our group show that SGM youth, compared to young heterosexuals, were 190% more likely to use illicit drugs 57, 85% and 200% more likely to experience depression and suicidality respectively 107, and 91% more likely to combine sex and alcohol (p values <.01) 108. HIV prevalence among young men who have sex with men is an astounding 7.2% 109. Bullying appears to be a driver of these health disparities. School-based studies found associations between peer victimization and suicidality, drug use, and sexual risk among SGM youth 62-64.

Making matters worse, anti-bullying programs that focus on perpetrators have shown small to moderate effects 65,110. SGM youth will therefore enter toxic school environments on an ongoing, daily basis.

The prevalence of bullying victimization, health outcomes, and associations between victimization and health outcomes are similar among SGM youth. Further, the needs of SGM youth who are bullied appear to be unique. For example, bullied SGM youth have less access to coping resources. Beyond typical fears of disclosing bullying, SGM youth often fear reactions by school staff and parents due to being SGM 16,17. The gay-related shame many SGM youth internalize 19,20 may make it more likely for them to blame themselves for bullying thus impacting their ability to cope.

We seek to improve health and academic outcomes of SGM youth through a game-based intervention they can easily access. Playing a game is advantageous as SGM youth are often "out" to no or few others off-line 111,112. The game will therefore be accessible to SGM youth who are insufficiently supported in offline programs 60,88,113. The game-based environment is relatively safe for SGM youth to gain coping skills 94,95. Game-based programs about sex 86,87, mental health114, alcohol use 72-75,115, asthma 116-119, and smoking 76-78 are effective for youth. It is important to note that while face-to-face interventions and game-based interventions incorporating contact with individuals usually, though not always, produce greater effects than "stand-alone" game-based interventions 120-127, our review suggests that "stand-alone" game-based programs produce significant change with respect to various health issues 72-74,76-85,87,128-134. Other advantages of

"stand-alone" game-based interventions are increased fidelity, cost-effectiveness and the ability to reach far larger numbers of individuals 133,135-140.

We chose a game format as 78% of teens play games 141. Games have promoted behavior change in asthma and cancer treatment, and weight control 90,91,93,142. Primary school students who problem solved in virtual situations were more likely to end real-life bullying than controls 3. Grade 7-10 students who experienced cognitive restructuring, graded exposure to and coaching in simulated situations were more likely than controls to stop bullying 4,143. These programs' effects were however moderate and short-term.

1.4 Significance: Why is it important that this research be conducted? What gaps in existing information or knowledge is this research intended to fill?

We believe our game-based intervention will produce larger and longer-term effects than the above programs because: 1) Our game will utilize more engaging storylines. 2) Prior programs primarily focused on bullying whereas our game also focuses on social and emotional learning (S&EL). S&EL programs build self-management, interpersonal, and problem solving skills, and produce more confident 144 and socially connected 99 youth and such youth report less bullying 105,106. 3) The above games did not address subgroups' needs. We will address experiences of SGM youth (e.g., gay-related shame; fear of "double victimization") 19,145. 4) Our game design and testing are based on state-of-the-art methods 90,146-150. It has been developed by an expert in game-based programs and experts in adolescence, SGM youth, bullying, and game-based programs. 5) The game is informed by an evidence-based logic model ensuring it will attend to behavior change theory and posited mediators.

To our knowledge, this game-based intervention is the:

- First online program targeting SGM youth who are bullying victims, a format that has the potential to reach far greater numbers of SGM youth than traditional face-to-face interventions.
- First bullying prevention program to utilize a gaming format to attract participation and build retention.
- First intervention addressing social and emotional learning with respect to help-seeking among SGMyouth.
- First online intervention with 14-18 year olds - as opposed to the typical focus on SGM "youth" who are 18+.

Section: Section 2 - Research Design and Methods

[reviewer notes¬]

2.1 Does this research study involve the *use* or evaluation of a drug, biological, or nutritional (e.g., herbal or dietary) supplement?

* No

[reviewer notes¬]

2.2 Will this research *use* or evaluate the safety and/or effectiveness of one or more devices?

* No

[reviewer notes¬]

2.3 Summarize the general classification (e.g., descriptive, experimental) and methodological design (e.g., observational, cross-sectional, longitudinal, randomized, open-label single-blind, double-blind, placebo-controlled, active treatment controlled, parallel arm, cross-over arm) of the proposed research study, as applicable.

Experimental randomized controlled trial

2.3.1 Does this research study involve a placebo-controlled arm?

* No

[reviewer notes¬]

2.4 Will any research subjects be withdrawn from known effective therapy for the purpose of participating in this research study?

* No

[reviewer notes¬]

2.5 Will screening procedures (i.e., procedures to determine research subject eligibility) be performed specifically for the purpose of this research study?

* Yes

2.5.1 List the screening procedures that will be performed for the purpose of this research study. Do NOT include the inclusion/exclusion criteria in this section as they will be addressed in section 3; questions 3.13 and 3.14.

To determine eligibility, potential participants will complete a brief online screening questionnaire before being entered into this study.

[reviewer notes¬]

	Section: Section 2 - Research Design and Methods

2.6

Provide a detailed description of all research activities (e.g., all drugs or devices; psychosocial interventions or measures) that will be performed for the purpose of this research study.

This description of activities should be complete and of sufficient detail to permit an assessment of associated risks.

At a minimum the description should include:

- **all research activities**
- **personnel (by role) performing the procedures**
- **location of procedures**
- **duration of procedures**
- **timeline of study procedures**

DESCRIPTION OF PARTICIPANT FLOW
1. Advertisements direct potential participants to Screener survey
2. Participants complete screener (in REDCap)
3. If eligible, participants complete informed assent/consent (in REDCap)
o If ineligible, participants are thanked for their time and no more contact is made with them.
4. If consent is provided, participants are emailed/texted a link to the baseline survey (T1) to complete (in REDCap)
o Incentive: $10 when T1 survey is completed
5. Researchers then randomize participants to intervention or control (in REDCap)
6. All participants (both intervention and control groups) receive a list of website resources related to study outcomes. [This document is located in the 'Supporting Documentation Section' of this IRB Protocol.]
7. Intervention group receives Intervention Download Instructions (via Redcap) [This document is located in the 'Supporting Documentation Section' of this IRB Protocol. IRB Reviewers can use this document to download the game.]
o Until participants download the game, email reminders (5 maximum) will be emailed to participants every 3 days (automatically performed in REDCap). If participants also provided a phone number where we can text them, we will remind them via text message to complete the REDCap survey.
8. Participants complete first follow-up survey (T2) (in REDCap)
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o Intervention group will also complete questions about satisfaction with the game.
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o Until participants complete the survey, email reminders (5 maximum) will be emailed to participants every 4 days (automatically performed in REDCap). If participants also provided a phone number where we can text them, we will remind them via text message to complete the REDCap survey.

2.6.1

Will blood samples be obtained as part of this research study?

Section: Section 2 - Research Design and Methods

* No

*If submitting a protocol for expedited review, it should be clear that the planned blood draws are within the parameters described here: http://www.hhs.gov/ohrp/policy/expedited98.html (see Expedited Research Category #2)

If **Yes**, address the frequency, volume per withdrawal, the total volume per visit, and the qualifications of the individual performing the procedure:

Study Flow Chart:

Name	Modified Date
StudyDesignProcedures_v2_121817.docx	12/18/2017 1:52 PM

[reviewer notes¬]

2.7 Will follow-up procedures be performed specifically for research purposes? Follow-up procedures may include phone calls, interviews, biomedical tests or other monitoring procedures.

* Yes

Detailed procedures listed in the textbox below:

Participants will be emailed or texted follow-up surveys immediate post-intervention (time 2; 1 month after baseline survey) and 1-month post-intervention (time 3; 3.5 months after baseline survey). Participants will be reminded up to five times via email/text to complete follow-up surveys.

[reviewer notes¬]

2.8 Does this research study involve the use of any questionnaires, interview or survey instruments?

* Yes

Upload a copy of all materials except for the SCID or KSADS which are on file at the IRB. The use of all instruments must be addressed in question 2.6 and/or question 2.7 (except for an exempt submission where they should be addressed on the appropriate uploaded exempt form).

Name	Modified Date
T3Survey_v2_121817.docx	2/21/2018 3:02 PM
T2Survey_v2_121817.docx	2/21/2018 3:01 PM
T1Survey_v2_121817.docx	2/21/2018 3:00 PM

Previously the name and publisher for commercially available materials were listed in the textbox below but effective 9/1/2015, all materials (except for the SCID and KSADS) must be uploaded using the Add button above.

	Section: Section 2 - Research Design and Methods

[reviewer notes¬]

2.9 **If subjects are also patients, will any clinical procedures that are being used for their conventional medical care also be used for research purposes?**

* n/a

If **Yes,** describe the clinical procedures (and, if applicable, their frequency) that will be used for research purposes:

2.10 The blood sample question was moved to 2.6.1.

[reviewer notes¬]

2.11 **What is the total duration of the subject's participation in this research study across all visits, including follow-up surveillance?**

* 3 months

[reviewer notes¬]

2.12 **Does this research study involve any type of planned deception?**
If Yes, you are required to request an alteration of the informed consent process (question 4.7)

* No

[reviewer notes¬]

2.13 **Does this research study involve the use of UPMC/Pitt protected health information that will be de-identified by an IRB approved "honest broker" system?**

* No

	Section: Section 2 - Research Design and Methods

[reviewer notes¬]

2.14 **Will protected health information from a UPMC/Pitt HIPAA covered entity be accessed for research purposes or will research data be placed in the UPMC/Pitt medical record?**

* No

2.14.1 **Will protected health information from a non-UPMC/Pitt HIPAA covered entity be obtained for research purposes or will research data be placed in the non-UPMC/Pitt medical record?**

* No

[reviewer notes¬]

2.15 **Does this research study involve the long-term storage (banking) of biological specimens?**

* No

[reviewer notes¬]

2.16 **Will research participants be asked to provide information about their family members or acquaintances?**

* No

[reviewer notes¬]

2.17 **What are the main outcome variables that will be evaluated in this study?**

The primary outcomes of this study are related to feasibility. This includes the domains of acceptability, demand, implementation, practicality, integration, adaptation, expansion, and preliminary efficacy testing (based on Bowen, et al., 2009, Am J Prev Med). Below, we present each of the feasibility domains, how they will be measured, and corresponding hypotheses (in parentheses).

ACCEPTABILITY
- Measured using the Gaming Experience Questionnaire (average ≥2 in each domain)
- Would you recommend that your friends play this game? (≥75%)
- How likely would you be to tell your friends about this game? (≥80%)

DEMAND
- The number of hours the game was played (≥75% who played for ≥1 hour)
- Intervention group's self-reported use of the game in hours (≥75% who played for ≥1 hour)

IMPLEMENTATION
- How many participants in in the intervention arm downloaded the game? (≥80%)
- How many people played the game? (≥80%)
- How many people completed surveys at T1, T2, T3? (≥80% each survey wave)

- How many people completed ALL surveys? (≥75%)
- How many people completed at least 2 surveys? (≥85%)
- How many reminders before people completed the surveys? (exploratory)
- How well they did in the game? Did they meet the milestones in the game? (exploratory)
- How many times texted before they completed survey? (exploratory)
- How many times contacted? (exploratory)
- Percent of people who consented post screening (80%)
- How long does it take to get 240 people to enroll in the study? (exploratory)
- Did randomization work? (yes, we hypothesize no group differences in demographics at baseline)
- How many got randomized? (240 participants)
- How many people recruited from which venue? (exploratory)

PRACTICALITY
- How many people have PC or Mac computers in our screening procedures (exploratory)
- Screening based on having an email address (exploratory)
- How easily was the game downloaded without contacting our research coordinator? (exploratory)
- Feelings of safety with regards to password protection? (exploratory)
- Feelings of safety with regards to having other people see the game? (exploratory)
- Did the game interfere with other activities? (exploratory)

INTEGRATION
- How could this better fit into the youth's life? (exploratory)
- How well does this fit into youth's life now? (exploratory)
- How could the game be improved? (exploratory)

ADAPTATION
- Would you want to be able to play this game on your phone (an app)? (exploratory)
- Did you like this game on the computer? (exploratory)
- This game may not be appropriate for older kids. (how much do they agree with this? Exploratory)
- We will examine the Gaming Experience Questionnaire scores by gender, sexual orientation, race/ethnicity, age (exploratory)

EXPANSION
- How could the game be improved? (exploratory)
- What would you like to be added to the game? (exploratory)
- What would you like removed from the game? (exploratory)

PRELIMINARY EFFICACY TESTING
We hypothesize that the intervention group (versus control group) will have greater levels of change over time in the following outcomes:
1. Increased help-seeking self-efficacy, intentions, and behaviors
2. Increased coping strategies and coping flexibility
3. Increased knowledge and use of online resources
4. Decreased bullying and cyberbullying victimization
5. Decreased loneliness
6. Decreased mental health problems (anxiety, depression, suicidality)
7. Decreased substance use (alcohol, tobacco, and other drugs)
8. Decreased internalized sexual and gender minority stigma

2.18 Describe the statistical approaches that will be used to analyze the study data.

* Addressed below:

For the measures of acceptability, demand, implementation, practicality, integration, adaptation, and expansion, we will report results using descriptive statistics (i.e., percentages and frequencies for categorical variables, or means and standard deviations for continuous variables).

For the preliminary efficacy testing outcomes, we will use repeated measures (i.e., multilevel) statistical models using logistic or linear regression, depending on the distribution

Section: Section 2 - Research Design and Methods

of the outcomes. To examine whether there were greater improvements over time in the intervention group versus control group, we will test the interaction term of time by group. While we are powered to find medium effects (based on Cohen), our primary interest is in estimating the effect size and confidence interval width, which will help us power a future, larger randomized controlled trial.

[reviewer notes¬]

2.19

Will this research be conducted in (a) a foreign country and/or (b) at a site (e.g., Navajo Nation) where the cultural background of the subject population differs substantially from that of Pittsburgh and its surrounding communities?

* No

Note that copies of training records, licenses, certificates should be maintained in the study regulatory binder and are subject to audit by the Research Conduct and Compliance Office (RCCO).

In addition, individuals planning to conduct human subject research outside the United States must complete an optional module on the CITI training website: International Studies. Click here to access the instruction sheet for accessing optional CITI modules.

[reviewer notes¬]

2.21

Will this research study be conducted within a nursing home located in Pennsylvania?

* No

Section: Section 3 - Human Subjects

[reviewer notes¬]

Section 3 - Human Subjects

3.1 What is the age range of the subject population?

14-18

3.2 What is their gender?

* Both males and females

Provide a justification if single gender selected:

3.3 Will any racial or ethnic subgroups be explicitly excluded from participation?

* No

If **Yes**, identify subgroups and provide a justification:

3.4

For studies conducted in the U.S., do you expect that all subjects will be able to comprehend English?

* Yes

[reviewer notes¬]

3.5 Participation of Children: Will children less than 18 years of age be studied?

* Yes

3.5.1

Specify the age range of the children to be studied.
(Check all that apply below:)

*

Choices
14-17 years of age

3.5.2

Provide a rationale for the specific age ranges of the children to be studied:

This is an intervention designed specifically for young sexual and gender minority (SGM) youth. All game development procedures have been conducted in consult with SGM aged 14-17 and experts in the field of SGM youth.

Please see the background section of this IRB protocol. Generally, SGM youth are at far higher risk to be bullied by peers. There is very little systematic support available for these youth to help them cope with such bullying. Our program will focus on this age range to decrease negative outcomes associated with bullying victimization among this population.

3.5.3

Describe the expertise of the study team for conducting research with children within this age range:

Drs. Egan and Coulter have studied SGM youth for the past 10 years including the assessment of sexual orientation, gender identity, bullying victimization, protecting SGM youth in schools, and longitudinal assessment of SGM populations. They have led qualitative and quantitative studies of SGM youth including the assessment of sexual

orientation, gender identity, bullying, mental health, substance use, HIV risks among SGM youth.

3.5.3.1

Have you obtained the following clearances from all research staff who may have direct contact with children under the age of 18? Direct contact under the law includes face-to-face, and telephonic or electronic, contact with minors. Please see the Child Clearances guidance document for further explanation?

Pennsylvania Department of Public Welfare Child Abuse History Clearance;
Pennsylvania State Police Criminal Record Check; and
FBI Criminal Background Check

Yes

Note: If No, once all clearances are obtained, a modification must be submitted.

If you selected N/A, please explain:

It is important to note that "direct contact" refers not only to face-to-face meetings but also extends to communication via phone (including text messaging), social media or internet. Direct contact also includes the care, guidance, supervision or control, or routine interaction with, minors. Conversely, a participating investigator or support staff member who does not have direct contact, either electronically or in person, with children does not need to obtain clearances (e.g., statistician, non-clinical laboratory personnel, etc.). If your research study provides babysitting services, the babysitters must have the required child clearances.

* **Note:** It is the **responsibility of the principal investigator** to ensure that all research staff have these clearances prior to any interaction with children. Contact Human Resources at 412-624-8150 for assistance with this process.

3.5.4

Describe the adequacy of the research facilities to accommodate children within this age range:*
Not applicable; research will be conducted in the child's normal environment.

Note: Experts and non-experts alike consider the use of computers and games to be a part of the normal environment for children. Various studies have implemented game-based intervention studies in this environment.

3.5.5

Permitted Categories of Research: The Federal Policy and FDA regulations governing human subject protections specify that research involving children must fall into one of the following permitted categories.

*
The research does not involve greater than minimal risk *[45 CFR 46.404/21 CFR 50.51].*

45 CFR 46.406

- The risk represents only a minor increase over minimal risk.
- The research procedures present experiences to the subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations.
- The research procedures are likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for understanding or amelioration of the subjects' disorder or condition.

Section: Section 3 - Human Subjects

45 CFR 46.407

- The risk is justified by the anticipated benefit to the subjects; and the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches.

Provide a justification which **must address all considerations** related to the designated category of research:

The probability and magnitude of harm or discomfort anticipated in our research study are not greater in and of themselves than those ordinarily encountered in daily life (i.e., of the general population).

Asking sexual and gender minority (SGM) youth questions about help-seeking behaviors, bullying experiences, mental health, substance use experiences, and their experience with the game intervention should be regarded as minimal risk. The probability and magnitude of harm or discomfort anticipated in our research study are not greater in and of themselves than those ordinarily encountered in daily life (i.e., of the general population).

The survey questions to be asked are questions and discussions that youth normally have. Additionally, these survey questions are routinely as part of the Youth Risk Behavioral Surveillance Survey (YRBSS) throughout the United States as part of their high-school experience.

We should reiterate that all participants will be given information about contacting the PI Dr. Egan should they have questions or concerns about the study or their reactions to it. The participants will also be provided with national hotlines for SGM youth should they require support. Of note, ALL individuals will automatically be given information about the Trevor Project which is a well respected hotline that can be accessed either online or by phone that specializes in the support of suicidal SGM youth.

It should also be mentioned that the confidential nature of the surveys greatly reduces risk to participant.

[reviewer notes¬]

3.6 Does this research study involve prisoners, or is it anticipated that the research study may involve prisoners?

* No

[reviewer notes¬]

3.7 Will pregnant women be knowingly and purposely included in this research study?

* No

	Section: Section 3 - Human Subjects

[reviewer notes¬]

3.8 Does this research study involve neonates of uncertain viability or nonviable neonates?

* No

[reviewer notes¬]

3.9 Fetal Tissues: Does this research involve the use of fetal tissues or organs?

* No

	Section: Section 3 - Human Subjects

[reviewer notes¬]
--->

3.10

What is the total number of subjects to be studied at this site, including subjects to be screened for eligibility?

Note: The number below is calculated by summing the data entered in question 3.11. Any additions or changes to the values entered in 3.11 will be reflected in 3.10.

* 480

3.11

Identify each of the disease or condition specific subgroups (include healthy volunteers, if applicable) that will be studied.

Click on the "Add" button and specify for each subgroup:

1) how many subjects will undergo research related procedures at this site; and

2) if applicable, how many subjects will be required to undergo screening procedures (e.g., blood work, EKG, x-rays, etc.) to establish eligibility. Do Not include subjects who will undergo preliminary telephone screening.

*

	Subgroup	Number to undergo research procedures	Number to undergo screening procedures
View	Control	120	240
View	Intervention	120	240

3.12 **Provide a statistical justification for the total number of subjects to be enrolled into this research study at the multicenter sites or this site.**

* Described below:

This is a feasibility study, which is primarily being conducted to inform a larger randomized controlled trial. For a majority of our outcomes, we are reporting simple descriptive statistics (e.g., how long the game was played by participants). For preliminary efficacy testing, we are primarily interested in effect size and confidence interval estimation; we are NOT necessarily interested in finding statistically significant effects (see Bowen, 2009, Am J Prev Med). Nevertheless, we are powered to find medium effect sizes (based on Cohen, 1988).

Section: Section 3 - Human Subjects

[reviewer notes¬]

3.13 Inclusion Criteria: List the specific criteria for inclusion of potential subjects.

- Aged 14 to 18 years old
- English literate
- Lives in the United States
- Identifies as Sexual or Gender Minority
- Has a PC or Mac that is able to download games
- Has an email address
- Has been bullied or cyberbullied in the past 12 months

3.14 Exclusion Criteria: List the specific criteria for exclusion of potential subjects from participation.

- Not bullied or cyberbullied in the past 12 months
- Identifies as cisgender (i.e., their assigned sex at birth matches their current gender identity) and heterosexual
- Identifies as cisgender and is unsure of their sexual identity

3.15 Will HIV serostatus be evaluated specifically for the purpose of participation in this research study?

* No

If **Yes**, provide a justification:

	Section: Section 4 - Recruitment and Informed Consent Procedures

[reviewer notes¬]

4.1 Select all recruitment methods to be used to identify potential subjects:
Advertisements
Pitt + Me

Advertisements

Upload the advertisements for review:

Name	Modified Date
VideogamersAdWithoutPic_v2_121817.docx	12/18/2017 2:44 PM
Final R21 Facebook pics for trans youth.docx	11/13/2017 10:14 AM
VideogamerAd_v2_121817.docx	12/18/2017 2:44 PM
Finalized Facebook ads-RCT_v2_122017.docx	12/20/2017 9:49 AM
Final R21 Facebook pics for lesbian youth.docx	11/13/2017 10:13 AM
IRB modification - new pictures.docx	5/8/2018 4:06 PM
Finalized R21 Facebook pics for gay youth.docx	11/13/2017 10:14 AM

4.2

Provide a detailed description of your recruitment methods, including identifying and initiating contact with participants:

We will advertise on Facebook to a wide audience of SGM youth. We intend to create a formal Facebook ad. It is a side-bar ad. We are not using an in-line ad. An individual who is interested in participating will click on the advertisement (see 4.1).

We will also recruit participants from SGM-related online gaming groups, such as geeksout.org, Gay Geeks (Facebook group), GaymerX (Facebook group), Transmission Gaming, and the following Reddit Gaymer forums:

https://www.reddit.com/r/gaymers/
https://www.reddit.com/r/Gaymer/
https://www.reddit.com/r/LGBTFC/
https://www.reddit.com/r/transgamers/
https://www.reddit.com/r/lgbt/)

All potential participants will be taken to a REDCap survey page that will present the screening questions. See the screening consent script in section 4.6.3.

We will also have a Facebook page, where we will advertise our study. No one, except us, is able to post comments on the Facebook page. We will continue to monitor this page to ensure that this setting remains constant.

	Section: Section 4 - Recruitment and Informed Consent Procedures

Note: Questions jump from 4.2 to 4.6 as questions 4.3-4.5 have been removed and the information is now captured in 4.1

[reviewer notes¬]

4.6 **Are you requesting a waiver to document informed consent for any or all participants, for any or all procedures? (e.g., a verbal or computerized consent script will be used, but the subjects will not be required to sign a written informed consent document. *This is not a waiver to obtain consent*.**

* Yes

4.6.1

Identify the specific research procedures and/or the specific subject populations for which you are requesting a waiver of the requirement to obtain a signed consent form.

All research procedures and all subject populations

If not all, identify the specific procedures and/or subject populations for which you are requesting a waiver:

4.6.2

Indicate which of the following regulatory criteria is applicable to your request for a waiver of the requirement to obtain a signed consent form.

45 CFR 46.117(c)(2)

45 CFR 46.117(c)(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

45 CFR 46.117(c)(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

4.6.2.1

Address why the specific research procedures for which you are requesting a waiver of the requirement to obtain a signed consent form present no more than minimal risk of harm to the research subjects:

Asking sexual and gender minority (SGM) youth questions about help-seeking behaviors, bullying experiences, mental health, substance use experiences, and their experience with the game intervention should be regarded as minimal risk. The probability and magnitude of harm or discomfort anticipated in our research study are not greater in and of themselves than those ordinarily encountered in daily life (i.e., of the general population).

The survey questions to be asked are questions and discussions that youth normally have. Additionally, these survey questions are routinely as part of the Youth Risk Behavioral Surveillance Survey (YRBSS) throughout the United States as part of their high-school experience.

We should reiterate that all participants will be given information about contacting the PI Dr. Egan should they have questions or concerns about the study or their reactions to it. The participants will also be provided with national hotlines for SGM youth should they require support. Of note, ALL individuals will automatically be given information about the Trevor Project which is a well respected hotline that can be accessed either online or by phone that specializes in the support of suicidal SGM youth.

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It should also be mentioned that the confidential nature of the surveys greatly reduces risk to participant.

4.6.2.2

Justify why the research listed in 4.6.1 involves no procedures for which written informed consent is normally required outside of the research context:

None of the research procedures including the playing of a computer game and answering survey questions contain any risk that is greater than any risk ordinarily encountered in daily life.

4.6.3

Address the procedures that will be used and the information that will be provided (i.e., script) in obtaining and documenting the subjects' verbal informed consent for study participation:

The study will use a 'click to consent' procedure. Potential participants will be directed to an online script describing the project and instructed to "click to consent" to participate. Those who click, and thereby consent, will be then directed to the survey. Those who do not click, thereby not consenting, will be directed to a page that will thank them for their time.

Upload Scripts:

Name	Modified Date
00. Screener for IRB Submission - v2.docx	10/5/2017 10:12 AM
Assent_Consent Form_v2_121817.docx	12/18/2017 2:27 PM

[reviewer notes¬]

4.7 **Are you requesting a waiver to obtain informed consent or an alteration of the informed consent process for any of the following?**

* Yes

4.7.1 **If Yes, select the reason(s) for your request:**

Parental permission and/or child assent

General Requirements: The Federal Policy **[45 CFR 46.116 (d)]** specifies in order for a waiver of consent to be approved, the request must meet four criteria. For each request, you will be asked to provide a justification addressing how each of these criterion is met.

Parental Permission and/or Child Assent

The research involves no more than	The probability and magnitude of harm or discomfort anticipated in our research study are not greater in and of themselves than those ordinarily encountered in daily life (i.e., of the general population).

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minimal risk to the subjects; **[45 CFR 46.116 (d) (1)]**	Asking sexual and gender minority (SGM) youth questions about help-seeking behaviors, bullying experiences, mental health, substance use experiences, and their experience with the game intervention should be regarded as minimal risk. The probability and magnitude of harm or discomfort anticipated in our research study are not greater in and of themselves than those ordinarily encountered in daily life (i.e., of the general population). The survey questions to be asked are questions and discussions that youth normally have. Additionally, these survey questions are routinely as part of the Youth Risk Behavioral Surveillance Survey (YRBSS) throughout the United States as part of their high-school experience. We should reiterate that all participants will be given information about contacting the PI Dr. Egan should they have questions or concerns about the study or their reactions to it. The participants will also be provided with national hotlines for SGM youth should they require support. Of note, ALL individuals will automatically be given information about the Trevor Project which is a well respected hotline that can be accessed either online or by phone that specializes in the support of suicidal SGM youth. It should also be mentioned that the confidential nature of the surveys greatly reduces risk to participant.
The waiver or alteration will not adversely affect the rights and welfare of the subjects; **[45 CFR 46.116 (d) (2)]**	A description of the risks to subjects and procedures for protecting against these risks follows as a demonstration that the waiver or alteration will not adversely affect the rights and welfare of the subjects. Potential risks to subjects: 1) Risk of being "outed." It is possible that someone will see what the individual is answering questions or playing a game with SGM content. 2) Risk to confidentiality. 3) Difficult feelings could arise due to answering questions. 4) Will not obtaining parental consent for minors place these youth at risk? Procedures for Protecting Against Risk: Note: This is an confidential survey. 1) Risk of being "outed." It is possible that someone will see what the individual is answering questions or playing a game with SGM content. Youth will be told in the assent/consent pages that this is a risk and will be told how to protect against this. Specifically, they will be told that it is important to be aware of their surroundings during the survey while answering questions and while playing the game. They will be told that it is prudent to be concerned in the same way as they normally are concerned when engaging in any SGM-related content online (to the extent that being "outed" is a concern to each individual). Additionally, the game will have login procedures in which only the participants are given unique information (username and password) for logging into the game. 2) Risk to confidentiality. An Internet study has a slightly different risk to confidentiality than conventionally-based studies. On the one hand, there is an inherent risk to confidentiality in conventional studies just by subjects being required to go to a site (e.g., a hospital, service organization, University) where someone might see them and intuit why they are there. Similarly, mail surveys may be intercepted by third parties' snooping. By comparison, Internet studies can be conducted at any location chosen that the individual feels most comfortable (e.g., at home, school, coffee-house) thus providing the

Section: Section 4 - Recruitment and Informed Consent Procedures

individual with more choices and control over this element of risk. Since our recruitment strategy is through Facebook, by definition, all potential participants in this study will have engaged in a level of risk to confidentiality that is comparable to their regular Internet usage by publicly declaring themselves to be sexual or gender minority youth.

Our study has in place a number of safe-guards to protect participants. All data will be stored on fire-walled servers. Please remember that the data collection will be done in a confidential fashion. Administrative accounts will use strong passwords. Additionally, the game will have login procedures in which only the participants are given unique information (username and password) for logging into the game.

3) Difficult feelings could arise due to answering questions.

Will difficult feelings arise due to answering questions about experiences of help-seeking, bullying, substance use, and mental health problems? We have argued to our IRB previously that asking SGM youth questions of these types should be regarded as minimal risk. The University of Pittsburgh IRB has agreed with this. The probability and magnitude of harm or discomfort anticipated in our research study are not greater in and of themselves than those ordinarily encountered in daily life (i.e., of the general population).

Asking sexual and gender minority (SGM) youth questions about help-seeking behaviors, bullying experiences, mental health, substance use experiences, and their experience with the game intervention should be regarded as minimal risk. The probability and magnitude of harm or discomfort anticipated in our research study are not greater in and of themselves than those ordinarily encountered in daily life (i.e., of the general population).

The survey questions to be asked are questions and discussions that youth normally have. Additionally, these survey questions are routinely as part of the Youth Risk Behavioral Surveillance Survey (YRBSS) throughout the United States as part of their high-school experience.

We should reiterate that all participants will be given information about contacting the PI Dr. Egan should they have questions or concerns about the study or their reactions to it. The participants will also be provided with national hotlines for SGM youth should they require support. Of note, ALL individuals will automatically be given information about the Trevor Project which is a well respected hotline that can be accessed either online or by phone that specializes in the support of suicidal SGM youth.

4) Will not obtaining parental consent for minors place these youth at risk?

We have received waivers of parental consent for prior studies of SGM youth. We have successfully argued that by requiring consent it would be possible to place youth at risk because of situations in which youth "come out" to their parents in order to participate in studies, without considering the potential consequences of "coming out" (see IRB Protocol PRO16020455). Further, by requiring parental consent the study would necessarily have participants that are in least need of support as the sample would be biased in the direction of having supportive and accepting parents. And SGM youth who are being bullied and who have supportive and accepting parents are probably at less risk for negative outcomes as compared to those youth who are bullied with rejecting and even abusive parents.

Finally, the assent/consent process described in other parts of this application describe a process for ensuring that participants have understood the risks associated with the study and the voluntary nature of the study before they agree to participate.

The research SGM youth are at significant risk for rejection and even abuse by parents.

Section: Section 4 - Recruitment and Informed Consent Procedures

could not practicably be carried out without the waiver or alteration; **[45 CFR 46.116 (d) (3)]**	We know based on the research and our work with these youth that many such youth would not participate in a study because they are not "out" to their parents and requiring parental support for such a study would necessitate them coming out to their parents and facing potential rejection. Restricting our study to SGM youth who are "out" to their parents will would be a huge impediment with respect to achieving the aims of the study (e.g., understanding help-seeking behaviors of youth who are closeted. Further, we need youth who have been bullied to participate in this study and many such bullying incidents are related to these adolescents' sexual orientation. Again, revealing this to their parents could put these youth in harms way.
Whenever appropriate, the subjects will be provided with additional pertinent information after participation. **[45 CFR 46.116 (d) (4)]**	We should reiterate that all participants will be given information about contacting the PI Dr. Egan should they have questions or concerns about the study or their reactions to it. The participants will also be provided with national hotlines for SGM youth should they require support. Of note, ALL individuals will automatically be given information about the Trevor Project which is a well respected hotline that can be accessed either online or by phone that specializes in the support of suicidal SGM youth.

4.7.2 Under what circumstances (if any) will you obtain consent from some of these subjects?

We will obtain individuals' assent for this study.

The assent process is described in detail above, including the provision of the assent script.

[reviewer notes¬]

4.8

Are you requesting an exception to the requirement to obtain informed consent for research involving the evaluation of an 'emergency' procedure?

Note: This exception allows research on life-threatening conditions for which available treatments are unproven or unsatisfactory and where it is not possible to obtain informed consent.

* No

	Section: Section 4 - Recruitment and Informed Consent Procedures

[reviewer notes¬]

4.9

Upload all consent documents for watermarking:

Draft Consent Forms for editing:

Name Modified Date

Approved Consent Form(s):
Name Modified Date

[reviewer notes¬]

4.10 **Will all potential adult subjects be capable of providing direct consent for study participation?**

*
Yes

[reviewer notes¬]

4.11

At what point will you obtain the informed consent of potential research subjects or their authorized representative?

After performing certain of the screening procedures, but prior to performing any of the research interventions/interactions

4.11.1

Address why you feel that it is acceptable to defer obtaining written informed consent until after the screening procedures have been performed.

Screening procedures are quite brief, composed of minimal risk, and have little burden compared to the assent/consent procedures. We decrease participant burden by having them wait to complete the assent/consent procedures until after the short screening questions.

4.11.2

Taking into account the nature of the study and subject population, indicate how the research team will ensure that subjects have sufficient time to decide whether to participate in this study. In addition, describe the steps that will be taken to minimize the possibility of coercion or undue influence.

Please see the assent process and the assent script described above. We believe that this is a very thorough and non-coercive process that will provide potential participants will sufficient time to decide whether to participate in this study. The assent script makes it clear that there is little possibility of coercion or undue influence. Actually, the fact this this is an online study makes these possibilities quite low. However, the nature of the dialogue in the assent script makes it clear that potential participants will have every possibility of declining to participate without undue coercion or influence.

	Section: Section 4 - Recruitment and Informed Consent Procedures

[reviewer notes¬]

4.12 Describe the process that you will employ to ensure the subjects are fully informed about this research study.

* Addressed below:

This description must include the following elements:

- who from the research team will be involved in the consent process (both the discussion and documentation);
- person who will provide consent or permission;
- information communicated; and
- any waiting period between informing the prospective participant about the study and obtaining consent

In addition, address the following if applicable based on your subject population:

- process for child assent and parental permission
  - continued participation if a child subject turns 18 during participation
- process for obtaining proxy consent and assent for decisionally impaired subjects
  - continued participation if subject regains capacity to consent

The study will use a "click to consent" procedure. Potential participants will be directed to an online script describing the project and instructed to "click to consent" to participation. Those who click, and thereby consent, will be then directed to the survey. Those who do not click, thereby not consenting, will be directed to a page that will thank them for their time. An email address for the PI (Dr. Egan) will be made available for participants to use to ask any questions that they may have. There will be no waiting period.

4.13 Are you requesting an exception to either IRB policy related to the informed consent process?

- For studies involving a drug, device or surgical procedures, a *licensed physician who is a listed investigator* is required to obtain the written informed consent unless an exception to this policy has been approved by the IRB
- For all other studies, a *listed* investigator is required to obtain consent (Note: In order to request an exception to this policy, the study must be minimal risk)

* No

If **Yes**, provide a justification and describe the qualifications of the individual who will obtain consent:

4.14 Will you inform research subjects about the outcome of this research study following its completion?

* No

If **Yes**, describe the process to inform subjects of the results:

	Section: Section 5 - Potential Risks and Benefits

[reviewer notes¬]

5.1

Describe potential risks (physical, psychological, social, legal, economic or other) associated with screening procedures, research interventions/interactions, and follow-up/monitoring procedures performed specifically for this study:

*

View

Research Activity:	Intervention Game Play
Common Risks:	*No Value Entered*
Infrequent Risks:	1) Risk of being "outed." It is possible that someone will see what the individual is answering questions or playing a game with SGM content. 2) Risk to confidentiality. 3) Difficult feelings could arise due to answering questions. 4) Will not obtaining parental consent for minors place these youth at risk?
Other Risks:	*No Value Entered*

View

Research Activity:	Questionnaire Completion
Common Risks:	*No Value Entered*
Infrequent Risks:	1) Risk of being "outed." It is possible that someone will see what the individual is answering questions or playing a game with SGM content. 2) Risk to confidentiality. 3) Difficult feelings could arise due to answering questions. 4) Will not obtaining parental consent for minors place these youth at risk?
Other Risks:	*No Value Entered*

5.1.1 Describe the steps that will be taken to prevent or to minimize the severity of the potential risks:

A description of the risks to subjects and procedures for protecting against these risks follows as a demonstration that the waiver or alteration will not adversely affect the rights and welfare of the subjects.

Potential risks to subjects:

1) Risk of being "outed." It is possible that someone will see what the individual is answering questions or playing a game with SGM content.
2) Risk to confidentiality.
3) Difficult feelings could arise due to answering questions.
4) Will not obtaining parental consent for minors place these youth at risk?

Procedures for Protecting Against Risk:

Note: This is an confidential survey.

1) Risk of being "outed." It is possible that someone will see what the individual is answering questions or playing a game with SGM content.

Youth will be told in the assent/consent pages that this is a risk and will be told how to protect against this. Specifically, they will be told that it is important to be aware of their surroundings during the survey while answering questions and while playing the game. They will be told that it is prudent to be concerned in the same way as they normally are concerned when engaging in any SGM-related content online (to the extent that being "outed" is a concern to each individual). Additionally, the game will have login procedures in which only the participants are given unique information (username and password) for

logging into the game.

2) Risk to confidentiality.

An Internet study has a slightly different risk to confidentiality than conventionally-based studies. On the one hand, there is an inherent risk to confidentiality in conventional studies just by subjects being required to go to a site (e.g., a hospital, service organization, University) where someone might see them and intuit why they are there. Similarly, mail surveys may be intercepted by third parties' snooping. By comparison, Internet studies can be conducted at any location chosen that the individual feels most comfortable (e.g., at home, school, coffee-house) thus providing the individual with more choices and control over this element of risk. Since our recruitment strategy is through Facebook, by definition, all potential participants in this study will have engaged in a level of risk to confidentiality that is comparable to their regular Internet usage by publicly declaring themselves to be sexual or gender minority youth.

Our study has in place a number of safe-guards to protect participants. All data will be stored on fire-walled servers. Please remember that the data collection will be done in a confidential fashion. Administrative accounts will use strong passwords. Additionally, the game will have login procedures in which only the participants are given unique information (username and password) for logging into the game.

3) Difficult feelings could arise due to answering questions.

Will difficult feelings arise due to answering questions about experiences of help-seeking, bullying, substance use, and mental health problems? We have argued to our IRB previously that asking SGM youth questions of these types should be regarded as minimal risk. The University of Pittsburgh IRB has agreed with this. The probability and magnitude of harm or discomfort anticipated in our research study are not greater in and of themselves than those ordinarily encountered in daily life (i.e., of the general population).

Asking sexual and gender minority (SGM) youth questions about help-seeking behaviors, bullying experiences, mental health, substance use experiences, and their experience with the game intervention should be regarded as minimal risk. The probability and magnitude of harm or discomfort anticipated in our research study are not greater in and of themselves than those ordinarily encountered in daily life (i.e., of the general population).

The survey questions to be asked are questions and discussions that youth normally have. Additionally, these survey questions are routinely as part of the Youth Risk Behavioral Surveillance Survey (YRBSS) throughout the United States as part of their high-school experience.

We should reiterate that all participants will be given information about contacting the PI Dr. Egan should they have questions or concerns about the study or their reactions to it. The participants will also be provided with national hotlines for SGM youth should they require support. Of note, ALL individuals will automatically be given information about the Trevor Project which is a well respected hotline that can be accessed either online or by phone that specializes in the support of suicidal SGM youth.

4) Will not obtaining parental consent for minors place these youth at risk?

We have received waivers of parental consent for prior studies of SGM youth. We have successfully argued that by requiring consent it would be possible to place youth at risk because of situations in which youth "come out" to their parents in order to participate in studies, without considering the potential consequences of "coming out" (see IRB Protocol PRO16020455). Further, by requiring parental consent the study would necessarily have participants that are in least need of support as the sample would be biased in the direction of having supportive and accepting parents. And SGM youth who are being bullied and who have supportive and accepting parents are probably at less risk for negative outcomes as compared to those youth who are bullied with rejecting and even abusive parents.

Finally, the assent/consent process described in other parts of this application describe a process for ensuring that participants have understood the risks associated with the study and the voluntary nature of the study before they agree to participate.

Section: Section 5 - Potential Risks and Benefits

5.2 **What steps will be taken in the event that a clinically significant, unexpected disease or condition is identified during the conduct of the study?**

* **Not Applicable**

5.3 All the risk questions (screening, intervention/interaction, follow-up) have been merged into one question (5.1).

[reviewer notes¬]

5.4 **Do any of the research procedures pose a physical or clinically significant psychological risk to women who are or may be pregnant or to a fetus?**

* No

[reviewer notes¬]

5.5 **Do any of the research procedures pose a potential risk of causing genetic mutations that could lead to birth defects?**

* No

[reviewer notes¬]

5.6 **Are there any alternative procedures or courses of treatment which may be of benefit to the subject if they choose not to participate in this study?**

* No

If **Yes**, describe in detail:

[reviewer notes¬]

5.7 **Describe the specific endpoints (e.g., adverse reactions/events, failure to demonstrate effectiveness, disease progression) or other circumstances (e.g., subject's failure to follow study procedures) that will result in discontinuing a subject's participation?**

* Not applicable - There are no anticipated circumstances that would lead to discontinuing a subject's participation in this research study.

	Section: Section 5 - Potential Risks and Benefits

[reviewer notes¬]

5.8

Will any individuals <u>other</u> than the investigators/research staff involved in the conduct of this research study and authorized representatives of the University Research Conduct and Compliance Office (RCCO) be permitted access to research data/documents (including medical record information) associated with the conduct of this research study?

* Yes

5.8.1

Identify the 'external' persons or entity who may have access to research data/documents and the purpose of this access:

We do not know of any 'external' persons who need immediate access to the data. Prior to permitting anyone access to these data, we will notify and get approval from the Pitt IRB and other appropriate Pitt offices about the permitting access to the 'external' persons.

5.8.2

Will these 'external' persons or entity have access to identifiable research data/documents?

*

No; the research data/documents will be coded and subject identifiers removed prior to access by the external persons

If **Yes**, describe how they will protect the confidentiality of the research data:

5.9

Has or will a Federal Certificate of Confidentiality be obtained for this research study?

* Yes

5.10

Question has been moved to 5.17

5.11

Question has been moved to 5.16

	Section: Section 5 - Potential Risks and Benefits

[reviewer notes¬]

5.12 Does participation in this research study offer the potential for direct benefit to the research subjects?

Yes - Describe the direct benefit that subjects may receive as a result of study participation. Indicate if all, or only certain, of the subjects may derive this potential benefit.

Describe the benefit:
There is no direct benefit from participating in the study, however, playing the game may be helpful to youth.

5.13 Describe the data and safety monitoring plan associated with this study. If the research study involves multiple sites, the plan must address both a local and central review process.

The conduct of this study and the protection of the enrolled subjects are the responsibility of the principal investigator. Accrual, confidentiality, subject complaints, subject withdrawals, and any unanticipated problems will be reviewed on an ongoing basis by the research coordinator and monthly by the principal and co-investigators. All breaches of confidentiality or other unanticipated problems will be promptly reported to the Institutional Review Board.

There is no central data and safety monitoring board associated with this minimal-risk project. The local data and safety monitoring plan for this study will involve routine (i.e., monthly) monitoring by the principal investigator of any conditions that may negatively impact the confidentiality of information contained within this study. The principal investigator will be responsible for reporting aggregate data and risk/benefit summaries to the IRB at the time of annual renewal unless the information contained in these reports changes the benefit-to-risk ratio of study participation as defined in the currently approved research protocol and consent form, in which case a modification will be immediately submitted to the IRB as per the IRB Reference Manual.

[reviewer notes¬]

Section 5 - Potential Risks and Benefits of Study Participation

5.14

What precautions will be used to ensure subject privacy is respected? (e.g. the research intervention will be conducted in a private room; the collection of sensitive information about subjects is limited to the amount necessary to achieve the aims of the research, so that no unneeded sensitive information is being collected, drapes or other barriers will be used for subjects who are required to disrobe)

The surveys will be self-administered online via REDCap and game play will be completed via the participant's own PC/Mac at the time of their choosing. Our assent/consent procedures tell participants to select a private setting to complete surveys and game play. The participants can complete all study procedures at any time of day, thereby allowing them to choose a safe and private time.

5.15

What precautions will be used to maintain the confidentiality of the research data during collection, transmission and storage? It is important that you indicate the data security measures for all data types.

Go to the A-Z Guidance, download the Data Security Assessment Form, complete, and upload using the Add button below. Depending on the data type, you may need to consult with your data manager to address some of the sections. Email irb@pitt.edu if you have any questions.

Section: Section 5 - Potential Risks and Benefits

*** Upload Data Security Form:**

Name	Modified Date
R21 Data Security Assessment Form - v2.docx	11/30/2017 2:18 PM

Address what precautions will be used to maintain the confidentiality of the research data collected in paper format if applicable:
N/A

5.15.1

Does your research study require a data security review? Answer Yes if any of the following conditions are met:

- Identifiable or *coded data will be collected, stored, or transmitted using any of the following technologies: mobile app, web-based site or survey, wearable device, text messaging, electronic audio, photographic, or video recording or conferencing **and/or**
- The IRB requested a data security review during their review of the study

* Yes

*__Coded__: Identifying information (such as name) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a code (number, letter, symbol, or any combination) and a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens

5.16

If the subject withdraws from the study, describe what, if anything, will happen to the subject's research data or biological specimens.

If the subject withdraws from the study, we will delete all the subject's data from our databases.

5.17

Following the required data retention period, describe the procedures utilized to protect subject confidentiality. (e.g., destruction of research records; removal of identifiers; destruction of linkage code information; secured long-term retention)

Data will be devoid of all subject identifiers and stored in secure password-protected Pitt BOX drive. De-identified data will be retained indefinitely.

Section: Section 6 - Costs and Payments

[reviewer notes¬]

6.1

Will research subjects or their insurance providers be charged for any of the procedures (e.g., screening procedures, research procedures, follow-up procedures) performed for the purpose of this research study?

*

No

[reviewer notes¬]

6.2 **Will subjects be compensated in any way for their participation in this research study?**

* Yes

6.2.1

Describe the amount of payment or other remuneration offered for complete participation in this research study.

Participants will be paid $10 for completing baseline (Time 1) survey, $25 for Time 2 survey, and $50 for Time 3 survey.

We have received a man on the street waiver. Rather than WePay, we will pay participants in iTunes or Google Play gift cards. Similar methods were approved in a previous protocol (see PRO16020455).

6.2.2 **Describe the amount and term of payment or other remuneration that will be provided for partial completion of this research study.**

Participants are able to skip as many survey questions as they would like in each of the surveys. Therefore, upon hitting the REDCap 'submit' button, participants will be paid the full amount of incentive for partially completed surveys. Upon hitting the REDCap 'submit' button, participants will be paid $10 for partially completing baseline (Time 1) survey, $25 for partially completing Time 2 survey, and $50 for partially completing Time 3 survey.

We have received a man on the street waiver. Rather than WePay, we will pay participants in iTunes or Google Play gift cards. Similar methods were approved in a previous protocol (see PRO16020455).

	Section: Section 7 - Qualifications and Source(s) of Support

[reviewer notes¬]

7.1

Summarize the qualifications and expertise of the principal investigator and listed co-investigators to perform the procedures outlined in this research study.

DR. JAMES EGAN

Dr. Egan holds a PhD from the Department of Behavioral and Community Health Sciences, Graduate School of Public Health, University of Pittsburgh. He is currently an Assistant Professor in the Department of Behavioral and Community Health Sciences in the Graduate School of Public Health at the University of Pittsburgh. He has worked for over 15 years in the HIV field. Dr. Egan is experienced in the design, implementation, data analysis, and dissemination of findings for both qualitative and quantitative studies exploring substance use and HIV risk and resilience among MSM. His dissertation work focused on the influences of specific neighborhoods (e.g. home, social, and sexual) on HIV risk, mental health and substance use among Gay, Bisexual and other MSM in New York City for which he was the lead qualitative researcher. Dr. Egan's current research interests include mixed-methods bio-behavioral research investigating episodic PrEP use among MSM and research exploring the production of resiliencies among Gay, Bisexual and other men who have sex with men, the impact of resiliencies on health and their role in improving health-related interventions.

DR. ROBERT COULTER

Dr. Coulter is currently a Postdoctoral Scholar in the Clinical and Translational Science Institute at the University of Pittsburgh. Dr. Coulter completed his PhD at the University of Pittsburgh's Graduate School of Public Health, where he is specialized in the health of sexual and gender minority (SGM) young people. Dr. Coulter has experience in conducting statistical analyses, implementing intervention studies, and working with SGM youth.

	Section: Section 7 - Qualifications and Source(s) of Support

[reviewer notes¬]

7.2 Indicate all sources of support for this research study.

*

Selections

Federal: Upload a copy of the entire grant application **(including the cover sheet)** if our site is the awardee institution; for federal contracts, upload a copy of the research plan

If **Federal** support, provide the sponsor information:

	Federal sponsor	Grant Title	Grant number	Awardee institution	Federal grant application
View	NIH/NICHD	Online Intervention to Help Gay Youth Cope with Bullying	R21HD083561	University of Pittsburgh	resubmission R21 March 2015.pdf(0.01)

For projects not supported by a federal grant, upload the research plan that was submitted for funding:

Name Modified Date

If **Industry** support, provide the sponsor information and level of support:

If **Foundation** support, provide the sponsor information:

If **Other** support, provide the support information and level of support:

[reviewer notes¬]

7.3

Is this study funded in part or whole by a PHS Agency?

* Yes

Does any investigator* involved in this study (select all that apply):

	Name
☐	**A.** Have a financial interest (aggregated value of equity and remuneration** during the past or next twelve months) in a **publicly-traded entity** that either sponsors*** this research or owns the technology being evaluated or developed that exceeds **$5,000 but not $10,000**?
☐	**B.** Have a financial interest (aggregated value of equity and remuneration during the past or next twelve months) in a **publicly-traded entity** that either sponsors this research or owns the technology being evaluated or developed that exceeds **$10,000**?
☐	**C.** Receive remuneration (during the past or next twelve months) from a **non-publicly traded entity** that either sponsors this research or owns the technology being evaluated or developed that exceeds **$5,000 but not $10,000**?

Section: Section 7 - Qualifications and Source(s) of Support

Name

- [ ] **D.** Receive remuneration (during the past or next twelve months) from a **non-publicly traded entity** that either sponsors this research or owns the technology being evaluated or developed that exceeds **$10,000**?
- [ ] **E.** Have equity in a **non-publicly traded entity** that either sponsors this research or owns the technology being evaluated or developed?
- [ ] **F.** Receive reimbursement or sponsorship of travel expenses (for one trip or a series of trips during the past or next twelve months) by an outside entity that either sponsors this research or owns the technology being evaluated or developed that exceeds **$5,000**?
- [ ] **G.** Have rights as either the author or inventor of **intellectual property** being evaluated or developed in this research that is the subject of an issued patent or has been optioned or licensed to an entity?
- [ ] **H.** Have an officer or management position**** with a **Licensed Start-up Company** overseen by the COI Committee that either sponsors this research or owns the technology being evaluated or developed?
- [ ] **I.** Receive compensation of any amount when the value of the compensation would be affected by the outcome of this research, such as compensation that is explicitly greater for a favorable outcome than for an unfavorable outcome or compensation in the form of an equity interest in the entity that either sponsors this research or owns the technology being evaluated or developed?
- [x] **None of the above options apply and there are no other financial conflicts of interest in the conduct of this research.**

***Investigator** means the PI, co-investigators, and any other member of the study team, regardless of title, who participates in the design, conduct, or reporting of this research, as well as his/her spouse, registered domestic partner, dependents, or other members of his/her household. **The PI is responsible for ensuring that s/he and all other relevant members of the study team review the above questions describing Significant Financial Interests.**

****such as salary, consulting fees, honoraria, or paid authorship

*****through the provision of funds, drugs, devices, or other support for this research

******Such as serving on the Board of Directors or Board of Managers or a position that carries a fiduciary responsibility to the company (e.g., CEO, CFO, CTO, or CMO).

	Section: Supporting Documentation

[reviewer notes¬]

Supporting Documentation Section

References and Other Attachments

Additional documents:

Name	Modified Date	Version
Instructions for Downoading Game.docx	11/21/2017 9:19 AM	0.01
List of LGBT Resources Nationwide.docx	11/21/2017 9:14 AM	0.01
References.pdf	9/17/2017 1:52 PM	0.01

Please use the Add button to the left to upload additional documents if needed.

[reviewer notes¬]

ClinicalTrials.gov is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world.

"Applicable clinical trials" are required **by federal law** to be registered in ClinicalTrials.gov.

Applicable Clinical Trials (ACTs) are studies that meet the following criteria:

- The study is an interventional study AND
- The study intervention is a drug, biologic, medical device, radiation or genetic AND
- The Study is not Phase 0 or 1 AND
- The study has at least one site in the United States or is conducted under an investigational new drug application or investigational device exemption

NIH Policy

Effective January 18, 2017, revised NIH Policy requires that all clinical trials funded in whole or in part by the NIH be registered and results information posted on ClinicalTrials.gov.

As defined by the NIH, a clinical trial is:

> *A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health related biomedical or behavioral outcomes.*

The NIH Policy extends beyond the Food and Drug Administration Amendment Act (FDAAA 801) requirements in that it requires registration and results reporting of:

- clinical trials of behavioral, surgical and other types of health and medical interventions
- phase 1 studies of drugs and biological products
- small feasibility studies of device products

Failure to submit all required registration and results information requested on ClinicalTrials.gov can jeopardize University grant funding, the future funding of the grantee and subject the University of Pittsburgh to future monetary penalties.

In addition, to promote transparency of the clinical trials process, the International Committee of Medical Journal Editors (ICMJE) has established a policy requiring the entry of clinical trials in a public registry, such as ClinicalTrials.gov, prior to subject enrollment as a condition of consideration for publication of the trial results.

Section: Supporting Documentation

* **Based on the above information, will this study be registered in ClinicalTrials.gov?**
Yes

Who will serve as the Responsible Party? UPMC/Pitt Investigator or IND/IDE Pitt Sponsor

Why are you registering your study? (Check all that apply)

It is strongly encouraged by the NIH

It is required for publication by the **International Committee of Medical Journal Editors** (*Registration is required in a publically available, searchable database system prior to informed consent being obtained from the first study participant*)

If you are not yet registered and need to establish an account for the PI or other research staff that may need to access the record, please send an email to the University of Pittsburgh PRS administrator at ctgov@pitt.edu with the following information for each individual:

- Full name
- Telephone number
- Pitt or UPMC email address

If you have any questions or concerns, please email us at ctgov@pitt.edu.

To find out additional information about how to register your study go to:
https://www.clinicaltrials.gov/ct2/manage-recs/how-register