Official Title: Sexual and Gender Minority Youth (SGMY) and Online Interventions to Increase Help-seeking for Anxiety and/or Depression
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PittPRO | Pitt Protocol Review Online

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View: Pitt SF: Basic Study Information 8.2

Basic Study Information

1. * **Title of study:**
   Optimizing Technology Interventions for Help-Seeking for Depression and Suicidality in Sexual and Gender Minority Youth Factorial Trial

2. * **Short title:**
   SGMY Mental Health Help-Seeking Factorial Trial

3. * **Brief description:**
   We will conduct a randomized factorial trial to evaluate the feasibility, usability, and acceptability of low-fidelity prototypes of four different brief online interventions to promote mental health help-seeking in sexual and gender minority youth.

4. * **What kind of study is this?**
   Single-site study

5. * **Will an external IRB act as the IRB of record for this study?**
   ○ Yes ● **No**

6. * **Local principal investigator:**
   Ana Radovic
   * **Is this your first submission, as PI, to the Pitt IRB?**
   ○ Yes ● **No**

7. * **Does the local principal investigator have a financial interest related to this research?**
   ○ Yes ● **No**

8. **Attach the protocol:**
   - Sponsor/Multicenter/Investigator-initiated protocol
   - Coordinating Center supplement
   - Emergency Use Consent/ Protocol/ FDA Form 3926
   - Exempt Application form

   Document Category Date Modified Document History
   There are no items to display

View: Pitt SF: Funding Sources (not integrated with Grants)

Funding Sources

1. * **Indicate all sources of support:**
   External funding

2. * **Identify each organization supplying funding for the study:**

Funding Source	Sponsor's Funding ID	Grants Office ID	Attachments	Pitt Awardee	Grant Recipient
National Institute on Minority Health and Health Disparities	1R21MD015806-01A1		GrantApplication FINAL PDF 11.2020.pdf	yes	Ana Radovic

Study Team Members

1. * **Identify each person involved in the design, conduct, or reporting of the research:**
> available upon request

Name	Roles	Department/School Affiliation	Involved in	Qualifications	Financial

2. **External team member information: (Address all study team members in item 1. above and leave this section blank)**

Name	Description
There are no items to display	

3. **Have you,** Ana Radovic**, verified that all members of the research team have the appropriate expertise, credentials, training, and if applicable, child clearances and/or hospital privileges to perform those research procedures that are their responsibility as outlined in the IRB application?**

* ● **Yes** ○ No

Study Scope

Check all that apply

1. * Will this study actively recruit any of the following populations?

- [ ] Adults with impaired decision-making capacity
- [x] Children (under the applicable law of the jurisdiction in which the research will be conducted (<18 years for PA))
- [ ] Children who are Wards of the State
- [ ] Employees of the University of Pittsburgh/UPMC
- [ ] Medical Students of University of Pittsburgh as primary research group
- [ ] Students of the University of Pittsburgh
- [ ] Neonates of uncertain viability
- [ ] Non-viable neonates
- [ ] Non-English speakers
- [ ] Nursing home patients in the state of Pennsylvania
- [ ] Pregnant women
- [ ] Prisoners
- [ ] N/A

2. * Will any Waivers be requested?

- [x] Waiver/Alteration of Consent
- [ ] Waiver to Document Consent
- [ ] Waiver/Alteration of HIPAA
- [ ] Exception from consent for emergency research
- [ ] N/A

3. * Will this study involve any of the following?

- [ ] Specimens
- [ ] Honest Broker to provide data/specimens
- [ ] Return of Results to Subjects or Others
- [ ] Fetal tissue
- [x] N/A

4. * Will Protected Health Information be collected?

- [ ] Pitt medical records
- [ ] UPMC medical records
- [ ] Other Institutions' medical records
- [x] N/A

5. * Other Requests?

- [ ] Deception (if not Exempt, also requires Waiver/Alteration of Consent)
- [ ] Emergency Use / Single Patient Expanded Access (using FDA Form 3926)
- [ ] Placebo Arm
- [ ] Withdraw from usual care
- [x] N/A

6. * Determining Scientific Review:

Department Scientific Review (this option MUST be picked if there is DoD funding)

*** Choose the appropriate organization to conduct the scientific review:**

U of Pgh | School of Medicine | Pediatrics

7. * Has this study (or substantially similar study) been previously disapproved by the Pitt IRB or, to your knowledge, by any other IRB?

○ Yes ● **No**

Review the HRPO policy, if participating in research at the VA Pittsburgh Healthcare System or using funding from the VA

8. * **Does the study use an approved drug or biologic, use an unapproved drug or biologic, or use a food or dietary supplement to prevent, diagnose, cure, treat, or mitigate a disease or condition?**
   ○ Yes ● **No**

9. * **Does the study evaluate the safety or effectiveness of a device (includes in-vitro laboratory assays)?**
   ○ Yes ● **No**

10. * **Is this application being submitted to convert an approved study from OSIRIS to PittPRO?** (Tip Sheet)
    ○ Yes ● **No**

11. * **Does your research protocol involve the evaluation or use of procedures that emit ionizing radiation and, after reviewing this** HUSC guidance**, does your research protocol require HUSC review? (If yes, upload the** HUSC form **in the Local Supporting Documents section). If you are unsure of review requirement, select yes.**
    ○ Yes ● **No**

Research Sites

1. **Choose all sites that apply:**
   University of Pittsburgh

   * **Select the University of Pittsburgh sites where research will be conducted:**
   Main Campus – Pittsburgh

   List university owned off-campus research sites if applicable:

2. **Describe the availability of resources and the adequacy of the facilities to conduct this study:**
   The University of Pittsburgh (PITT) has approved research procedures for remote data collection. If necessary to continue physical distancing, this research protocol can be conducted feasibly in the context of the pandemic due to remote data collection feasibility. PITT has access to remote IT resources including free and discounted research software download with access to necessary products for this proposal such as NVivo, as well as Zoom Video Conferencing, Microsoft Teams, and DocuSign eSignature Service. PITT IT also has a Center for Research Computing, Enterprise Cloud Computing, Cloud Storage Solutions including for Box and Microsoft OneDrive, as well as Virtual Desktops. PITT offers secure access to research servers through PittNet VPN (PulseSecure) and Duo Mobile Multifactor Authentication. In addition, PITT offers on-demand courses for PITT researchers on IT Cloud Computing, Microsoft Teams, and courses on using other essential IT tools. 24/7 IT support is available by phone, help ticket, chat, email, and virtual support via Zoom.

Recruitment Methods

* **Will you be recruiting individuals for participation in this study?**
● **Yes** ○ No

1. * **Describe who will be recruiting individuals for participation for this study:**
Research team members including PI, research assistants, and research coordinators will be involved in research recruitment. Research team members are professionals and students with training in mental health and experience working with sexual and gender minority youth. Other parties that will share our flyer.

2. * **Select all methods to be used for recruitment:**
Flyers/Posters or Brochures
Website/Social Media
Other

* **Enter description of 'Other' method of recruiting:**
We will use a list of applicants from the first year of the study who indicated during screening that they had interest in future studies (they have not participated in the first part of the study however)

3. * **Provide details on your recruitment methods:**
The same recruitment methods utilized in STUDY21030121 SGMY Mental Health Help-Seeking Usability Study. There are about 200 individuals in that study who responded they would be agreeable to being contacted about future research and so these individuals will be contacted first with an offer to participate in the current study.

Social Media: We will work with a local digital advertising firm, Gap Up, to target recruitment (create different advertisements) of adolescent social media users on Facebook and Instagram and other social media, especially those whose characteristics may suggest depression or anxiety symptoms (e.g. high frequency of social media use or specifically stated interests) and SGM status. We will design 5 different ads (ads will have different photos, but have the same headline and text). These ads will be managed by Gap Up. We will either create these photos ourselves or use free photos from places like unsplash.com Unsplash.com is a website that gives free permission to anyone to use their stock photos. The license for unsplash can be found here: https://unsplash.com/license. Ads will be targeted at potential participants, that is individuals 14-19 age and who identify as a sexual and/or gender minority (e.g. lesbian, bisexual, gay, transgender). In both Instagram and Facebook, the potential advertisement audience is selected by the website using an algorithm based on user topics of interest (e.g. LGBT rights). Researchers do NOT have access to private information from potential participants that could potentially be used to target this particular population. Online recruiting will help target a hard-to-reach population.

Online RedCAP Recruitment: Immediately after clicking on the study advertisement, potential participants will be redirected to a separate secure RedCAP survey to review study information and complete self-screening. If eligible, prospective participants will be asked to provide their contact information. Those that are eligible will then be directed to the consent/assent and survey. Upon reviewing and completing this they are enrolled in the study and we will reach out via text with a unique link to take the baseline survey. Automatic reminders will then be scheduled for every two days for the following 10 days. We have uploaded a copy of our consent/assent video to the IRB SharePoint folder.

Our flyer will contain a basic overview of the study and a link to the initial screening on redcap.

Some participants require additional screening to ensure residency in the United States. During the enrollment process, our use of Discord revealed the IP addresses

of some participants to be outside of the United States.

We will create an additional survey that asks if they are in the United States while collecting their IP address and for any that do not meet these criteria will be removed and any data collected will be erased.

Additionally, any who do not complete the survey will also be removed and their data erased.

4. * **Describe all compensation/incentives offered to participants and timing of these offers:**

Participants will receive up to $100.00 for participation in the study:

Part 1: $35 for the completion of the baseline survey.
Part 2: Complete a follow up survey for $65
This will be given via electronic gift cards.

5. **Recruitment materials:** (attach all material to be seen or heard by subjects, including advertisements and scripts)

	Document	Category	Date Modified	Document History
View	USResidencyVerification_SGMYTr.pdf(0.01)	Recruitment Materials	4/30/2024	History
View	SGMYTRIALInitialScreen_SGMYTri.pdf(0.02)	Recruitment Materials	4/19/2024	History
View	SOVA Year 2 Flyer.pdf(1)	Recruitment Materials	3/21/2024	History
View	SGMY Study Video Script_Version_0.03.docx(3)	Recruitment Materials	12/6/2023	History
View	IRB SGMY Study Year 2 Demo Advertisement(1)	Recruitment Materials	2/22/2023	History
View	IRB SGMY Study Year 2 Advertisement.docx(1)	Recruitment Materials	2/8/2023	History

Study Aims

1. * **Describe the purpose, specific aims, or objectives and state the hypotheses to be tested:**
We have developed 4 low-fidelity prototypes to simulate an intervention component without requiring hard coding. We are calling these "mini interventions" IPs or intervention principles.

We will use a factorial trial to understand each IP prototype's individual and combined feasibility, usability, acceptability, and change in help-seeking intention in an online sample of diverse (racially, ethnically, age, gender identity, sexual orientation) sexual and gender minority youth (SGMY).

2. * **Describe the relevant prior experience and gaps in current knowledge including preliminary data. Provide for the scientific or scholarly background for, rationale for, and significance of the research based on existing literature and how it will add to existing knowledge:**
Depression and anxiety are leading contributors to adolescent morbidity, and suicide is the second leading cause of death in this age group. However, fewer than half of affected adolescents access treatment. Rates of depression and suicidality are higher among sexual and gender minority youth (SGMY) and they are less likely than other youth to seek care. Although adolescents with depressive symptoms may be identified in school clinics or primary care settings, identification does not always result in treatment. Adolescents with negative beliefs about diagnosis or treatment and lacking social and parental support are less likely to receive treatment. SGMY at risk of depression are especially difficult to reach as they are less likely to attend preventive primary care visits where routine screening is performed. They may have concerns about confidentiality and disclosing their sexual orientation or gender identity to healthcare or mental health providers, and fear rejection, discrimination, or unsupportive environments. A facilitator of mental health help-seeking, parental support, is often lacking in SGMY who experience more severe depression and suicidality. There is a critical need to develop and test interventions that increase the likelihood of seeking evidence-based treatment among SGMY with depression, anxiety, and suicidality in non-clinical settings.

With SGMY actively immersed online, internet-based interventions are an obvious and promising route to meet SGMY where they are. Yet a recent systematic review found a dearth of evidence-based online mental health interventions for SGMY. Even when online interventions exist, real-world uptake is low. Lack of engagement in online interventions is a known concern. Unfortunately SGMY who actively engage in online support interventions still experience low rates of mental health help-seeking. Targeted interventions are needed to address unique factors like double stigma (mental health and SGM status) in SGMY preventing help-seeking.

For the past 7 years, our team has used iterative stakeholder-informed approaches employing human computer interaction (HCI) techniques to design interventions directed at modifiable targets such as stigma and social support to enhance depression and anxiety treatment initiation in adolescents. In this project we plan to use an efficient approach to technology intervention design. Based on the Behavioral Intervention Technology Model, we will study intervention principles (IPs), or theoretical concepts including intervention aims and behavioral strategies, to understand which mechanisms of action hold promise while iterating on user design. The overall goal of the proposed project is to develop and test the usability, feasibility, and acceptability of an online intervention to increase help-seeking behavior among SGMY. Specifically we will use the HCI framework, Discover, Design/Build, and Test (DDBT).

We have completed a qualitative study with 25 SGMY to understand their needs for a mental health help-seeking intervention and found that the main topics that serve as barriers to seeking care include concerns about multiple identities and how those conflict with help-seeking; confidentiality and privacy concerns; having difficulty with

garnering parent or guardian support for mental health and/or LGBTQ status; and the process of finding affirming professionals. Adolescents were interested in intervention modalities to include online peer-led support groups, resource lists, and digital storytelling.

Study Design

1. **Total number of subjects to be enrolled at this site (enter -1 for chart reviews, banking, registries):**
200

2. **Describe and explain the study design:**
This intervention trial will use a randomized factorial trial design where each of the 96 participants is randomly assigned to one of 16 combinations of the four study mini-interventions (IPs). There will be 16 possible combinations for the four IPs. For example, one combination will include no IP, and one combination will include all four IPs, and four combinations will include only one of the IPs. The rest of the 10 combinations will include a combination of two or three of the IPs (e.g. IP 1 + 2; IP 1 + 2 + 3; IP 2 + 3; IP 1 + 3, etc.) With n=6 individuals randomly assigned to each of the 16 combinations, this will yield n=48 with a given IP versus n=48 without the given IP (averaging over other combinations of the other three IPs) for the test of each main effect.

3. **Describe the primary and secondary study endpoints:**
The primary endpoints are feasibility, usability, and acceptability of the IP.
The secondary study endpoint is change in help-seeking intention.

4. **Provide a description of the following study timelines:**

Duration of an individual subject's active participation:
1 month
Duration anticipated to enroll all subjects:
1 year
Estimated date for the investigator to complete this study (complete primary analyses):
4/30/2024

5. **List the inclusion criteria:**
Adolescents ages 14-19 will be included if they provide their assent and/or consent if 18 or above; have access to a smartphone; have finished 6th grade; have access to and intellectual and physical ability to use the internet; fit demographic criteria (SGMY); and have symptoms of depression and/or anxiety that are mild or more severe (PHQ-8 and/or GAD-7 = 5 or above)

We will routinely monitor the sample to ATTEMPT to reach close to the following proportions based on recruitment and enrollment flow (e.g. if recruitment and enrollment flow is at a steady rate and we have reached the proportions below we may begin to exclude those being oversampled to obtain balance - because of the pilot nature of the study this may not be possible if recruitment flow is slower than anticipated)

50% ages 14-16 and 50% ages 17-19
50% identify as sexual minority but cisgender and 50% identify as not cisgender
at least 40% identify as a racial or ethnic minority

6. **List the exclusion criteria:**
Younger than 14 older than 19, no access to smart phone or internet, did not complete the 6th grade, not able to use internet, depression and anxiety are less than mild (PHQ-8 and GAD-7 scores <5); presently are in ongoing psychotherapy (i.e. have attended or plan to attend more than 1 session). No therapy within the past 3 months. If the person is not living in the US or will be traveling to a into any countries governed by the EEA regulations within three months of joining the study.

7. **Will children or any gender, racial or ethnic subgroups be explicitly excluded from participation?**

● Yes ○ No

* **Identify the subgroups and provide a justification:**

Children under the age of 14 will not be included in study participation.

The intervention is specifically targeting adolescents in middle adolescence (high school age). This is a time period when they may seek mental health help without parental consent in some states (Pennsylvania) and the interventions will be designed for youth who may be able to seek help with or without parental support.

(Note: the interventions we are developing are not treatment interventions, they are interventions to promote help-seeking for actual mental health treatment in SGMY).

Subgroups will not be explicitly excluded in the beginning but once specific proportions are reached (see inclusion criteria), if the recruitment flow is adequate, we will then change our entry based on the proportion not yet reached. We may not be able to do this due to the pilot nature of this study. We aim to have at least 40% of our sample (38/96 individuals) represent a racial or ethnic minority, so once 60% of the sample (58/96 individuals) is recruited that identifies as not belonging to a minority, new interested participants will then begin to be excluded from then on.

8. **Describe the power analysis used and cite your method of statistical analysis. If a power analysis is not possible, thoroughly justify the sample size required for the study, including appropriate literature citation (alternatively provide page reference in attached protocol):**

Participants (N=200) will be enrolled. (N=96 will be given baseline. With groups of n=6 randomly assigned to each of the 16 combinations, this will yield n=48 with a given IP versus n=48 without the given IP (averaging over other combinations of the other three IPs) for the test of each main effect. Based on a two-sample t-test, this will yield 80% power for an effect size of 0.58. For testing any two-IP combination, i.e. yes for the first and second IP (versus no for at least one of those two), this will yield n=24 with a given combination of those two IPs versus n=72 without the given combination of two IP; this yields 80% power to detect an effect size of 0.67. Similarly, for testing any three-IP combination, this will yield n=12 with a given combination of those two IPs versus n=84 without the given combination of two IP; this yields 80% power to detect an effect size of 0.87. In summary, we have sufficient power for detecting a moderate effect size in each of the above scenarios.

We will report all baseline characteristics (with counts (%) or mean (SD), median (IQR)) by intervention group, and will follow all reporting guidelines of the CONSORT extension to randomized trials of nonpharmacologic treatment[Boutron 2017], including creating a CONSORT diagram for transparent reporting.The primary analyses for the intervention trial will use an analysis of variance (ANOVA) model[Collins 2014](or equivalently a linear model as defined in Equation 1) with the Likert scale response (1-7, which are expected to be normally distributed) for help-seeking intention as the primary outcome and the assigned treatment factors as the explanatory variables; each xj= 1 if the participant is assigned to the jthIP, and xj= 1 otherwise.

(1)$y=\beta0+\beta1x1+\beta2x2+\beta3x3+\beta4x4+\beta5x1x2+\beta6x1x3+\beta7x1x4+\beta8x2x3+\beta9x2x4+\beta10x3x4+\beta11x1x2x3+\beta12x1x2x4+\beta13x1x3x4+\beta14x2x3x4+\beta15x1x2x3x4$The main effect for the 1stIP, for instance, can then be defined as the contrast testing $(\beta1+\beta5+\beta6+\beta7+\beta11+\beta12+\beta13+\beta15)-(\beta0+\beta2+\beta3+\beta4+\beta8+\beta9+\beta10+\beta14)=0$, where the first set of 8 coefficient correspond to conditions with x1= 1, and the second set include x1= 0. We will also test two-and three-way combinations of the different IPs through similar contrasts. For instance, the test for having both the first and second IP (versus no for at least one of those two, averaging over other IP combinations) will be tested using the following contrast: $(\beta5+\beta11+\beta12+\beta15)-(\beta0+\beta1+\beta2+\beta3+\beta4+\beta6+\beta7+\beta8+\beta9+\beta10++\beta13+\beta14)=0$. While the linear model and factorial design also allow for testing interactions, e.g. whether the effect of the first IP differs by presence or absence of the second IP, these effects were of less interest for our hypotheses, and will therefore only be considered as exploratory analyses. The other outcome measures and exploratory analyses and can be tested in the same manner with the above linear model. Normality of outcomes will be

assessed using a normal probability plot (where linearity between the empirical quantiles and the expected quantiles of a standard normal distribution reflect normal) of the residuals from the regression model. If data are systematically different from normality, transformations will be used to produce more normal data. Other generalized linear models will also be considered as appropriate if normality cannot be achieved via transformations.

Research Activities

1. * **Provide a detailed description of all research activities (including screening and follow-up procedures) 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.**

Screening

Immediately after clicking on the study advertisement, potential participants will be redirected to a separate survey using the secure RedCAP online survey and database tool to review study information and complete self-screening (see SGMYTRIALInitialScreen uploaded under Recruitment Materials).

If a potential participant is ineligible, they will be provided with information about resources including crisis resources (see those in self-screen survey).

If a potential participant is eligible, they will be asked to provide contact information, (preferred name, phone number and email address), and will then be redirected to the next RedCAP survey to review the online consent.

Consent

Within this RedCAP survey, the potential participant will be given the option to review the consent at that time or at a later time. They may pause the consent at any time and ask to be contacted by the research team first to answer any questions. Those who do not pause will go on to watch a video reviewing the study and consent information, and then will review the text consent information, be asked to answer questions reviewing their understanding of the information in the consent and then to provide electronic consent. We request a waiver of parental permission as discussed in the consent section. Participants will be asked for personal identifiable information needed to assign a global unique identifier.

Baseline Survey

Those individuals who provide consent will be redirected to complete an online survey over RedCAP. Data will be captured on demographics including age, sexual identity, gender identity, race, ethnicity, education, parent/guardian support, homelessness, socioeconomic and social status, transportation access, prior mental health treatment, whether they have a PCP, health insurance status, access to mental health professionals as determined by county and HRSA Health Professional Shortage Area score, and past discriminatory experience by a mental health provider. Mechanistic and outcome survey constructs will at baseline assess: mental health personal and perceived stigma, SGM stigma (internalized homophobia and transphobia), attitudinal barriers toward seeking therapy, antidepressant outcome expectations, expectance of rejection due to SGM, concealment of SGM from others, confidentiality concerns, brief depression/anxiety knowledge, emotional support, help-seeking intention from multiple sources, a single help-seeking intention Likert scale likelihood question (i.e. 'I intend to seek help from a counselor or therapist for my mental health problems' scale 1-795), perceived need, actual help-seeking, depression symptoms (PHQ-8), anxiety symptoms (GAD-7), social isolation (UCLA scale), and perceived health (SF-12). Once the baseline survey is completed, then the participant will be provided with information that the research team will contact them soon with next steps.

Randomization

Once the adolescent completes the baseline survey, RedCAP software will be used to conduct randomization. For those who do not complete the baseline survey, they will not be randomized. The randomization schema will be pre-determined by the study statistician using the RedCAP randomization module. There will be 16 groups to be randomized to with 6 individuals randomized to each group. The mini-interventions or intervention principles (IPs) will be described below.

Intervention
Each individual will be invited to join a private virtual Discord server (https://discord.com). They will be asked to create a new Discord account for purposes of participating in the study which does not include any identifiable contact information.

The Discord server is similar to a Microsoft Teams or Slack where there are different channels available for different individuals. Each user, based on which Group they were randomized to will have access to a different set of channels which allow them to view their assigned intervention. All participants will be asked to sign in at least once a week to Discord to review and complete intervention activities and will be prompted with a text message reminder. The Discord settings will be set to not allow private messaging between individuals to allow for monitoring of all content. Each individual will be asked to agree to and review ground rules of participating which include acknowledging that the intervention does not provide crisis services, to maintain anonymity, to not bully, and that any content our team feels will be hurtful to others will be removed. The research team will download and save Discord transcripts from text conversations.

There are four "mini-interventions" or IPs: IP1, IP2, IP3, IP4.

There will be 16 groups with iterations of these interventions as described below:
Group 1: No IP, only a specific discord channel that asks individuals to at least post once a week responding to a single question about what makes them interested in participating in research
Group 2: IP 1
Group 3: IP 1, IP2
Group 4: IP 1, IP 2, IP 3
Group 5: IP 1, IP 2, IP 4
Group 6: IP 1, IP 2, IP 3, IP 4
Group 7: IP 1, IP 3
Group 8: IP 1, IP 3, IP 4
Group 9: IP 1, IP 4
Group 10: IP 2
Group 11: IP 2, IP 3
Group 12: IP 2, IP 3, IP 4
Group 13: IP 2, IP 4
Group 14: IP 3
Group 15: IP 3, 4
Group 16: IP 4

Each intervention will include the same format with regards to modalities and structure. There will be 3 specific channels with (1) A channel for video content vetted by our research team from existing educational websites or publicly available online content including testimonials from individuals with similar identities sharing their experiences with the specific topic and how they navigated it. Below this video content there will be prompts for a discussion around reactions to the video content. (2) A forum channel with prompts to answer to facilitate asynchronous conversation around that topic. (3) A "try it" channel which provides existing resources around the topic and "how to" guides around that topic. For example "how to schedule a therapy appointment" or "how to ask your insurance company about behavioral health." Prompts will include to ask individuals to provide their personal reviews of resources they tried accessing, or "how to" guides they tried using.

IP 1 Description: Intersectionality concerns. Specific identities and how they influence the experience of being a sexual and gender minority youth seeking help. For example, masculine individuals and the stereotype that men's emotional range is limited, or that they experience toxic masculinity, and how this prevents help-seeking. Introducing the topic of stereotype threat and the stress experienced with the anticipation of how you may be perceived by others because of your identity - whether race, ethnicity, socioeconomic status, education, geographical location, etc.

IP 2 Description: Confidentiality and privacy. Adolescents may not seek help due to concerns about whether their privacy will be maintained. Learning about

confidentiality laws by state and what rights do they have to keeping what they say during therapy confidential, how they can ask providers about confidentiality. How they can maintain privacy online when seeking health information.

IP 3 Description: Difficulty with garnering parent or guardian support of mental health and LGBTQ status. Finding the words to communicate with their parent, or for themselves regarding names and identities for how they feel. Anticipating dismissal of their concerns and how they can find other supportive adults who can help them navigate communicating with a parent or guardian. Specific resources that they can offer to their parent (i.e. support groups, reading material, professionals) so their parent can receive assistance navigating their child's LGBTQ status instead of them having to educate their parent.

IP 4 Description: Finding affirming professionals. How to identify whether mental health professionals are competent in working with LGBTQ+ youth. Reviewing resources that help to identify mental health friendly spaces online. Reviewing what questions they can ask of a provider or a healthcare setting to know whether they would be affirming. What the law says about conversion therapy.

The research team will moderate all online discussions and provide feedback to individuals to guide them to factual information that can help answer their questions. Individuals will be prompted by text message each week to remind them to contribute to the Discord community.

Follow Up Survey (1 month)

All randomized individuals will receive a follow-up survey 30 days after they complete the baseline survey. Mechanistic and outcome survey constructs will be repeated in this survey. Additionally, in all but Group 1, we will measure Feasibility (i.e. proportion of IP tasks completed, length of time IP used); Usability utilizing the System Usability Scale (SUS); and Acceptability using open-ended questions regarding whether each IP group was helpful, affirming of SGM status, if timing and amount of content were appropriate, if privacy and confidentiality were maintained, and if they had any negative consequences of participation (e.g. parent questioning them).

Participants will be compensated for each research activity as described in compensation.

2. **Upload a copy of all materials used to collect data about subjects: (Attach all surveys, interview/focus group scripts, and data collection forms except for case report forms, SCID or KSADS):**

	Document	Category	Date Modified	Document History
View	SMASI (Modified, using items 14-16) (1.0)	Data Collection	6/22/2023	History
View	Global Unique Identifier Information.docx(0.01)	Data Collection	2/24/2023	History
View	Demographics_SGMY Trial.docx(0.01)	Data Collection	2/24/2023	History
View	UCLA Loneliness Scale.pdf(0.01)	Data Collection	2/24/2023	History
View	PHQ-8.pdf(0.01)	Data Collection	2/24/2023	History
View	List of all measures with description(0.02)	Data Collection	2/24/2023	History
View	Perceived Health(0.01)	Data Collection	2/17/2023	History
View	Gender Identity Self-Stigma Scale Timmins 2017.pdf(0.01)	Data Collection	2/17/2023	History
View	Internalized Homophobia Scale.pdf(0.01)	Data Collection	2/17/2023	History

	Document	Category	Date Modified	Document History
View	Barriers to Adolescents Seeking Help Scale Brief Version(0.01)	Data Collection	2/17/2023	History
View	Actual Help Seeking Questionnaire(0.01)	Data Collection	2/17/2023	History
View	Depression and Anxiety Literacy Questionnaires(0.01)	Data Collection	2/17/2023	History
View	Antidepressant Meanings Scale(0.01)	Data Collection	2/17/2023	History
View	Depression Stigma Scale(0.01)	Data Collection	2/17/2023	History
View	Patient Health Questionnaire Modified(0.01)	Data Collection	2/17/2023	History
View	Generalized Anxiety Disorders 7-item(0.01)	Data Collection	2/17/2023	History
View	Medical Outcome Study Social Support Scale(0.01)	Data Collection	2/17/2023	History
View	General Help Seeking Questionnaire(0.01)	Data Collection	2/17/2023	History
View	System Usability Scale.docx(0.01)	Data Collection	2/17/2023	History

3. * **Will blood samples be obtained for research purposes?**

○ Yes ● **No**

Consent Process

Enter N/A in response to the following questions if a Waiver of Consent is requested for all research activities or if no subjects are being enrolled.

1. * **Indicate where the consent process will take place and at what point consent will be obtained:**
Assent and consent processes will take place before conducting any of the research activities described in the research activities section. After the participant indicates study interest and screens in to the study, the participant will be redirected to complete an electronic consent form via Redcap. At that point, they will be given the option to immediately continue with assent/consent procedures or to be contacted by the research team at a later time after which they have had time to review the assent/consent in more detail.

We will ensure assent/consent by having the participant type their name, parent/guardian last name, and date of birth.

2. * **Describe the steps that will be taken to minimize coercion and undue influence, including assurance that there is sufficient time for subjects to make an informed decision:**
All individuals who indicated study interest and are eligible for the study, will be redirected to the assent/consent materials also via RedCAP. They will be given an opportunity to watch an easy-to-understand video, then review the text of the assent/consent, then proceed to a brief quiz, and then provide electronic assent/consent. If the participant prefers to pause the assent/consent process and either pick it up again at a later time after they have had more of a chance to review (and they will be provided a copy of the consent to review) - or they prefer to talk to the research team and ask questions prior to signing assent/consent, they may do so.

During this process, they will be informed that their participation is voluntary, that they can stop participation at any time without penalty.

3. **For studies that involve multiple visits, describe the process to ensure ongoing consent:**
Participants will receive a baseline and follow-up survey. On the follow-up survey, there will be language about consent and the desire to stop or continue to ensure continued assent/consent.

4. * **Steps to be taken to ensure the subjects' understanding:**
After the individual reviews the assent/consent video and assent/consent text and prior to providing electronic assent/consent, they will be asked to complete a brief quiz reviewing the material within the assent/consent. They can retake the quiz as many times as they would like but will be required to answer the questions correctly prior to proceeding with the electronic assent/consent.

Participants will be reminded of the purpose, procedures, risks and benefits of participation prior to accessing the Follow-up survey as well.

5. * **Are you requesting an exception to the IRB policy related to the informed consent process:**
● Yes ○ No

* **Provide a justification and describe the qualifications of the individuals who will obtain consent:**
Assent/consent will be obtained electronically after the individual reviews the RedCAP assent/consent materials. If an individual requests to pause the assent/consent process to have more time to review it and is then contacted by the reseach team to complete the assent/consent process, then the individuals who will obtain assent/consent will be research team members including research assistants,

MSW graduate students, and interns who have certificates from CITI and taught best practices in obtaining informed consent.

Since children will be enrolled, address the following questions:

* **Describe the process for determining who is legally able to provide consent for the child:**
A waiver of parental permission is being requested due to the nature of the study with regards to recruiting sexual and gender minority youth who may or may not have a parent who is aware of their sexual and gender minority status or about their mental health. For some teens, coming out to their parent may lead to harm and the consent process would require notifying a parent that the study is for teens who are sexual or gender minorities. Therefore the teen should be able to provide permission for themselves as this reduces the potential risk of identity exposure, embarrassment, and potential hate crimes.

* **Describe the process that will be used to obtain assent from developmentally able children:**
Assent from developmentally able children will be obtained through the process described in boxes 1 and 2 in this section.

Assent will be obtained by the participant in Redcap. If the participant has any questions or concerns during the informed consent process, they may contact the study team for more information and these will be addressed and documented.

If child participants may turn 18 while enrolled in the research, describe the process of obtaining their consent for continued participation:
If a child participant turns 18 while enrolled in the research, we will resend the consent via email form. We will then affirm over a phone call that they want to continue to participate. This call will be documented in RedCAP.

Consent Forms

1. **Consent Forms:**

	Document	Category	Date Modified	Document History
View	14-17 Assent SGMY Mental Health Help-Seeking Factorial Trial_Version_0.08.docx(0.08)	Consent Form	9/27/2023	History
View	18+ consent SGMY Mental Health Help-Seeking Factorial Trial_Version_0.08.docx(0.08)	Consent Form	9/27/2023	History
View	Turned 18 consent for continued participation SGMY Mental Health Help-Seeking Factorial Trial_Version_0.04_Version_0.01.docx(0.06)	Consent Form	6/22/2023	History

Refer to the following templates and instructional documents:

- Guidance - Consent Wording
- Template - Consent Document - Short Form
- HRP-090 - SOP - Informed Consent Process for Research
- HRP-091 - SOP - Written Documentation of Consent

Waiver/Alteration of Consent

1. * **Select all options that apply to the request to waive the requirement to obtain informed consent:**
Parental permission and/or child assent

*General Requirements: The Federal Policy (45 CFR 46.116 (d)) as well as guidance issued by the FDA requires the following criteria to be met for a waiver or alteration of consent to be approved with one exception.The FDA does not include a biospecimen provision (Item #4 below). You **MUST** provide a justification addressing how **each of the criterion are met for each option chosen** in Item #1.*

2. * **The research involves no more than minimal risk to the subjects;**
We believe that all aspects of the study involve no more than minimal risk as the main risks are due to breach of confidentiality, and we will take many precautions to avoid breach of data security. Participants will be assured of their right to not respond to individual items and/or discontinue participation in the study at-will.

3. * **The waiver or alteration will not adversely affect the rights and welfare of the subjects;**
The rights and welfare of the adolescent participants are not adversely affected by a waiver of parental permission as youth will provide direct assent/consent for their own participation in the research rather than having a parent provide permission. This recognizes the adolescents' autonomy, and actually enhances the youth's rights and welfare.

4. **If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format (enter N/A for FDA regulated studies);**
In order to obtain a signature for consent, and for purposes of creating a GUIN (global universal identifer number) we will need to have identifiable private information collected.

5. * **The research could not practicably be carried out without the waiver or alteration;**
As these studies involve hard-to-reach youth we anticipate that it will be difficult to access their parents to provide permission. Additionally, a number of youth who identify as SGM may not have revealed this to their parent, and asking for parental permission to participate in the study may jeopardize the child's confidentiality and safety. In short, if parental permission is required, youth who do not have a parent or legal guardian that they are willing to approach due to the study being about SGMY youth and available to provide permission will be unjustly left out of the study. The resulting sample of SGMY would be nonrepresentative and any interventions based on those results may not be effective.

6. * **Whenever appropriate, the subjects will be provided with additional pertinent information after participation;**
All subjects will receive information about crisis. All will also receive information about other LGBTQ+ friendly resources at the very end of the study (as some resources are used in different interventions to prevent cross-over). Participants will be able to contact the PI and study staff at any point during the study to request information about the research objectives and process.

7. * **Under what circumstances (if any) will you obtain consent from some of these subjects:**
All subjects will provide assent or consent; however we will not obtain parental consent for any subject.

Electronic Data Management

1. * **Will only anonymous data be collected (select NO if identifiers will be recorded at anytime during the conduct of the study)?**
   ○ Yes ● No

Select all identifiers to be collected during any phase of the research including screening:

Name:	☑	**Internet Protocol (IP) Address:**	☑
E-mail address:	☑	**Web Universal Resource Locators (URLs):**	☐
Social security #:	☐	**Social security # (for Vincent payment only):**	☐
Phone/Fax #:	☑	**Full face photo images or comparable images:**	☐
Account #:	☐	**Health plan beneficiary #:**	☐
Medical record #:	☐	**Device identifiers/serial numbers:**	☐
Certificate/license #:	☐	**Vehicle identifiers/serial #/license plate #:**	☐
		Biometric identifiers, finger and voice prints:	☐

* **a: Will you be collecting any of the following location data: geographic subdivisions smaller than a State such as street address, city, county, precinct, zip, geocodes, etc.?** ● Yes ○ No

* **b: Will you be collecting any date information such as birth date, death, admission, discharge, date of surgery/service?** ● Yes ○ No

c: List any other unique identifying numbers, characteristics or codes related to an individual that are to be collected:

Email Addresses and Phone numbers are collected for contacting and following up with participants throughout the survey via a Pitt/UPMC email OR Google Voice. For the purpposes of generating a Global Unique Identifier (GUID) we will collect first, middle, and last name, sex assigned at birth, date of birth, and city/municipality of birth.

We will collect zip codes for comparison of data between different geographic regions

d: Will you be collecting any data subject to the General Data Protection Regulation (GDPR)? ○ Yes ● No

* **For ALL identifiable data collected, will you be coding the data by removing the identifiers and assigning a unique study ID/code to protect the identity of the participant?** ● Yes ○ No

* **Will the data be HIPAA de-identified?** ● Yes ○ No

* **Briefly describe your plan to store coded data separately from the identifiable data:**

Contact and Identifiable information will be stored on Redcap. RedCAP survey data or other research data (downloads of Discord content) will be saved in a project separate to that of

the contact information. It will be stored in a secure Pitt server and will be accessd via the OneDrive.

2. **During this study, will restricted data as defined by the University's Data Risk Classification matrix (https://www.technology.pitt.edu/security/data-risk-classification-and-compliance) be processed, stored, or transmitted?**
   ● **Yes** ○ No

3. * **During this study, will sensitive data (https://www.hrpo.pitt.edu/electronic-data-security) be collected where disclosure of identifying information could have adverse consequences for subjects or damage their financial standing, employability, insurability, educational advancement, reputation or place them at risk for criminal or civil liability?**
   ● **Yes** ○ No

4. * **Select all locations where data will be stored or archived(including e.g., personal / employer laptop or desktop): If you have access to University owned or controlled resources, facilities, or repositories, such as computer servers, please choose that option to comply with the Research Data Management Interim Policy R1 14.**

   Please note that to address Research Security Requirements, University data must be stored in University owned, controlled, or approved repositories, such as Pitt OneDrive. If UPMC or external electronic repositories must be used, they must be approved by Pitt IT.

	Storage Device	Description	Identifiable Data	Sensitive Data	De-Identified/Anonymous Data
View	UPMC owned desktop, laptop or other device	These devices will only be used to access data, not store data.	no	no	no
View	PITT: OneDrive / Sharepoint	Microsoft OneDrive	yes	yes	yes
View	Other: Personal desktop, laptop, or other device	These devices will only be used to access data, not store data. Personal devices require secure mechanisms to access any data (VPN client)	no	no	no
View	PITT owned desktop, laptop or other device	These devices will only be used to access data, not store data.	no	no	no

5. * **Select all technologies being used to collect data or interact with subjects: Technologies selected in this section may require a Vendor Security Risk Assessment, which can be requested here.**

Mobile App
Text messaging
Web-based site, survey, or other tool

6. * **Mobile App – identify all mobile applications, including text messaging apps, used to collect data during any phase of the research:**

name	Identifiable
Discord	no

7. * **Text Messaging - Identify all uses of SMS / cellular text messaging:**

name	Identifiable
Text Message	no

8. * **Web Based Technologies – identify all web based technologies to be used to collect data during any phase of the research:**

name	Identifiable
View Pitt Redcap Version	

Data Safety and Monitoring

1. * **Describe your plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe. The plan might include establishing a data monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor:**
Dr. Radovic, the PI, will be responsible for the data and safety monitoring of the study. She and the research team will be in contact at least once once per month to ensure data integrity and safety of research participants. They will discuss any concerns regarding recruitment procedures, enrollment, withdrawals, confidentiality, data security, and any safety concerns or unanticipated problems. If there is a lack of clarity or further guidance needed, they will meet with Dr. Escobar-Viera to provide further input.

The following procedures will be followed to ensure confidentiality of research participants and integrity of the data:

1.) All quantitative data collected by online self-report will be de-identified and stored on a password-protected encrypted University of Pittsburgh server.
2.) Almost all data is electronic but if any paper research materials are needed they will be stored in locked offices and filing cabinets belonging to Dr. Radovic.
3.) All trial data will be de-identified and stored on a password-protected encrypted University of Pittsburgh server.
5.) The research team will conduct quarterly audits to ensure that data is securely maintained and participant confidentiality is upheld.
6.) The research team will be in contact with the IRB coordinator to ensure data is securely maintained and participant confidentiality is upheld.
7.) All safety concerns will be immediately reported to the IRB.
8.) All unanticipated events will also be reported to the IRB coordinator.

Specifically, we will monitor all study progress including participant recruitment and retention rate, data quality (e.g. patterns of missing data, abnormal response patterns), general participant reaction to study procedures (e.g. any privacy concerns, fatigue), any anticipated or unanticipated adverse events or safety concerns, procedures to maintain privacy of participants and confidentiality of data.

We will follow the policies and procedures of the University of Pittsburgh Institutional Review Board (IRB), which are designed to remain compliant with the NIMH Reportable Events Policy (https://www.nimh.nih.gov/funding/clinical-research/nimh-reportable-events-policy.shtml). We recognize
this policy requires timely reporting to our NIMH program officer in the event of IRB suspensions or
terminations (within 3 business days), deaths related to study participation (within 5 business days), and all
serious adverse events (SAEs), unanticipated problems involving risks to subjects or others, and serious or
continuing noncompliance (within 10 business days), as well as adverse events and protocol deviations (upon
annual progress reports). Per this policy, we will follow the Office for Human Research Protection's definition
of a serious adverse event, which is any adverse experience that:
• Results in death
• Is life-threatening
• Results in inpatient hospitalization or prolongation of existing hospitalization
• Results in a persistent or significant disability/incapacity
• Results in a congenital anomaly/birth defect, or
• Based upon appropriate medical judgment, may jeopardize the subject's health and may require
• Medical or surgical intervention to prevent one of the other outcomes listed in this definition

We do not anticipate there will be any such Serious Adverse Events.

As we feel this study is minimal risk and have conducted similar studies with online recruitment and waiver of parental permission in the past to provide usability data on technology interventions which were found by our University of Pittsburgh Human Research Protection Office (IRB) to be minimal risk, it would therefore not require a data safety and monitoring board.

The University of Pittsburgh Human Research Protection Office is available to the research team for consultation regarding any data and safety monitoring questions.

2. * **Describe your plan for sharing data and/or specimens:**

Only de-identified data will be shared with other researchers. De-identified data will be shared via email or Onedrive. We intend to make all data generated from this proposal freely available to the scientific community. The primary mechanism of sharing data will be through submission of abstracts resulting from research findings to regional, national, and international meetings as well as submission of manuscripts to widely read peer-reviewed journals. We will submit accepted manuscripts through the NIH manuscript submission process through PubMed Central as required by public access policies of NIH. Dr. Radovic will serve as a liaison with other investigators in sharing additional materials if necessary. Office of Sponsored Programs will be contacted prior to sharing data to determine if a DUA is necessary. We will follow resource sharing expectations per NOT-MH-19-033. We will share data using the NIMH Data Archive (NDA).
We will plan to submit the 'treatment assignment' data structure, the clinical trial protocol including the assessment schedule, the manual of procedures and case report forms, and the survey instruments. The collected data that will be shared includes the quantitative survey data.
We will plan to collect personally identifiable information in order to generate the secure Global Unique Identifier, and we will include appropriate language in the informed consent document. We will submit specific data used for publications by creating an NDA study to enhance rigor and reproducibility.

3. **If any research data is collected, stored, or shared in a paper format, address what precautions will be used to maintain the confidentiality of the data:**

No data will be collected stored or shared in paper format. If any paper research materials are needed they will be stored in locked offices and filing cabinets belonging to Dr. Radovic. A UPMC or PITT ID is required to enter the office suite.

Risk and Benefits

1. * Enter all reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related to subjects' participation in the research:

View

Research Activity	**Survey completion**
Common Risks	**Mild Psychological disturbance if reflecting on mood and other psychological symptoms**
Infrequent Risks	**Breach of Confidentiality; Fatigue; Being "outed"**
Other Risks	***No Value Entered***

View

Research Activity	**Participating on Discord Server**
Common Risks	**Mild psychological disturbance if reflecting on prior difficult experiences with seeking mental health help or being part of LGBTQ+ community**
Infrequent Risks	**Breach of confidentiality**
Other Risks	***No Value Entered***

2. * Describe the steps that will be taken to prevent or to minimize risks:

We believe all aspects of the study involve no more than minimal risk. In daily life, many adolescents use applications on smartphones regularly without requiring parental permission.

The risk of breach of confidentiality is low as survey data will be identified by an individualized code and not the patient's name. Any data downloaded from RedCAP will be stored on a secure University of Pittsburgh server.

Discord is not encrypted and there is some risk that information could be intercepted, however we will explain these risks during the consent process and will also seek to minimize the sharing of any identifying information by participants. A research team will review all content on the Discord survey every weekday daily and remove any information that is identifiable or could be offensive to any other user. The Discord settings will be set to not allow private messaging between individuals to allow for monitoring of all content. Prior to joining Discord, each individual will be asked to agree to and review ground rules of participating which include acknowledging that the intervention does not provide crisis services, to maintain anonymity, to not bully, and that any content our team feels will be hurtful to others will be removed. Our research team has years of experience moderating online interventions on the sova.pitt.edu website and maintaining anonymity. Discord settings for all notifications of new content on the server will be sent to the study email.

3. Financial risks - will the subject or insurer be charged for any research required procedures?

○ Yes ● **No**

4. Describe the steps that will be taken to protect subjects' privacy:

We will ask participants to password protect their phone a
nd email. When we send emails and text messages about the study (e.g. online surveys being due) we will use vague language to not identify the individual as being involved in a mental health study. E.g. "Hi, its Kayla! :) Its time for your survey! here is the link: [LINK INSERTED HERE]"

Participants will be instructed not to share real names, locations, etc. and participants will be discouraged from contacting each other outside of the Discord channels for their assignments.

5. **What steps will be taken in the event that a clinically significant, unexpected disease or condition is identified during the conduct of the study:**
We do not expect to uncover any clinically significant, unexpected disease or condition from the data during the study.

In case the patients call the team regarding their medical status or anything that is not about the study, they will be referred to Dr. Radovic. If Dr. Radovic is unavailable, call the on-call physician for the Center for Adolescent and Young Adult Health (CAYAH) will be contacted. Dr. Radovic is a physician at CAYAH and her or her team is routinely on call for adolescent and young adult medicine at UPMC Children's Hospital of Pittsburgh.

Experiencing crisis and suicidality is not an anticipated risk of this study, but it is one inherent to the studied population. All individuals in the study will be provided with a list of crisis resources at the beginning and end of the study.

We will not be specifically asking about suicidality in the survey. If any participant shares suicidality with the team during the study, or any other clinical concern, Dr. Radovic will conduct a safety assessment call. Dr. Radovic will assess level of ideation, existence of plan, prior attempts, and ask the adolescent permission to notify a supportive adult. Dr. Radovic will offer to research local resources based on the participants location and refer to mental health and/or crisis resources.

Although the IPs in Study 2 will aim to increase help-seeking behavior, negative experiences may occur due to
help-seeking. For example, the participant may interact with a mental health professional who is not affirming
of SGMY. We will measure whether any SGMY experience negative consequences of help-seeking. We will
also provide information throughout all IPs about how to seek help while also maintaining confidentiality and
evaluating whether the source of help is appropriate, knowledgeable, and affirming.

We will use multiple opportunities to provide ALL participants with crisis resources including at screening,
consent, and after each survey is taken.
For example, they will receive the following information:
"If you feel like you may be at risk of hurting yourself or someone you love, please let someone know, like an
adult you trust or your parent/guardian. Most counties in the U.S. have a phone number you can call if you are
experiencing a crisis, and the person on the other line will help you figure out what to do. You can call the
National Suicide Prevention Lifeline at 1.800.273.8255 and they will connect you to your local crisis center. The
Trevor Project has a national 24-hour toll free confidential suicide hotline for LGBTQ youth. It is 18664887386.
To use text instead you can text START to 678678. Otherwise, you can call 911. If you prefer texting or online
chatting, you can chat with a trained crisis counselor online at Crisischat.org, or you can text someone for help
(crisistextline.org). Simply text "START" to 741-741 to start the conversation."

6. **Describe the potential benefit that individual subjects may experience from taking part in the research or indicate if there is no direct benefit. Do not include benefits to society or others:**
No direct benefit for adolescent subjects. Will receive crisis resources.

7. **Do you anticipate any circumstances under which subjects might be withdrawn from the research without their consent?**
○ Yes ● **No**

8. **Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection and data already collected:**
If subjects ask to withdraw from research, only data collected up to that point will be used.

Conflict of Interest

Institutional Financial Interests

1. * **To the best of your knowledge, has the University of Pittsburgh optioned or licensed technology that will be tested or evaluated in this research?**
   ○ Yes ● **No**

Ancillary Reviews

1. **Ancillary reviews or notifications selected below are required based on previous answers to questions. If a selection is incorrect, return to the appropriate page and adjust the answers to questions on that page:**

- [ ] Conflict of Interest (**COI**)
- [ ] Clinical and Translational Research Center (**CTRC**)
- [x] Data Security
- [ ] Honest Broker
- [ ] UPMC Investigational Drug Service
- [ ] Pitt Medical School Review
- [ ] Pitt+Me
- [ ] IND & IDE Support(**IIS**)
- [ ] Radioactive Drug Research Committee (**RDRC**)(study involves the evaluation or use of procedures that emit ionizing radiation)
- [ ] ORP Business **Manager** (required for industry sponsored studies)
- [ ] Religious Directives
- [x] Scientific Review
- [ ] Health Record Research Request (**R3**) (required if using UPMC clinical data and authorization for other UPMC data sources for research)
- [ ] UPMC Office of Sponsored Programs and Research **Support** (using UPMC facilities and/or UPMC patients during the conduct of the study)

2. **Additional ancillary reviews the PI may choose to include as needed for the research:**

- [ ] Human Stem Cell Oversight (**hSCRO**)
- [ ] Institutional Biosafety Committee (**IBC**)(study involves deliberate transfer of recombinant or synthetic nucleic acid molecules)

Good Clinical Practice (GCP) Training

1. * **Regardless of funding source, is this study a clinical trial (**as defined by the NIH**)?**
   ● **Yes** ○ No

ClinicalTrials.gov Information

Visit the University of Pittsburgh Office for ClinicalTrials.gov website or contact ctgov@pitt.edu for further information.

2. * **Was this study registered, or will it be registered, on ClinicalTrials.gov?**
   ● **Yes** ○ No

3. * **Is the University of Pittsburgh or UPMC the Sponsor Organization for this study record?**
   ● **Yes** ○ No

   * **Who will be the Responsible Party for this study record?**

   Principal Investigator of this IRB application

Supporting Documents

1. **Attach any additional supporting documents not previously uploaded. Name the documents as you want them to appear in the approval letter:**

	Document	Category	Date Modified	Document History
View	Peds Scientific_Version_0.01 Lindhiem.pdf(0.01)	Other	2/28/2023	History

Add Storage Information

1. * **Select a Storage Type:**
   UPMC owned desktop, laptop or other device

2. **Description:**
   These devices will only be used to access data, not store data.

3. * **Will identifiable data be stored in this location?**
   ○ Yes ● **No**

4. * **Will sensitive data be stored in this location?**
   ○ Yes ● **No**

5. **Will de-Identified or anonymous data be stored in this location?**
   ○ Yes ● **No**

6. * **Is anti-virus software installed and up to date on all devices and are the operating systems kept up-to-date on all devices?**
   ● **Yes** ○ No

7. **Provide additional information as needed:**

Add Storage Information

1. * **Select a Storage Type:**
   PITT: OneDrive / Sharepoint

2. **Description:**
   Microsoft OneDrive

3. * **Will identifiable data be stored in this location?**
   ● Yes ○ No

   * **Describe how the data will be transferred, how the data be encrypted in transit and how the data be encrypted when stored:**
   When working with identifying information we will download directly from RedCap.

4. * **Will sensitive data be stored in this location?**
   ● Yes ○ No

5. **Will de-Identified or anonymous data be stored in this location?**
   ● Yes ○ No

6. **Provide additional information as needed:**
   OneDrive is used for purposes of collaboration between the research team members on manuscript preparation and grant writing.

7. **Will access to the files or folders be restricted to only those research team members involved in the study(e.g., Specific people are granted access)?**
   ● Yes ○ No

Add Storage Information

1. * **Select a Storage Type:**
   Other: Personal desktop, laptop, or other device

2. **Description:**
   These devices will only be used to access data, not store data. Personal devices require secure mechanisms to access any data (VPN client)

3. * **Will identifiable data be stored in this location?**
   ○ Yes ● **No**

4. * **Will sensitive data be stored in this location?**
   ○ Yes ● **No**

5. **Will de-Identified or anonymous data be stored in this location?**
   ○ Yes ● **No**

6. * **Is anti-virus software installed and up to date on all devices and are the operating systems kept up-to-date on all devices?**
   ● **Yes** ○ No

7. **Provide additional information as needed:**

Add Storage Information

1. * **Select a Storage Type:**
   PITT owned desktop, laptop or other device

2. **Description:**
   These devices will only be used to access data, not store data.

3. * **Will identifiable data be stored in this location?**
   ○ Yes ● **No**

4. * **Will sensitive data be stored in this location?**
   ○ Yes ● **No**

5. **Will de-Identified or anonymous data be stored in this location?**
   ○ Yes ● **No**

6. * **Is anti-virus software installed and up to date on all devices and are the operating systems kept up-to-date on all devices?**
   ● **Yes** ○ No

7. **Provide additional information as needed:**

Risk

1. * **Research Activity:**
   Survey completion

2. **Common Risks:**
   Mild Psychological disturbance if reflecting on mood and other psychological symptoms

3. **Infrequent Risks:**
   Breach of Confidentiality; Fatigue; Being "outed"

4. **Other Risks:**

Risk

1. * **Research Activity:**
   Participating on Discord Server

2. **Common Risks:**
   Mild psychological disturbance if reflecting on prior difficult experiences with seeking mental health help or being part of LGBTQ+ community

3. **Infrequent Risks:**
   Breach of confidentiality

4. **Other Risks:**