Social and Behavioral Sciences Human Research Protocol

Version 4.0
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PROTOCOL TITLE: Piloting a Web App for Sexual and Gender Minority Youth Mental Health

INTRODUCTION AND PURPOSE:

The purpose of this study is to assess the psychosocial effects of a novel web application (web app) called "immi" (short for 'i am me')," designed to provide sexual and gender minority youth (SGMY) with tools for affirming their identities and coping with minority stress. Prior research demonstrates that interventions that focus on providing SGMY with resources for adaptively coping with minority stress have the potential to improve their mental health and wellbeing. However, few digital resources exist to address this need. The goal of the proposed research is to test whether this novel and scalable web-based intervention has the potential to impact key psychosocial outcomes among SGMY ages 13-19, such as coping self-efficacy and symptoms of anxiety and depression. Please see the Background section of this application for more information.

OBJECTIVES:

Objective 1: To test whether SGMY randomly assigned to use the immi web app report significantly higher identity affirmation, subjective connectedness to the LGBTQ+ (Lesbian, Gay, Bisexual, Transgender, Queer/Questioning, and other sexual and gender minority identities) community, use of adaptive cognitive and behavioral coping skills, and psychosocial wellbeing (e.g. higher positive and negative affect, lower symptoms of depression and anxiety, and greater life satisfaction) than youth randomly assigned to a 'resource list' control group. The resource list control group will receive a list of technology-based psychosocial resources that are currently freely available to SGMY.

Objective 2: To assess how individual differences in usage and satisfaction with the immi web app relate to the outcomes listed in Objective 1, and to identify areas for further tool optimization. We will achieve this by linking web app usage data to outcome data, as well as through collecting quantitative and qualitative data measuring user satisfaction and suggestions for improvement.

BACKGROUND:

Compared to their cisgender, heterosexual peers, sexual and gender minority youth (SGMY) are at increased risk of experiencing a wide variety of negative mental health outcomes. SGMY are twice as likely as their non-SGMY counterparts to report feeling sad or hopeless, and three times as likely to have considered attempting suicide.[1] In one recent national survey, 65% of SGMY reported symptoms of moderate to severe depression as compared with 31% of their straight, cisgender peers.[2]

The minority stress model provides a framework for understanding the higher prevalence of psychological distress and negative mental health outcomes for SGMY, as well as for identifying interventions to improve sexual and gender minority (SGM) mental health. Minority stress theory proposes that SGM health disparities can be explained in large part by discrimination from a homophobic and hostile culture,

[1] Centers for Disease Control and Prevention Youth Risk Behavior Survey (2017)
[2] Coping With Covid-19: How Young People Use Digital Media To Manage Their Mental Health (2021)

which creates stressors unique to minority identity, including harassment, victimization, internalized homophobia, and expectations of rejection.[3] Efficacious mental health interventions for SGMY have focused on providing resources for coping with minority stress, including affirming SGM identities, teaching cognitive and behavioral coping skills, and strengthening supportive social connections.[4,5,6]

While prior research suggests that interventions that include these components may improve the mental health of SGMY, interventions have primarily been delivered within the context of time intensive, in-person sessions, limiting their reach. Many SGMY face significant barriers to accessing affirming in-person services[7], an issue that has been exacerbated by the COVID-19 pandemic.[8] Digital technologies can be utilized to help bridge this gap by meeting a pressing need within a medium in which youth are already seeking support. Over half of SGMY report spending over five hours a day online,[9,10,11] and SGMY are more likely than those who identify as heterosexual to report going online for health information, including for support with depression (76% vs. 32%) and anxiety (75% vs. 36%)[12]. However, to date, there is little research examining the efficacy of web-based platforms for helping SGMY cope with minority stress.

The proposed research seeks to fill this need by testing the efficacy of a web app for SGM ages 13-19. This web app is designed to facilitate SGM identity affirmation, promote a sense of connectedness to the LGBTQ+ community, and encourage cognitive and behavioral coping skill practice. This tool was built by Hopelab, a nonprofit social innovation lab, in collaboration with CenterLink, an international nonprofit organization and member-based association of LGBTQ (Lesbian, Gay, Bisexual, Transgender, and Queer) centers serving their local and regional communities. The goal of the proposed research is to assess the efficacy of this web app for improving key psychosocial outcomes among SGMY, such as coping self-efficacy and symptoms of anxiety and depression.

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CHARACTERISTICS OF THE STUDY POPULATION:

1. Target Population and Accrual:

We will recruit 300 participants from across the United States, ages 13-19, who self-identify as sexual or gender minorities. To ensure that our results generalize to SGM of color, who face multiple forms of intersecting minority stress, we will over-recruit non-white participants such that they comprise approximately 75% of our sample (~225 participants). Non-Hispanic white participants will comprise approximately 25% of our sample (~75 participants). Participants will be recruited through social-media based advertisements posted on platforms such as Facebook, Tumblr, Instagram, Reddit, Jack'd, Grindr, and Twitter. Participants will be randomly assigned to a condition [experimental vs. control] in a 1:1 fashion. See the statistical analysis section for more details on statistical methods and theoretical justification for the sample size.

2. Key Inclusion Criteria:

Participants will be eligible if they:

1. Are between 13-19 years of age (inclusive)
2. Self-identify as a sexual or gender minority
3. Are English literate
4. Reside within the United States
5. Have access to a device that has internet access, a web browser, and SMS capabilities, such as a smartphone, computer, or tablet
6. Willingness to participate in study activities

Additionally, given that this is an online intervention, in order to be considered enrolled in the study, individuals must pass enrollment verification procedures which are detailed in the attached "SOP-Applicant Verification.pdf." If all criteria are met, participants will be randomized into a study arm and considered enrolled into the study.

Justification

We are testing the product with 13-19 year olds because the web app itself was designed in collaboration with young people in this age range, and the content of the app developmentally targets their specific questions and concerns. Additionally, this age range is critical for this research because adolescence is a pivotal period for sexual and gender identity development, and one in which SGM youth exhibit significantly higher levels of identity-related mental health problems compared to their straight cis-gender peers (Marshal et al., 2011). Thus, interventions aimed at affirming SGM identities and managing identity-related minority stress--such as the proposed intervention--have the potential for greatest impact when delivered to this age group. It is important to study this "vulnerable population" because they are at risk for negative cognitive, behavioral, and mental health outcomes. The development and testing of interventions targeted to this age group has the potential for significant gains in health for this age group.

The immi web app is specifically designed to teach cognitive and behavioral coping skills for responding to minority stress. We are proposing over-recruiting non-white (i.e., those who self-identify as at least one race or ethnicity other than white) participants because we want to ensure that our results are generalizable to those who face multiple forms of intersecting minority stress.

3. Key Exclusion Criteria:

Exclusion criteria for enrollment into the study include:

1. Age younger than 13 or older than 19
2. Do not self-identify as SGM
3. Not English-literate
4. Reside outside of the United States
5. Do not have access to a device that has internet access, a web browser, and SMS capabilities, such as a smartphone, computer or tablet
6. Are not willing to participate in study activities

4. Subject Recruitment and Screening:

We will reach the study population using social media ads on platforms including Facebook, Tumblr, Instagram, Reddit, Jack'd, Grindr, and Twitter, and other comparable social media platforms (see example copy and images in "Recruitment materials.pdf"). Social media platforms allow us to specify our audience based on socio-demographic characteristics (e.g., age, race/ethnicity) to increase their specificity to our population.

Ads will link interested individuals to a 5-10 minute uncompensated Qualtrics screener where they may verify their eligibility or email the team if they have questions. The screener survey will provide potential participants with basic information about the study purpose, procedures, and compensation. Individuals will then be asked for consent to take the screener. Those who consent will be asked questions to determine their eligibility, and asked to provide their first name, email address, and phone number. Those who do not consent to take the screener will be routed to a public site (e.g., Google).

All individuals who complete the screener will be asked if they would like to be contacted about other research studies in the future, then will be routed to a public site (e.g., Google). For those who are eligible based on their screener responses and pass the initial fraud verification process, we will email them with a link to the informed consent form. Individuals who consent will complete a 30- to 40-minute baseline survey. Compared to the gold standard (in-person interviewing), a limitation of online research – like mail and phone surveys – is the challenge of verifying a respondent's authenticity. Using best practices[13][14] (see SOP-Applicant Verification.pdf), we will attentively reduce the likelihood of duplicative entries, bots, and/or catfishing (fake online personas). Verified participants will be randomized into one of the two study arms.

Web-based recruitment screener: The online survey is hosted by Qualtrics. It will include the eligibility script, consent/assent to be screened, and the screener questions. It will ask for the first name, email, and phone number of the applicant. We use Secure Socket Layer (SSL) encryption for online transfers of information, and data will be stored on Qualtrics' secure, HIPAA-compliant servers.

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5. Early Withdrawal of Subjects:

Participants are told in the consent form that they can withdraw from the study by contacting Dr. José Bauermeister at the University of Pennsylvania by email (bjose@nursing.upenn.edu).

Participants may also be withdrawn by the study PI at any time for the following reasons:

- A participant is flagged to have a duplicate or fraudulent registration during the fraud detection process. Fraudulent entries will not be counted towards study recruitment totals.
- Failure to follow study instructions
- Other circumstances in which a PI determines that continued study participation is not in the best interest of a participant
- The subject becomes incarcerated or placed in detention during the study
- Death of the subject

No further data collection will occur from the date the decision is made to permanently discontinue the subject from the study.

6. Vulnerable Populations:

This research specifically targets a vulnerable population, children (ages 13-17). Please see “Vulnerable populations - children.doc” attached to this application for more information.

7. Populations vulnerable to undue influence or coercion:

Using online recruitment methods and consent processes where the intervention is not pitched by a recruiter minimizes the risk of potential coercion. Instead, individuals will be able to click on the recruitment advertisement and decide if they wish to learn more or not. Consent documents will fully explain the study procedures, potential risks, and potential benefits. Participants will also be reminded that the study participation is voluntary and that refusing to participate in the study or withdrawing from the study is an option at any time.

STUDY DESIGN:

The research activities involve a two-arm prospective RCT enrolling a sample of 300 SGMY (ages 13-19). After consent and completion of the online baseline survey, SGMY will be randomized to either the control or experimental condition (Control, n=150; Experimental, n=150). A self-completed online follow-up survey will be conducted at 4 weeks for all participants.

Participants randomized to the control group will be given access to a website that includes a list of freely available web-based resources for SGMY. They will have access to resources on this list for the 4-week active study period, but will not receive any engagement reminders, matching the conditions present in real world contexts in which web-based resource lists are available to SGMY.

Participants randomized to the experimental group will be given access to the study web app and will be encouraged to engage with the web app as much as they like over the four-week active study period. During the active study period, they will receive periodic reminders via SMS and/or email to visit the web app.

The goal of the proposed research is to test whether a novel and scalable web application (app) designed to provide SGMY with tools for affirming their identity and coping with minority stress has the potential to impact key psychosocial outcomes (e.g., coping self-efficacy and symptoms of anxiety and depression) among a sample of 300 SGMY.

Overall, the estimated data collection time for participants includes 10 mins for the initial recruitment, and two online surveys that are each approximately 30-40 mins. Thus, the total amount of time spent on the study activities (not including web app or online resource site usage) would be approximately 1-1.5 hrs. The amount of time spent using the web app will vary, depending on the interest and engagement of the participants. The web app is designed to facilitate delivery of SGMY identity affirming content and cognitive and behavioral coping skills exercises that average 5-10 minutes in length. However, the participants are free to use the guides as little or as much as they like. The amount of time experimental participants spend using the web app is unrelated to their compensation.

The study is funded for 8 months (Project Period: 07/01/2021 to 02/28/2022). Once consented, participants will be active in the study for 4 weeks.

METHODS:

1. Study Instruments:

Participants will complete two online surveys during the trial (baseline and a follow-up survey on Day 28). Assessments will take 30-40 minutes to complete. Assessment measures fall into four categories: 1) psychological targets, 2) psychosocial wellbeing and mental health, 3) intervention acceptability and satisfaction, and 4) demographics and other baseline assessments.

Psychological Targets. The immi web app is designed to 1) affirm SGM identities, 2) promote a sense of connectedness to the SGM community, and 3) teach adaptive cognitive and behavioral coping skills. Aligned with our theory of change, we will measure psychological targets that map onto each of these three constructs at baseline and at follow-up.

Specifically, to measure change in SGM identity related constructs, we will administer the identity affirmation subscale from Lesbian Gay and Bisexual Positive Identity Measure.[15] We will also administer the concealment motivation, internalized homonegativity, and acceptance concerns subscales of the Lesbian Gay and Bisexual Identity Scale.[16] A single item measure of 'outness' to friends and family will be included to assess change in willingness to disclose one's SGM identity.[17]

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To measure change in a sense of connectedness to the SGM community, we will administer the community subscale from the Lesbian Gay and Bisexual Positive Identity Measure.[18] To assess change in coping and coping self-efficacy we will administer the Brief Coping Orientations to Problems Experienced Inventory[19] which measures the use of specific cognitive and behavioral coping skills; the Coping with Discrimination Scale[20] which measures coping in response to instances of SGM related discrimination, and the Stress Appraisals Measure for Adolescents,[21] which measures coping self-efficacy.

Psychosocial Wellbeing and Mental Health Measures. To determine the effect of the intervention on psychosocial wellbeing and mental health, we will assess the following constructs at baseline and follow up: 1) perceived stress (4-item Perceived Stress Scale)[22] 2) symptoms of anxiety (Generalized Anxiety Disorder Screening (GAD-7)[23], 3) symptoms of depression (Patient Health Questionnaire (PHQ-8))[24], 4) positive and negative affect (The 10-item Positive and Negative Affect Scale for Children (PANAS-C))[25], 5) feelings of shame and guilt (Shame and Guilt Scale)[26], 6) perceived belonging (the Thwarted Belongingness subscale of the Interpersonal Needs Questionnaire (INQ))[27], and 7) subjective wellbeing (the Flourishing Scale)[28]. We will also measure change in substance use behaviors from pretest to posttest using the Car, Relax, Alone, Forget, Friends, Trouble Screening Test (CRAFFT).[29]

Intervention Acceptability and Satisfaction. At follow-up, participants in the experimental group will report on the acceptability of the intervention. We will ascertain participants' opinions about the relevancy and appropriateness of the intervention to SGM young people using a modified version of LGBTQ

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[18] Riggle, E. D., Mohr, J. J., Rostosky, S. S., Fingerhut, A. W., & Balsam, K. F. (2014). A multifactor lesbian, gay, and bisexual positive identity measure (LGB-PIM). *Psychology of Sexual Orientation and Gender Diversity*, *1*(4), 398-411.

[19] Carver, C. S. (1997). You want to measure coping but your protocol is too long: Consider the brief cope. *International journal of behavioral medicine*, *4*(1), 92-100.

[20] Ngamake, S. T., Walch, S. E., & Raveepatarakul, J. (2014). Validation of the coping with discrimination scale in sexual minorities. *Journal of homosexuality*, *61*(7), 1003-1024.

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[25] The 10-Item Positive and Negative Affect Schedule for Children, Child and Parent Shortened Versions: Application of Item Response Theory for More Efficient Assessment

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Appropriateness Scale[30]. We will assess the perceived usability of the web app with the Systems Usability Scale[31]. A measure of intervention satisfaction and suggestions for intervention improvement that was created in-house for the purpose of this study will also be included. This measure consists of multiple choice questions (e.g. 'How would you rate your overall experience of this product?' (1 = excellent to 7 = very bad) and free text responses (e.g. How could this product be more helpful to you? [text box]). We will measure intervention exposure using paradata from the intervention, including counts of user sessions, session lengths, and pages visited.

Demographics and other baseline assessments. To describe our sample and examine whether the experimental and control groups differ on any key demographic characteristics at baseline, we will include standard demographic measures (e.g. age, race, ethnicity etc.) as well as measures of gender identity, sexual orientation, preferred pronouns, sex assigned at birth, educational attainment, educational status, socioeconomic status, and living situation. To characterize our sample and to examine whether the effects of the intervention differ for adolescents experiencing differing levels of minority stress, we will include a short version of the Sexual Minority Adolescent Stress Inventory[32] at baseline. We will also include a measure of mental health and other affirmative LGBTQ+ resources accessed in the last 12 months at baseline to better characterize the degree to which our sample already has access to supportive resources (adapted from McInroy et al. 2019 & the Trevor Project, 2021)[33][34].

2. Group Modifications:

We modified the language in the following study instruments to make the instruments more inclusive of a range of SGM identities (e.g., the original question, "I prefer to keep my same-sex romantic relationships rather private" has been changed to, "I prefer to keep my LGBTQ+ identity rather private"):

Lesbian Gay and Bisexual Identiy Scale (LGBIS)
Lesbian, Gay, Bisexual Positive Identity Measure (LGB-PIM)

We also updated the wording in the Systems Usability Scale (SUS) to specify the name of our web app.

3. Method for Assigning Subjects to Groups:

Those who complete a baseline assessment and pass fraud checks will be randomized to the experimental or resource list control group on a 1:1 basis.

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[31] Brooke, J. (1996). SUS-A quick and dirty usability scale. *Usability evaluation in industry*, *189*(194), 4-7.
[32] Schrager, S.M., Mamey, M.R., Rusow, J., & Goldbach, J.T. (2021). The Sexual Minority Adolescent Stress Inventory – Short Form (SMASI-SF). [Manuscript submitted for publication].
[33] McInroy, L. B., McCloskey, R. J., Craig, S. L., & Eaton, A. D. (2019). LGBTQ+ youths' community engagement and resource seeking online versus offline. *Journal of Technology in Human Services, 37*(4), 315-333.
[34] The Trevor Project. (2021). 2021 National Survey on LGBTQ Youth Mental Health. West Hollywood, California: The Trevor Project.

4. Administration of Surveys and/or Process:

We will collect survey data via online self-completed Qualtrics surveys administered at baseline and 4 weeks. Participants will enter their own responses to questions directly into the survey on their personal computer, smartphone or tablet.

Individuals who complete the screener survey and are eligible will be sent a link to the informed consent form. Those who provide their consent will complete a baseline assessment which will take approximately 30-40 minutes. At the end of the 4-week active study period, participants will complete an online survey to assess key psychosocial outcomes. This follow-up survey will take participants approximately 30-40 minutes to complete.

The incentive for completing the baseline survey is $30 and the follow-up survey incentive is $40. These incentives are small enough to avoid coercion, yet sufficiently substantial to promote retention. In order for interventions to be evaluated as potential best evidence-based interventions through CDCs Prevention Synthesis Research activity, data must be available for at least a single follow-up time point for at least 70% of participants. As described below, a detailed retention plan for the study will draw on previously successful retention protocols to achieve at least an 80% retention rate for the follow-up survey.

If a participant does not complete their follow-up survey by Day 31, we will send a reminder message via email, SMS, or direct message via social media (depending on the participant's communication preferences). The participant will be recontacted using the same methods on Day 35, 39, and 42 if they still have not completed the survey. Each contact will be logged in a spreadsheet.

5. Data Management:

Qualtrics security

We will implement several strategies to offset risks of loss of confidentiality related to web survey data collection. Only authorized research team members with a login name and password will be able to access and open the survey through the Qualtrics site. All data files will have encryption and password protection. Any identifiable data will either be stored on University of Pennsylvania secure servers or will be on fully encrypted laptops. Surveys and online eligibility screening will take place on an encrypted commercial survey website, Qualtrics. This site has been used by the investigators for numerous online surveys with SGM participants with no data security breaches. Access to data will be on a role-based standard; only those study staff who require access to each type of data to complete their study-related roles will be allowed access. All study staff will be trained in security and confidentiality procedures.

We use SSL encryption for transfers of information online. Qualtrics uses Transport Layer Security (TLS) encryption (also known as Hypertext Transfer Protocol Secure (HTTPS)) for all transmitted data. Survey data are protected with passwords and HTTPS referrer checking. The data is hosted by third party data centers that are Statement on Standards for Attestation Engagements (SSAE)-16 Service Organization Control (SOC) II certified. All data at rest are encrypted, and data on deprecated hard drives are destroyed by U.S. Department of Defense methods and delivered to a third-party data destruction service.

Qualtrics deploys the general requirements set forth by many Federal Acts including the Federal Information Security Management Act (FISMA) of 2002. They meet or exceed the minimum requirements

as outlined in Federal Information Processing Standards (FIPS) Publication 200. All client data are considered confidential, and treated as such.

Related to HIPAA, Health Information Technology for Economic and Clinical Health Act (HITECH) are updated assessment rules to ensure that data are properly protected and best security practices are followed. By using secure and certified data centers, Qualtrics ensures the highest protection and testing as per HITECH requirements.

Participant survey data will be collected and stored separately from the web app intervention data, and will only be accessible to study staff. Survey and intervention data will be identified using study ID numbers, assigned by study staff, which will be unrelated to the participant's name or email address.

Memberspace security

After a participant completes their baseline survey and passes fraud checks, they will be randomly assigned to the experimental or control condition. At this point, we will securely pass study ID to MemberSpace. MemberSpace is the system on which participants will complete the enrollment process (by creating an account) for the study web app they are randomly chosen to receive.

MemberSpace secures all member login details using modern SSL encryption. Their primary data and servers are hosted on Amazon's AWS data centers in the United States and all access to MemberSpace's backend is secured over SSL (HTTPS), which ensures that the information is encrypted. Memberspace uses Bcrypt and a per user salt to save user passwords in the form of a hash value. They also use Cloudflare to protect against numerous types of potential attacks.

Memberspace also ensures that all employees and contractors have read, understood, and signed their customer data NDA and Company Handbook documents. They have a DevOps team that monitors their network traffic and data sources for abnormal issues and performs regular reviews such as:

- Review of all personnel security access
- Review any security measure updates personnel need to know about
- Review of backup procedures for all stored media
- Review of all 3rd party sub-processors

The study web app is built on SquareSpace so once a participant signs up, they will be interacting with content built on this platform. However, no data is stored or processed by SquareSpace.

Typeform security

While interacting with the web app, participants will be prompted to interact with/fill out embedded forms powered by Typeform. Typeform will store the participants' form responses and their study ID. Typeform is ISO 27001, SOC II, and HIPAA compliant. They hire well recognized security research firms to perform regular penetration tests on their platform. Their infrastructure is hosted on Amazon Web Services with their main servers sitting in the USA and backup servers in Frankfurt, Germany.

Typeform's environments are hosted in a Virtual Private Cloud (VPC) in AWS where their production networks are separated between public and internal services. No inbound internet traffic is allowed on the private subnets, and all application servers only reside in private subnets without public IP addresses. Only Amazon managed and maintained load balancers have ingress access to the application internal servers. Tight security groups control inbound and outbound access to the servers.

Firewalls, Intrusion Detection Systems, Web Application Firewalls, and other security state of the art perimetral controls are installed at the edge locations to provide an additional layer of internal and external network security. In short, all the networks that Typeform uses are as secure as they can manage. Access to their servers is strictly limited, and no outside traffic is permitted on them.

Fivetran security

We use Fivetran, a data collection and integration platform, to unify participant data that we are collecting through disparate systems (web hooks, Typeform, etc.). Fivetran follows the principle of least privilege within their system. Their data pipeline and web hooks are designed to ensure that data is always encrypted, whether at rest or in motion. Fivetran relies on a combination of ephemeral keys and HSM-backed customer master keys to protect data transiting through their system, as well as metadata and configuration data stored long-term. They deploy log-based monitoring and anomaly detection to enable their team to respond to threats in real-time and, to reduce the risk of accidental exposure, have implemented security protocols to ensure that pipeline data never remains after arrival at the destination. Fivetran undergoes an independent SOC II (Type 2) review every year.

BigQuery Security

Fivetran delivers all connected data to our central data warehouse, BigQuery. BigQuery automatically encrypts all data before it is written to disk. The data are automatically decrypted when read by an authorized user. To protect data as it travels over the Internet during read and write operations, Google Cloud uses Transport Layer Security (TLS).

Sigma Security

Sigma is a business intelligence and analytics tool that sits on top of BigQuery. Sigma is HIPAA, SOC II, GDPR, and CCPA compliant. Encryption is enforced between clients and Sigma and all components of the Sigma platform are using at least TLS 1.2. Sigma does not connect their cloud networks to their office networks and undergoes various forms of internal as well as third-party vulnerability checking on a regular basis to ensure maximum security.

6. Subject Follow-up:

This study involves one follow-up at 4 weeks after baseline survey completion. A detailed retention plan (see “SOP-Participant Retention.pdf”) will draw on our prior successful protocols with hard to reach populations to achieve ≥80% retention rate for the 4-week assessment. We will use best practices to retain participants while being sensitive to undue disclosure of SGMY participating in the study. Every effort will be made to reduce attrition as retention is critical to our study efforts. Correlates of missing data and attrition will be carefully examined. We will compare those who completed the follow-up survey with those who did not on key predictors from the baseline assessment to check for possible sample bias.

Participants will be discontinued from the study in the event that we are notified that they are imprisoned, committed to a mental hospital, hospitalized for long term care, admitted to a drug/alcohol residential program, or a residential living facility.

STUDY PROCEDURES

1. Detailed Description:

The research activities involve a two-arm prospective RCT enrolling a sample of 300 SGMY. After consent and completion of the baseline survey, SGMY are randomized to either the control or experimental condition (Control, n=150; Intervention: n=150). A self-completed online follow-up survey will be conducted at 4 weeks for all participants.

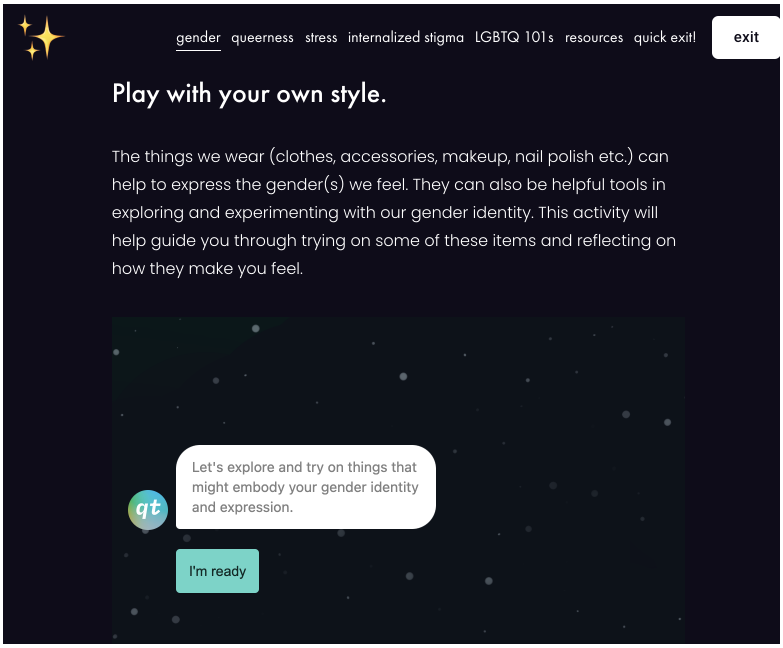
Attention Control Condition: Participants randomized to the control group will be given access to a website that includes a list of freely available web-based resources for SGMY. They will have access to resources on this list for the 4-week active study period, matching the conditions present in real world contexts in which web-based resource lists are available to SGMY.

Experimental Condition: The intervention component of the app aims to facilitate LGBTQ+ identity affirmation, promote connectedness to the LGBTQ+ community, and encourage cognitive and behavioral coping skill practice. Participants in the experimental arm will receive access to immi***,*** a web app with four main content areas: 1) gender identity (the *gender* guide), 2) sexual orientation (the *queerness* guide), 3) stress and coping (the *stress* guide), and 4) internalized stigma (the *internalized stigma* guide). The web app content can be engaged with at the discretion of the participant, in any order. See a short description of the content of each guide below.

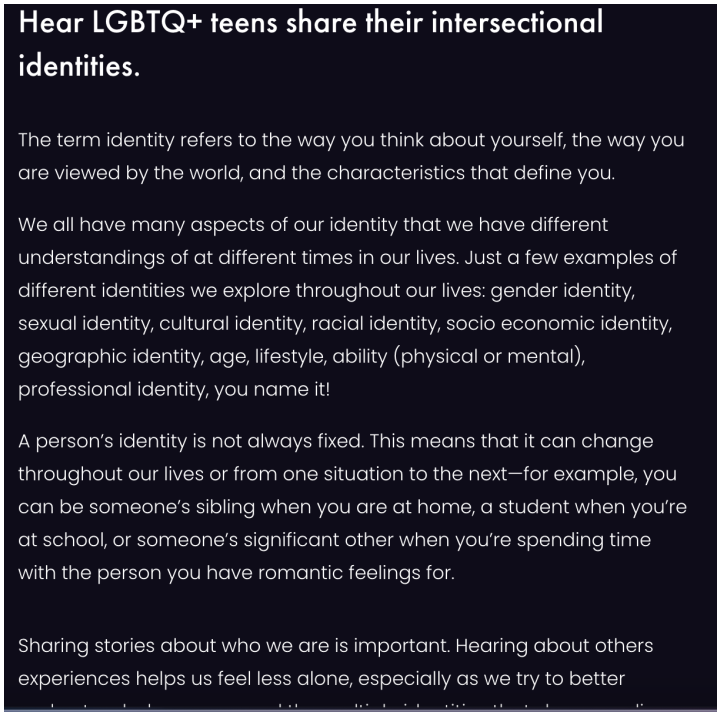
- The **gender** guide allows young people to explore their gender identities and expression through a wide range of activities. For example, one activity uses a chatbot to let users experiment with different names and pronouns that fit their gender identity and to reflect on how they feel using different names.
- The **queerness** guide allows users to reflect on different aspects of their sexual identities as well as to read the stories of other LGBTQ+ young people. For example, in one exercise, the user interacts with a chatbot to explore their own definition of queer through questions like, “What is a quote, picture, book, or other piece of content that embodies and affirms queerness for you?”
- The **stress** guide teaches cognitive and behavioral coping skills through activities, such as a guided breathing exercise, and an activity about how stress shows up in the body.
- The **internalized stigma** guide introduces the concept of internalized stigma and allows users to explore how internalized stigma shows up for them. For example, one activity uses a chatbot to explore positive self-talk to combat internalized stigma.

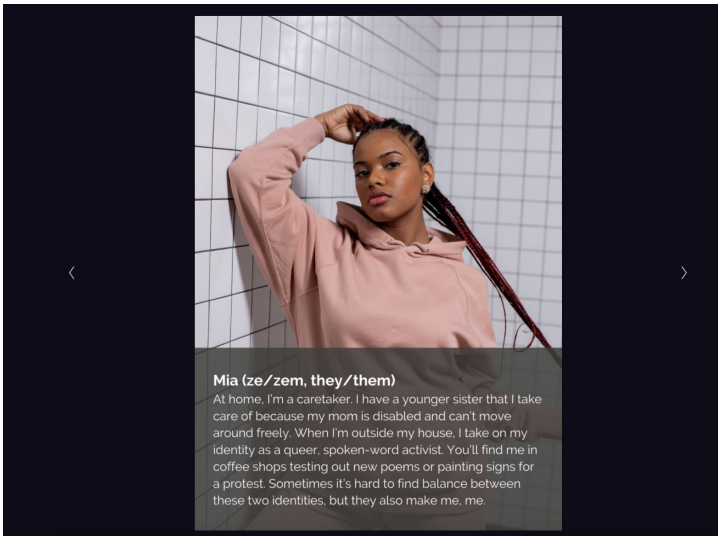
Within each of these four guides, there are exercises and informational resources aimed at:

1.) **Affirming LGBTQ+ identities**. For example, the following exercise, within the gender guide, allows users to experiment with and affirm their LGBTQ+ identities by prompting them to reflect on how wearing various types of clothing helps them experiment with and express their gender identity.

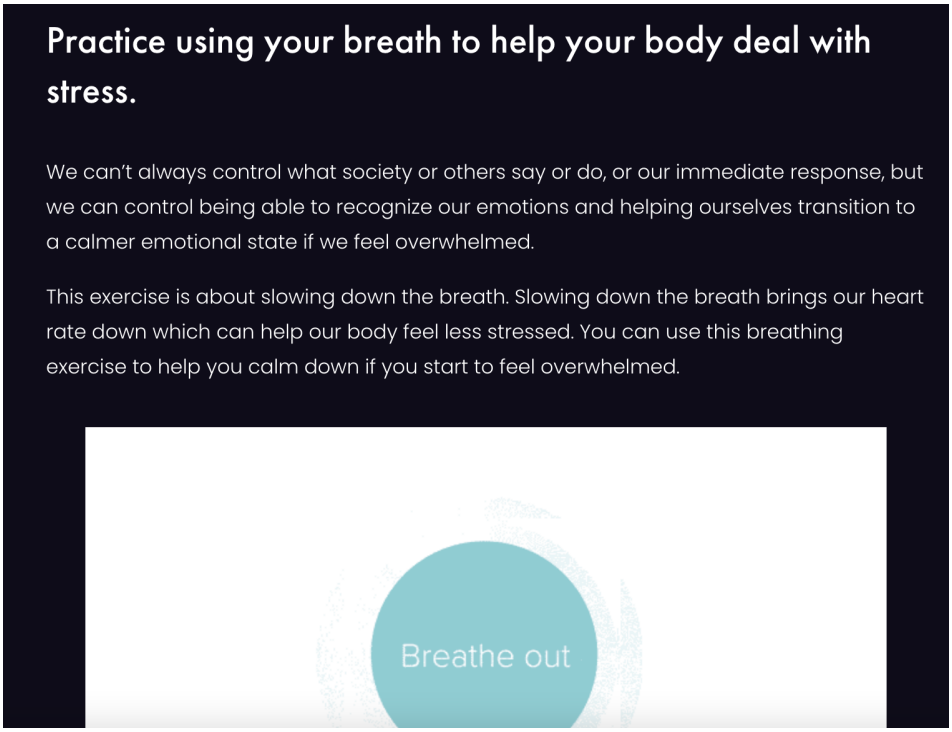


2.) **Promoting connectedness to the LGBTQ+ community.** For example, the product includes quotes and videos in which LGBTQ+ young people discuss their experiences. Below is an activity in the queerness guide that introduces the idea of intersectional identities and allows the user to flip through profiles that tell the stories of other LGBTQ+ teens.





3.) **Teaching cognitive and behavioral coping skills.** For example, the stress guide introduces the following interactive breathing exercise along with a description of why it is helpful.



App navigation

At the top of the screen, users will see a navigation bar with the names of the different guides. The guides also appear as “cards” on the home screen that users can click on. The cards and navigation bar items are labeled with the names of the guides: “Gender,” “Queerness,” “Stress,” “Internalized Stigma.” Additional features of the website include a crisis disclaimer and a link to the footer where crisis resources are listed and a quick exit button on the top right that is accessible in one click.

Strategies to Ensure Sample Diversity: We will reach the population using social media ads on sites including Facebook, Tumblr, Instagram, Reddit, Jack'd, Grindr, and Twitter. Ad targeting within social media sites allows us to specify the age range and other socio-demographic characteristics of individuals who will see the ads based on the information they provide in their online profiles. We will develop ads that promote our target population's interest by including diverse images of youth (i.e., images of different ages, portraying diverse race/ethnicity), as well as using ad-targeting specific to socio-demographic characteristics (e.g., delivering Facebook/Instagram ads only to youth based on their age, race/ethnicity and sex) and interests (e.g., TV shows with LGBT themes). Ads will link interested individuals to the study screener where they may verify their eligibility or email the team if they have additional questions about the study.

Data Collection & Retention: SGMY will click on social media advertisements and be taken to a Qualtrics page containing basic study information and a short description of study activities. ***Screening:*** Interested individuals will be asked to consent to and complete an online screener. We will use this approach as one of our strategies for filtering fraudulent or duplicate entries. Individuals who do not meet the eligibility criteria will be thanked for their interest and automatically routed to the Google page. We will not indicate why they were ineligible to avoid unintentional disclosure and to protect against fraud. ***Consent:*** Individuals who screened eligible and passed initial verification (see SOP-Applicant Verification.pdf) will be sent a link to the study consent form (a waiver of parental consent will be obtained for minor participants). SGMY who do not consent will be taken to a screen thanking them for their interest. ***Baseline & Randomization:*** Those who consent will complete the baseline survey. Study staff will perform a second round of verification once a baseline survey has been completed. Those who pass verification will be randomized 1:1 into the control or experimental condition. ***Registration:*** After randomization, participants will be sent a link to either the control condition website or the intervention web app. Once a participant registers for an account on the website or web app, they will receive their baseline incentive.

Measures to protect against fraud and hacking: We will use best practices to reduce the likelihood of online fraud: (1) Keep compensation sufficiently low (i.e., balance incentives with the effort required from respondents) to reduce the chances of respondents participating solely to gain incentive payments. (2) Cross-check information between the screener and baseline surveys (e.g., compare zip code entered on screener with City and State entered on baseline). This verification process is commonly used in online research and aims to prevent individuals from being enrolled in a study more than once, and to prevent bots from enrolling. (3) Verify IP address location is located in the United States. See "SOP-Applicant Verification.pdf" for detailed procedures.

2. Data Collection:

Not applicable

3. Genetic Testing:

Not applicable

4. Use of Deception:

Not applicable

5. Statistical Analysis:

Descriptive statistics of the psychosocial and demographic characteristics of the participants will be described for all and by intervention group. These will be compared between treatment groups using t-tests or Wilcoxon rank sum tests for continuous variables and chi-square tests for categorical variables.

Main intent-to-treat analyses will compare the experimental to the control group on self-assessed psychosocial outcomes immediately post-intervention, controlling for baseline values on those variables. For each construct (e.g. anxiety, depression, positive/negative emotions), a separate analysis will be used to evaluate the difference in magnitude of change from baseline to the week 4 follow-up assessment as a function of intervention condition (experimental vs control). We will also examine if there is a difference in change over time by examining the interaction of time by condition.

Descriptive statistics of the psychosocial and demographic characteristics of the participants will be described for all and by intervention group. We will also examine participants' web app usage, satisfaction with the web app, and how web app usage and satisfaction correlates with improvements in psychosocial wellbeing. We will report descriptive statistics for web app usage and satisfaction (e.g. means, medians, standard deviations, IQR), and will conduct pearson's or spearman's correlations to explore whether greater engagement with the web app (e.g. indexed by number of pages viewed, time spent in the web app) etc. is positively correlated with improvement in each outcome variable from week 0 to 4 within the experimental group.

In order to adequately power this trial to detect effects that are medium-in-size or larger (Cohen's d > = .50), we plan to recruit 300 participants, and randomly assign them to conditions in a 1:1 fashion. Medium effect sizes are roughly in line with those observed in prior psychosocial interventions for SGM teens and young adults (Craig et al. 2012; Craig et al., 2021; Lucassen et al. 2015; Pachankis et al., 2015). A sample of 300 participants was selected to account for a non-compliance and/or attrition rate of up to 35% of the recruited sample, a rate which is in line with conservative estimates of participant attrition from the trials cited above. This sample size will serve as a buffer to ensure that any participant loss will not undermine the power of the statistical analyses. After accounting for the potential loss to follow-up, a sample size of ~97 participants per group is necessary in order to detect moderately small to medium effect sizes for a two-sample comparison of means.

For all analyses, data will be reported as aggregated groups, and no individual identifying information will be used.

RISK/BENEFIT ASSESSMENT:

1. Risks:

The potential risks to participants are detailed as follows:

Emotional discomfort: This study involves asking questions about sexual and gender identity, one's thoughts and feelings about one's sexual and gender identity, psychosocial well-being, emotional states, and states of depression and anxiety. It is possible, although unlikely, that reflection in response to these psychosocial questions could result in psychological distress. However, the probability and magnitude of harm or discomfort anticipated in the research are not greater, in and of themselves, than those ordinarily encountered in daily life. To mitigate these risks and discomforts, participants will be informed in the

informed consent form that their participation is voluntary and that they can stop the study at any time without penalty. In addition, participants can choose to interact with the web app as much or as little as they want. The primary possible risk is a perception of burden (either in using the web app or completion of the study surveys), which can easily be addressed by withdrawing from the study or discontinuing use of the web app at any time.

Psychological distress is a potential risk to participants during the completion of the surveys and engagement with the experimental content. We will provide participants with contact information for the following crisis hotlines if they experience psychological distress related to participation in the study:

- Trevor Project Lifeline
- Trevor Chat/Trevor Text
- Trans Lifeline
- Crisis Text Line
- National Suicide Prevention Line

All hotlines are available 24 hours a day, 7 days a week.

Unintended disclosure is also a potential risk. Data will be protected by extensive confidentiality procedures as described below. Data will be collected confidentially; this will be fully described in the informed consent. We have extensive data procedures already in place to ensure security of the data and information provided by participants:

- Data will be encrypted at all times, from the point of entry into Qualtrics to the point of backup and to analysis. Data will be encrypted using standardized software (e.g., 256-bit, PGP).
- Data will be de-identified and linked by the Study ID to minimize risk of inadvertent disclosure.
- Data will never be released to non-study staff.
- All electronic data sharing will be done only on the secure server.

Study staff will be trained on confidentiality standards, which will include the following points:

- Always maintain anonymity of the participant data.
- Questionnaires are to be linked using the Study ID number.
- Protect the electronic security of all databases.
- Computers that can access electronic data should be physically secured and should be password-protected
- Only authorized persons are to have access to electronic databases.

Privacy and confidentiality concerns: Participants' confidentiality (names, email addresses, phone numbers) will be protected, but the possibility remains that their information could be lost or stolen or confidentiality could be breached.

Participants will be reminded at the beginning of each survey to consider their surroundings and the privacy of their device and internet connection. All communication between study staff and participants will not include sensitive information that may reveal their participation in a study about SGM or answers to any of the questions answered in the surveys. There is a possibility that participation in this research study could be disclosed in the following ways:

1. If someone besides the participant sees the control website or experimental web app
2. If someone besides the participant sees an email, text message, or direct message via social media sent from the study team and follows a link to the website/web app or a study survey

The risk of disclosure of participation in a research study through receiving study related emails, text messages, direct messages via social media, interacting with the online surveys, or with the intervention on a participant's device will be minimized in the following ways:

1. Participants must enter a password to first gain access to the website or web app
2. After 10 minutes of inactivity, the website will automatically redirect to www.google.com
3. Emails, text messages, and direct messages via social media that include links to study surveys will not contain any reference to the nature of the survey or study
4. Participants will be encouraged to delete any text messages received as part of the study to protect them from an unauthorized individual viewing the messages, and to interact with the study application when in private (e.g., turn on screen lock, complete surveys when alone). Participants will be notified of these risks in the consent process.

2. Benefits:

Participants will be asked about sensitive information, yet adequate protections for internet data collection are in place for this study. The main benefit of the proposed study to society is the development of a potentially feasible and acceptable web app that impacts key psychosocial outcomes among SGMY ages 13-19, such as coping self-efficacy and symptoms of anxiety and depression. Participants in the experimental condition may experience improvements in their adaptive cognitive and behavioral coping skills, psychosocial wellbeing, symptoms of depression and anxiety, and greater life satisfaction. Potential benefits for the research far outweigh the risks for the participants. Others will benefit because the study will result in increased knowledge about tools that may help SGMY affirm their identities and cope with minority stress. Therefore, the risk/benefit ratio is favorable.

3. Subject Privacy:

All study activities occur over the internet, with specific precautions taken to support participants' privacy. To minimize the risk of participants feeling uncomfortable about answering personal questions, we will use self-completed online surveys. Participants will input the answer to the question themselves. This format also allows participants to choose where and when they are comfortable completing study questionnaires.

4. Subject Confidentiality:

To minimize risks to confidentiality, we will secure study data with all appropriate physical, electronic, and operational protections. Data will be stored in a physically secure environment. All data files will have encryption and strong password protection. Any identifiable data will be stored on University of Pennsylvania's secure servers or on fully encrypted laptops.

We will collect email addresses so we can reimburse participants for their time (i.e., study incentives) and for internal auditing purposes. To ensure we have sent participants their incentives, we will keep the email addresses in a password-protected file on a password-protected secure server. In addition, we will use participant email, IP address, browser/operating system, and time taken to complete the surveys to flag potential fraudulent/suspicious entries.

Survey and intervention data files will identify participants using study ID numbers, assigned by study staff, which will be unrelated to the participant's name or email address. We will keep a file containing

contact information (i.e., email) and IP addresses separate from survey data. This file will be password-protected and stored within a restricted folder on a secure server. The reason for keeping this personal information is solely administrative (i.e., to ensure that we keep a record of incentive payments, and to verify that fraudulent data collection does not occur (e.g., individuals may seek to falsify information on the web survey in hopes of receiving an incentive more than once).

Online surveys and eligibility screening will take place on an encrypted commercial survey website, Qualtrics. This site has been used by the investigators for numerous online surveys with SGMY with no data security breaches. Access to data will be on a role-based standard; only those study staff who require access to each type of data to complete their study-related roles will be allowed access. All study staff will be trained in security and confidentiality procedures, and will sign a confidentiality agreement before receiving access to any participant data. No participant names or other identifying information appear on data documents or in data files as the contact information will be stored separately. Only designated staff will have access to the data.

All web survey data will be secured using SSL 256-bit encryption. SSL encryption is the standard for all web-based transactions that include any identifiable information, including names, addresses, and credit card numbers.

Participant contact information (name, email address, and phone number) will be destroyed at the end of the study, and will never be associated with the study data collected.

5. Protected Health Information

The following PHI will be collected in this study:

- First name
- City, State, zip code, and equivalent geocodes
- Birth month and year
- Telephone numbers
- Electronic mail addresses
- Internet IP addresses

6. Compensation:

Participants will receive $30 for the baseline survey and $40 for completion of the follow-up survey. This compensation is small enough to avoid undue influence, yet sufficiently substantial to compensate for time and effort, and promote retention.

All compensation and incentives will be paid as Amazon.comdigital gift cards. Payment for the baseline survey will be sent once participants have completed the survey and have registered for an account within their respective arm of the intervention. The incentive for the follow-up survey will be sent after the participant completes the associated survey.

7. Data and Safety Monitoring:

The Principal Investigator will provide oversight of all study procedures and quality assurance checks. The data safety and monitoring plan includes the following protocols:

- Electronic files and records will be stored in a firewalled, encrypted server at the University; only research staff will have access to this directory. To ensure participants' safety as well as the data's validity and integrity, only staff with extensive experience in studies with SGMY youth will be hired.
- All staff will have signed a confidentiality agreement. We have several mechanisms to ensure the security and integrity of the data. The intervention content, questionnaires, and personal information will be secured with role-based security that will provide different types of users with different access privileges.
- Survey data and web app data will be located on unique servers. Survey data and web app data will be linked using a unique Study ID.
- All study personnel will have completed the Human Subject Training established by the CITI program. In addition, in compliance with the NIH policy, University graduate students and staff will participate in at least 8 hours of mandatory case study and discussions regarding scientific integrity and human subjects. Any additional personnel who may join the project will complete this training before they handle any subject data.
- All research staff will be trained to recognize and document any unusual events or circumstances that occur during the study. Staff will be trained to immediately report any adverse events to the Principal Investigator and the University IRB.
- The Principal Investigator and Project Director will monitor staff closely. Staff deficient in any aspect of performance will be re-trained, closely monitored for proficiency, and if not adhering to established protocols and procedures, will be terminated.
- The Principal Investigator will be responsible for dissemination of study findings through presentations and publications. The Principal Investigator will also be solely responsible for handling any requests from other investigators to examine the data collected during this study.

8. Investigator's Risk/Benefit Assessment:

No more than minimal risk: The risks to research participants enumerated above are reasonable in relation to the anticipated increase in knowledge about LGBTQ+ identity and adaptive cognitive and behavioral coping skills. Our study is expected to result in a benefit to society since it will provide a basis of knowledge on the efficacy of a web app for improving key psychosocial outcomes among SGMY, such as coping self-efficacy and symptoms of anxiety and depression. Thus, the unlikely risks entailed by participation in this study are offset by its potential benefits.

INFORMED CONSENT:

1. Consent Process:

Informed consent will consist of an electronic document displayed to participants as a Qualtrics survey. The consent form is written in English and outlines the voluntary nature of the study, participant's freedom to discontinue the survey at any time, the nature of the study, study procedures, the kinds of information to be collected, the duration of the study, the principal investigator's contact information, instructions to reach out with any questions that may arise during the study, approval to retain email addresses to send incentives, and the procedures to guarantee their confidentiality. Currently, our consent has a literacy level of 8th grade (tested with the Coleman Liau index), which we believe makes it accessible for all ages, including 13-19 year-olds.

To encourage participants to read and understand the information provided in the Informed Consent, they will be asked after each consent form section to confirm they have read, understood, and agree to the terms before they can proceed to the next section.

A waiver of written documentation of consent is being requested of the IRB. Finally, we recognize that consent is an ongoing process. Participants will have access to the consent form at all times, as a copy will be available in the web app. If a participant wishes to end their participation in the study, they are given instructions in the web app to contact the study staff via phone or email.

2. Waiver of Informed Consent:

This study will require assent from minor participants, but will not require consent from parents or guardians. The content of the website intervention involves sensitive information related to gender and sexuality. In addition, to participate, youth and young adults must identify as a sexual or gender minority, and some youth may not have yet disclosed this information to their parents or guardians. If the IRB required parental consent, it would bias the sample to include only participants whose parents know their true gender identity and sexual orientation.

We will request that the UPenn IRB grant a waiver of parental consent to participate in this research study for youth participants who are 13 to 17 years of age. The research team has been granted waivers of parental permission for prior studies with sexual minority youth. Under 45 CFR 46.408 (c), an IRB has the authority to waive parental permission if it determines that "a research protocol is designed for conditions or a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects" and "an appropriate mechanism for protecting the children who will participate as research subjects is substituted" and "that the waiver is not inconsistent with Federal, State, or local law."

A waiver of parental permission for studies with lesbian, gay, bisexual, transgender, and queer (LGBTQ) youth that do not involve greater than minimal risk is a common practice among researchers working in the area of gay and lesbian health/mental health. This is done to avoid the selection biases operating in only recruiting youth whose parents are both aware of and comfortable with their sexual orientation. Commonly these youth have explored their sexual orientation without their parents' knowledge as the youth struggle with issues of disclosure and its consequences within the social, religious, and economic context of their families. A requirement for parental permission in this type of study could not only affect a person's willingness to participate, but could also potentially impact the ability of researchers to engage in this type of research with sexual minority youth.

If the purpose of requiring parental permission as stated in CFR is to protect the minor subject, then requiring parental permission for youth in these circumstances is not a reasonable requirement. Additional privacy protections are provided in that all assessments, notes, reports, and other records will be identified by only a coded number to maintain participant confidentiality. These records and any forms that do contain identifying information will be kept in a password-protected file on a secure server.

RESOURCES NECESSARY FOR HUMAN RESEARCH PROTECTION:

Because the aim of the study is to test the effectiveness of a web app designed for teenagers and young adults, we will take every available step to minimize the risk of identifying/linking data being subpoenaed, stolen, or inadvertently released. First, all research staff members are required to complete ethical clearance certification regarding protection of human's subjects through their IRB. Second, this study will have documented procedures to safeguard against the risk of the linking information being stolen by

keeping such information in password-protected files on secure servers. Only essential study personnel who have completed CITI certification for human subjects research ethics training (http://citiprogram.org) will have access to participant data.