Study title: Randomized Controlled Trial (RCT) of StriveWeekly for Anxiety and Depression Prevention for College Students During COVID-19

NCT #:NCT04927845

Document date: 11/15/2023

Protocol #IRB20-1337 approved by Harvard Institutional Review Board on 11/15/2023

## RESEARCHER INFORMATION

| | |
|---|---|
| Principal Investigator Name | Leslie Rith-Najarian |
| Affiliation (check all that apply) | ☐Faculty<br>☐Graduate Student<br>☐Post-Doc<br>☐Undergraduate<br>☐Extension School Student<br>☐Staff<br>☐Visiting Scholar<br>☒Other (specify): Lecturer, Assistant Dean to Harvard College |
| Faculty Sponsor (if PI is not PI Eligible) | Katie McLaughlin |
| Other Advisor Name (if applicable) | |

## STUDY INFORMATION

| | |
|---|---|
| Study Title | Randomized Controlled Trial of StriveWeekly during COVID-19 |
| ESTR Number | IRB20-1337 |
| Version Number | 12 |
| Is this a re-submission of a previous Harvard IRB-approved study that has been closed? | ☐Yes - Include previous IRB submission # here:<br>☒No |

## 1. FUNDING INFORMATION

**1.1 Is your study funded (either directly or through a sub-award) by a Federal Agency (i.e., HHS, NIH, NSF, DOD, DOE, DOJ, or EPA, etc.)?**

☐Yes
☒No

**1.2 Specifically, is your study funded (or will it be) by the National Institutes of Health (NIH)?**

☐Yes
☒No

**1.3 Does your study meet the definition of a "Clinical Trial" (see below)?**

☒Yes
☐No

HHS and NIH define a **clinical trial** as "a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes."

If your study meets the definition of a **clinical trial**, there are additional requirements that you must follow. Ask your assigned IRB Reviewer or see the HUA IRB website for more information.

## 2. RESEARCH COLLABORATIONS AND LOCATIONS

## LOCATIONS

*Locations refer to the geographic location where the research will take place, not to the people or institutions that you may be collaborating with. Knowing the location helps the IRB determine the local context of the research as well as if there are additional laws, regulations, and policies researchers need to adhere to. If conducting online studies, please indicate the location of the researcher who is hosting.*

**2.1 Where will this study take place?**

☒Harvard University
☐At another location in Massachusetts
☐In another US state ***(see below)***
☐Internationally ***(see below)***

***If you chose "in another US state" or "Internationally" describe the laws that will need to be considered:***

Technically, students can participate remotely from any location in the world

***Please ensure that what you have marked above matches what has been indicated in the ESTR SmartForm, section "Research Locations."***

**2.2 Are there any U.S. state laws, international laws, or other laws that the IRB will need to consider when reviewing this study?**

☒Yes ***(see below)***
☐No

***If "Yes" describe the laws that will need to be considered:***

See items in Section 10 regarding Waiver of Parental Consent

**2.3 Thinking about the locations where this study will take place, are there any permissions that must be obtained from cooperating institutions, community leaders, government officials? *This may include a review by a local ethics board, school district, Ministry of Health, or other institutional approval process, whether domestic or international. A statement that formal review is not required along with your source of information that the proposed research is in accordance with local laws, regulations, and customs is also acceptable.***

☒Yes ***(see below)***
☐No

***If "Yes" describe and if available, upload any permission documents to the ESTR SmartForm section "Local Site Documents."***

The corresponding Memorandum of Understanding with the Dean of Students Office has been upload to ESTR.

**2.4 Are there any community or cultural differences for the local population of participants that require consideration? *For example, cultural or gender dynamics or social structure considerations.***

☐Yes ***(see below)***
☒No

***If "Yes" describe:***

## COLLABORATIONS/SITES

*Collaborations, known as "sites" in ESTR, refer to people or institutions that are also taking part in the research study. An important part of knowing about these collaborations is knowing what each person/institution is doing in the research in order to determine the scope of IRB review.*

**2.5 Will you be collaborating with any researchers not affiliated with Harvard University Area to carry out this study? *HMS, HSPH, and HSDM are not part of Harvard University Area.***

☒Yes
☐No ***(skip to next section)***

**2.6 Will the actions of these collaborators include any of the following: Have contact with human subjects; Have access to data that is identifiable; OR Are responsible for the design, conduct, or reporting of the research?**

☒Yes
☐No ***(skip to next section)***

**2.7 Will these collaborators receive their own IRB review?**

☐Yes, all will receive their own IRB review (skip to next section)
☒No, none will receive their own IRB review
☐Some will receive their own IRB review and some will not

**2.8 Is another institution and/or researcher requesting that the Harvard University Area IRB act as the IRB of record ("Reviewing IRB") for that institution's or that researcher's activities on the study?**

☒Yes ***(Complete the HRP-220: Non-Harvard Personnel Form and attach to the ESTR SmartForm Section "Study Team Members" item 2. Note that those who are considered "volunteers" and are working under the auspice of Harvard University Area will also need to be included in HRP-220)***
☐No ***(see below)***

***If you chose "No" describe the compliance/ethical oversight that this researcher will have in place:***

# 3. STUDY TEAM QUALIFICATIONS AND TRAINING

**3.1 Describe the Principal Investigator's experience with the proposed research procedures, population, and local context.**

**Leslie Rith-Najarian, Ph.D.** is a lecturer and in the Department of Psychology and a research collaborator with Dr. McLaughlin. Dr. Rith-Najarian has expertise in intervention development, multi-stage intervention implementation research, and clinical trials, particularly for stress-related mental health problems. She received her doctorate in Clinical Psychology at the University of California Los Angeles, where her dissertation research included an open trial feasibility study and a randomized controlled trial of the StriveWeekly intervention. Dr Rith-Najarian was the principal investigator on

both those trial studies, supervising a team of research assistants. Dr. Rith-Najarian also completed her clinical internship at a university counseling center, and thus has both clinical and research experience working with university student populations.

**3.2 Describe how the study staff are trained to ensure that they are adequately informed about this study and study-related duties.**

Kevin Shani was a hired Graduate Assistant for this research study. He has experience with college residential life work, research dataset management, and clinical trial methods. Mr Shani has supervision meetings with Dr. Rith-Najarian once a week. Dr. McLaughlin will serve as a back-up contact for students with concerns about Dr. Rith-Najarian's potential conflict of interest.

Starting in 2022, Shayna Greenberg is taking over the Graduate Assistant role for this research study. She is a current doctoral student at Loma Linda University and advised by Maya Boustani, PhD. She has significant experience with research design, intervention delivery, data collection and management, as well as analysis. She will complete training to support study protocol and have weekly supervision meetings with Dr. Rith-Najarian. Shayna is serving as a volunteer study staff in a Harvard POI role, as opposed to representing Loma Linda University as a collaborator site.

Saul Urbina-Johanson is a residential proctor at Harvard College. Because staff in Residential Life attended presentations by the Dean of Students Office about this study, SJ is already informed about the purpose and design of the study. SJ has much experience working with undergraduate students, and will be trained to conduct the feedback interviews under the supervision of the PI.

**3.3 Are there any other additional study staff whose role in this study requires special qualifications in addition to ethics training (e.g., licensed clinical psychologist, phlebotomist, etc.)?**

☐Yes ***(see below)***
☒No

***If "Yes" describe:***

## 4. RESEARCH PURPOSE

**4.1 Provide a brief, non-technical description of the purpose of the research, including the research questions that you hope to answer.**

We aim to evaluate the effectiveness of StriveWeekly in preventing symptoms of anxiety and depression within a remote campus learning environment. The use of a waitlist condition will allow us to experimentally assess if the online intervention is responsible for decreasing / preventing worsened anxiety, depression, and stress symptoms over time. Given the previously established effectiveness of StriveWeekly as a universal prevention program, we expect students in the intervention condition to experience significantly better symptoms compared to the waitlist from baseline to posttest. Alternatively, if the remote campus learning environment and/or the broad pandemic context interferes with the acceptability or effectiveness of StriveWeekly, then we would expect to see no significant differences between the online intervention condition and waitlist condition from baseline to posttest. The results of this project are intended to contribute to generalizable, and publishable knowledge in the field.

Secondary aims include: (a) testing moderators of intervention effectiveness and (b) evaluating the intervention in terms of acceptability (e.g., feedback on program name; demographically representativeness of student user sample; satisfactory adherence and satisfaction rates). Exploratory moderation analyses across groups will help determine whether or not the intervention condition produces unique or additive effects for students with certain characteristics over and above changes demonstrated by similar students in the waitlist condition. Acceptability analyses will allow for more nuanced evaluation of StriveWeekly's effectiveness as a program, beyond its ability to facilitate symptom reduction. Secondary analyses and follow up interviews with diverse subsamples of students will help to assess generalizability of StriveWeekly outcomes, determine acceptability among underserved populations, and inform future research.

**4.2 Describe the scientific background, rationale for the study, and importance of this research in adding to existing knowledge.**

The burgeoning rise in higher education enrollment continues (Hussar et al., 2020), as young people seek opportunities to further learn, grow, and ultimately increase their chances of a rewarding career, or at least financial security. Although campuses are a place of intellectual pursuit, they are unfortunately also increasingly described as experiencing a "mental health crisis" (Xiao et al., 2017). If campuses are to fully support students, they need to offer effective mental health programming. The ideal mental health services are those that could be offered broadly on campus without further adding to the high demand on counseling centers (Xiao et al., 2017). Given that anxiety and depression are the most commonly reported mental health concerns by students in the United States (American College Health Association, 2020) and internationally (Auerbach et al., 2018), offering universal prevention programming for these concerns can target a large portion of the student population.

In contrast to face-to-face mental health services, online prevention programs offer several benefits for university students, including: convenience of time/location, privacy, ability to be self-reliant, and fewer stigma concerns (Kauer, Mangan, & Sanci, 2014). Reviews have identified many online programs that effectively improve anxiety, depression, and/or stress outcomes through randomized controlled trials with university students (Davies et al., 2014; Farrer et al., 2013; Rith-Najarian, Boustani, et al., 2019), further supporting their promise for dissemination on campuses. Despite online interventions' accessibility, evidenced effectiveness, and potential for large-scale service capacity, most programs tested with university students are of modest scale (i.e., tested with < 200 students; Rith-Najarian, Boustani, et al., 2019). Thus, it is importance to offer students online mental health programming that not only has research evidence to support its effectiveness but also its capacity to serve a large number of students.

StriveWeekly has demonstrated broadscale reach and effectiveness in reducing symptoms of anxiety and depression. In earlier implementation studies at the University of California – Los Angeles and at Yale University, StriveWeekly was found to reach hundreds of students with no prior mental health service use (e.g., therapy, psychiatric medication meditation groups, peer counseling; Rith-Najarian, Sun, et al., 2019). Moreover, students from traditionally underserved demographics groups (Asian- and Hispanic/Latinx-identified students) were proportionally represented (Rith-Najarian, Sun, et al., 2019). In a randomized controlled trial of StriveWeekly (ClinicalTrials.gov: NCT04361045), results showed that students assigned to the online intervention experienced small but significant improvements in total symptoms of depression, anxiety, and stress (d = 0.25). For students with high baseline motivation for change, intervention effects were even larger (d = 0.57). Moreover, symptom improvements were maintained at 3-month follow-up. The quality of the online platform and program content was rated as "good" or "excellent" by 72% of respondents. Only 59% of students initiated using the intervention, but of those students who did the average number of modules with logged skills practice activity was 3.72 (of 8 total).

With the COVID-19 pandemic completely altering the landscape of higher education, students are experiencing more stress than ever. While there has been a full return to in-person instruction for the 2021-2022 academic year, students are still navigating travel restrictions, isolation protocols, and social distancing. Thus, offering an online mental health program such as StriveWeekly will provide students with stress management support regardless of where they are. However, the online intervention's effectiveness has not been tested in the midst of a pandemic or after a remote learning setting. Additionally, the extant literature is limited in the ability to determine to what extent adaptations to therapeutic tools are needed to meet the psychological needs of Sexual and Gender Minority (SGM) individuals. Therefore, in addition to offering StriveWeekly as a service to students, a research trial will be conducted to evaluate the program's effectiveness in addressing anxiety and depression symptoms within this broader unprecedented context. Targeted analyses and follow-up interviews conducted with historically underserved sexual and gender minority students will additionally help support generalizability of StriveWeekly. The results of this trial will support evidence of the effectiveness of offering such online mental health interventions to university students, even when a campus is experiencing unique stressors.

## 5. STUDY PROCEDURES

**5.1 Provide a complete overview of the study:**

- **Describe the procedures participants will be asked to complete or undergo.**
- **Explain step by step what participants will be asked to do**
- **Include how long the procedures will take.**

***If your study includes multiple variations of the procedures, please make clear which procedures are included in the variations.***

**Recruitment.** Recruitment materials will be distributed via a mass email to all enrolled students from the Dean of Students Office (DSO), announcements over house emails lists (e.g., academic departments), and social media announcements.

**Pre-trial needs assessment and pilot.** Prior to the full RCT, we will conduct a campus-wide needs assessment survey to gather information about student needs and preferences related to mental health programming. Student responses will inform the specifics of StriveWeekly implementation during the academic year (e.g., preferred timing of programming, appropriateness of content across a diverse student population). After the needs assessment, we will invite a small group of students to participate in a small pilot of the revised StriveWeekly platform. Students who participate in the pilot will be invited to provide their program feedback via online surveys. Students who participate in the pilot data collection will still be eligible for the full RCT study, but may be excluded from the final data analysis sample.

**Pragmatic trial design.** For an RCT of a self-guided online intervention, it is important that the design mimics intended intervention use (Fleming et al., 2018). As examples, overly stringent inclusion criteria limit generalizability, or face-to-face assessments may provide added benefit beyond the intervention itself (Fleming et al., 2018). Therefore, as much as possible our methods simulate how a real-world campus might offer online services as usual. First, we are employing cluster randomization, for reasons elaborated below. Second, participants in either condition will be allowed to access other on- or off-campus mental health services and resources; in our statistical analyses we will control for service use rather than excluding such students. Third, all data collection and participant communications will be electronic rather than in-person to: (a) include all students remote or on-campus, (b) avoid unintentionally bolstering motivation (e.g., inducing social desirability to please researchers), and (c) avoid adding barriers (e.g., time demands, concerns about privacy). Finally, survey compensation

amount will be modest enough to increase participant response rates without artificially inflating adherence rates or self-reported improvement due to financial incentive.

**Random assignment.** Cluster randomization will be used to assign students according to their residential affiliation to the **immediate intervention condition** or the **waitlist condition** (i.e., delayed access). This randomization plan has been discussed with the Dean of Students Office and was preferred over a fully randomized assignment of students. Although cluster randomization can introduce statistical confounds for analyzing intervention outcomes at the individual participant level, they can be preferred: (a) to avoid intervention "contamination" effects (e.g., if participants in both conditions can regularly interact and thus might exchange health-related knowledge), and (b) if it allows the intervention to be delivered as it would be in real practice (Cook, Delong, Murray, Vollmer, & Heagerty, 2016). Moreover, the benefits of cluster randomization by residential house/dorm affiliation for this trial are crucial for the social aspects of the StriveWeekly program. For example, students will know who else is concurrently participating in the program (e.g., any of their friends in X, Y, Z house), allowing for peer-to-peer engagement. Also, this will allow for easier coordination of any optional complementary programming by residential staff at each house/dorm. A randomizer was already used to assign half the freshmen and upperclassman residential buildings to each condition:

| Immediate StriveWeekly Access | Delayed StriveWeekly Access |
|---|---|
| **Houses:** Adams, Cabot, Currier, Dudley, Mather, Quincy, Winthrop<br><br>**Freshmen:** Ivy Yard, Elm Yard | **Houses:** Dunster, Eliot, Kirkland, Leverett, Lowell, Pforzheimer<br><br>**Freshmen:** Crimson Yard, Oak Yard, Maple Yard |

**Data collection.** Prior to beginning any research procedures, students will provide their informed consent online via Qualtrics. Participants will be required to login to Qualtrics via HarvardKey Shibboleth, which will be configured to only allow currently active Harvard accounts. Once consent has been obtained for an individual student, they will be directed to an online survey for the study **baseline assessment**. The baseline survey will be open for two weeks. Students assigned to the intervention group will receive an access code in the email, allowing them to access the online platform and set-up their account. The intervention group will then be active for seven weeks, after which the **posttest survey** will open to the intervention group and waitlist group for one-two weeks. There will then be a pause in study activity and data collection from mid-November through winter break. Thereafter, there will be a **2-month follow-up survey** and students who were assigned to the waitlist group will gain access to the online intervention for seven weeks. After this delayed access group completes the intervention, there will be a **5-month follow-up survey** for all participants from both conditions. After the fourth survey, subsets of participants may be invited to additional compensated opportunities to provide further feedback as research data. See timeline table below.

| Activity | Timeline |
|---|---|
| Promotion | August 16 – Sept 6 |
| Recruitment + Baseline Survey | Sept 7 – Sept 17 |
| First Intervention Round | Sept 20 – Nov 7 |
| •Weekly goal-setting & Time management | Sept 20 - 26 |
| •Unhelpful thinking habits | Sept 27 - Oct 3 |
| •Quality time on values & fun | Oct 4 - Oct 10 |
| •Relaxation strategies & Mindfulness | Oct 11 - Oct 17 |
| •Sleep hygiene | Oct 18 - Oct 24 |
| •Physical exercise | Oct 25 - Oct 31 |

| | |
|---|---|
| •Wrap-up | Nov 1 - Nov 7 |
| Posttest Survey | Nov 8 – Nov 19 |
| Break | |
| 2-month Follow-up Survey | Jan 24 - Feb 4 |
| Second Intervention Round | Feb 7 – Apr 3 |
| •Weekly goal-setting & Time management | Feb 7 - Feb 13 |
| •Unhelpful thinking habits | Feb 14 - Feb 20 |
| •Quality time on values & fun | Feb 21 - Feb 27 |
| •Relaxation strategies & Mindfulness | Feb 28 - Mar 6 |
| •Sleep hygiene | Mar 7 - Mar 13 |
| Spring break | Mar 14 – Mar 20 |
| •Physical exercise | Mar 21 - Mar 27 |
| •Wrap-up | Mar 28 - Apr 3 |
| 5-month Follow-up Survey | Apr 4 - 15 |
| Additional feedback from subgroups TBD | April - May 2022 |

**Conditions**

**Intervention group.** When participants first access the platform (app.striveweekly.com) they are self-guided through an account set-up process. Then they customize their settings for timing and frequency of weekly reminder emails. Finally, the user engages in goal-setting, which includes selection of a program goals (e.g., mood management, anxiety reduction) and motivational enhancement strategies (e.g., writing reasons that this goal was important to them). The intervention program is then seven weeks long, including an introduction week module, five skills modules, and a maintenance planning module. Details of module contents are presented in below:

| Module | Strategies/Skills | Example activities |
|---|---|---|
| 1. Getting Set Up | Rationale and expectations<br>Self-monitoring prep<br>Time management | Watch the welcome video<br>Check out the "Progress" dashboard<br>Set SMART goals |
| 2. Reframe | Cognitive monitoring<br>Cognitive distortions<br>Cognitive restructuring | Identify any unhelpful thinking habits<br>Identify evidence for and against thoughts<br>Shift your attention |
| 3. Engage | Behavioral activation<br>Activity scheduling | Spend time on a hobby<br>Clean and organize<br>Good deeds |
| 4. Pause | Mindfulness<br>Relaxation | Deep breathing<br>Progressive muscle relaxation<br>Meditate mindfully |
| 5. Recharge | Sleep hygiene | Do relaxing activities pre-sleep<br>Make a worry list and set it aside |
| 6. Move | Physical exercise<br>Sleep hygiene | Try a new sport, fitness activity, or class<br>Spend time outdoors<br>Walk instead of ride |
| 7. Looking Ahead | Maintenance planning | Review progress<br>Print out copies of favorite materials |

. Plan for triggers

Every Monday participants receive an email directing them to the instructions section of the online platform. Each module presents a checklist of activities for participants to complete as well as tips and suggestions for how to practice each module's skill. At the beginning of the week, participants make a "plan" indicating which activities/skills they intended to try and any barriers they expected to encounter. Throughout the week, participants can visit their user dashboard to log skills practice for the current module (within a seven-day grace period) along with ratings of their mood and stress levels, which are plotted in their self-monitoring graph. NOTE: Students do not complete any of the activities within the app (e.g., users do not record their unhelpful thinking habits during week 3), but rather they submit a log after practicing a skill outside of the app. At the end of each module participants are prompted to complete weekly check-in questions about their personal goal progress. Weekly prize drawings (items of $10-40 value) will be offered to all participants submitting a weekly check-in. Students who had log activity for all modules will be eligible for the completer prize drawing (items of $100-200 value).

There is also a "Campus" section of their dashboard that provides students with: info about relevant campus resources; a notification center with campus-specific messages and updates; and an anonymous livestream of all campus users' activity, to provide a sense of community. See screenshots of the online platform in the **Supplemental Materials** uploaded.

Finally, residential staff will be encouraged to offer complimentary programming (e.g., relevant themed study breaks), if they are so interested in doing so. These events will not involve any data collection, but the PI will contact residential staff (through approved coordination with the Dean of Students office) to document which houses/dorms held additional events, so that such information can be treated as a covariate in data analyses.

**Waitlist group.** Participants in this group will receive no intervention or communications between their baseline randomization and the invitation for posttest survey. They will be provided access to the online program after completing the posttest survey.

***The below sections contain additional questions depending on the type of research that you are conducting and is meant to supplement the study overview. Please complete each section, as applicable.***

## SURVEYS/ QUESTIONNAIRES/PSYCHOMETRIC TESTING

*Skip this section if not applicable.*

**5.2 List the names of all surveys/questionnaires/psychometric tests to be used in this study and a description of any that are not standard/formally named (such as study-specific questionnaires).**

See full details in uploaded measure battery.

1. **Self-report demographic questionnaire** (age, gender, ethnicity, academic year).
2. **Branding feedback.** There will be a few questions about if students would have been more or less likely to sign-up for the program had it been under a different name (e.g. "The Happiness Challenge")
3. **Treatment Motivation Questionnaire (TMQ).** Questions from the Treatment Motivation Questionnaire (Ryan, Plant, & O'Malley, 1995) have been minimally adapted to apply to an online mental health promotion program instead of a treatment. Questions from the help-

seeking subscale were removed. This 20-question measure will assess participants' reasons for signing up and expectations for completing the program. The TMQ has significant predicted intervention completion in other research studies, for example in-person alcohol treatment (Ryan et al., 1995) and online trauma treatment (Alfonsson et al., 2016).

4. **Depression Anxiety and Stress Scale.** The primary symptom outcome measure will be the 21-item version of the Depression Anxiety and Stress Scale (DASS-21), which assesses self-reported symptoms related to depression, anxiety, and stress. The DASS-21 has demonstrated high internal consistency (.83 - .90) and good construct validity in university student samples (Norton, 2007). Note: There are no questions related to suicidality.

5. **Perceived Stress Scale**. This measure is a 10-item scale that is the most widely used psychological instrument for measuring the perception of stress. It is a measure of the degree to which situations in one's life are appraised as stressful. Items were designed to tap how unpredictable, uncontrollable, and overloaded respondents find their lives.

6. **Self-reported service use**. Students will be asked to indicate past and current use of health-related services on- and off-campus using a checklist of common resources/services (e.g., off-campus therapy, psychiatry at HUHS, etc.) as well as a write-in "other" option.

7. **Technology use.** Students will be asked to indicate the types of devices they use, their internet access, health data settings, etc.

8. **Checklists / weekly hour estimates of extracurriculars and regular behaviors.** See uploaded battery.

9. **Life Events Checklist.** Items combined from the following standardized measures: Life Events Scale for Children, Adolescent Perceived Events Scale, and Life Events Checklist for DSM-5 (LEC-5). Some original items added, including COVID-19-related items.

10. **General Belongingness Scale.** A standardized 12-item measure to assess a sense of general belongingness, which has been previously validated in student samples.

***Pilot / Posttest / Follow-Up Survey Only***

11. **Program satisfaction.** The posttest and follow-up surveys will include questions about experiences with the program for the respective group that just completed the intervention. This 5-item measure is adapted from the Client Satisfaction Questionnaire (Larsen, Attkisson, Hargreaves, & Nguyen, 1979), which has been found to be an appropriate measure of satisfaction with high internal consistency and concurrent validity across a broad range of intervention contexts (e.g., children's outpatient mental health services, Copeland, Koeske, & Greeno, 2004; adult outpatient setting, De Wilde & Hendriks, 2005; adult residential treatment setting, Kelly et al., 2018).
12. **Module preferences.** Students will be asked to rank the modules in order of the most to least favorite.
13. **Open-ended feedback.** There will be an open text field for participants to write any feedback they had about their experience.
14. **Tech-based intervention barrier scale.** A 10-item self-report scale to assess barriers experienced by users of tech-based interventions (Ramos, Hammons, Chavira, & Rith-Najarian, 2019)

**Follow-Up Interview**

15. **Study-specific semi-structured interview**. A subsample of students will be asked a series of open-ended questions to gather feedback about their experience with StriveWeekly and invite proposed adaptions to improve acceptability, feasibility, and engagement for a targeted sample of students endorsing identification with the LGBTQ+ community.

**5.3 How often will participants be asked to complete the surveys/questionnaires/psychometric tests and how long will it take to complete?**

- Baseline survey (approximately 10 minutes)
- Posttest survey (approximately 3-5 minutes)
- follow-up survey (approximately 3-5 minutes)

**5.4 Will you be using any survey software (such as Qualtrics)?**

☒Yes (see question below)
☐No

***If "Yes" which survey software will you be using? :***

Harvard Qualtrics

## INTERVIEWS/ORAL HISTORY/FOCUS GROUPS

*Skip this section if not applicable.*

**5.5 Explain where interviews/focus groups will take place (including possible online venues such as Skype, online chat rooms, etc.)**

Individual, semi-structured interviews will be conducted with a subset of consenting participants via Zoom for Harvard when follow-up surveys have been completed.

**5.6 Describe any steps you will take to protect the participant's privacy during the interview/focus group.**

Interviews will be conducted via Zoom for Harvard. Consenting students will be emailed a unique passcode and assigned participant ID to utilize as an identifier in the teleconference. Access to the meeting room will require entry of the passcode and will be manually managed by the research assistant via use of waiting rooms. Meetings will be audio-recorded and recordings will be stored on the encrypted Harvard Zoom cloud and as password-protected files on the PI's O365 Harvard OneDrive, such that research data will be accessible only to the research team while logged into Harvard's network via Cisco VPN. All recordings will be deleted after they have been transcribed and analyzed. Participants will be informed about the data collection, transfer, and storage process during the electronic consent procedure.

**5.7 Describe the number of interviews/focus group sessions you anticipate for each participant and approximately how long you expect each interview/focus group to last.**

At the time the email invitation for the fourth survey is sent to participants, it will also include an invitation to sign-up for optional interviews. The opportunity to participate in a paid individual interview will be offered to all participants in the study sample. Eligible students are those who (a) used the StriveWeekly platform at least once, (b) completed all study surveys, and (c) either identify as LGBTQ+ or want to provide feedback about program inclusivity for this community. Each student will participate in a single interview lasting approximately 30 to 60 minutes. It is anticipated that approximately 20 to 30 individual interviews will be conducted to achieve saturation.

**5.8 Do you plan to quote the remarks of participants in your study?**

☒ Yes (*Refer to the consent template that you will be using for additional text to include.)*
☐ No

## OBSERVATIONAL/ETHNOGRAPHIC RESEARCH

*Skip this section if not applicable.*

**5.9 If you will be actively participating in the field (as in participant-observation), describe what this will entail.**

**5.10 Describe what and who will be observed and in what settings (such as public events, religious ceremonies, household activities, work meetings, internet chat-rooms and social media sites, etc.)**

**5.11 Will any observational data be considered private, according to the standards of that community?**

☐Yes ***(see below)***
☐No

***If "Yes" describe the information that would be private.***

**5.12 Will the data you collect contain any information that identifies specific individuals?**

☐Yes
☐No

**5.13 Do you plan to quote the remarks of participants in your study?**

☐Yes (*Refer to the consent template that you will be using for additional text to include.)*
☐No

**5.14 Will you notify participants that they are being observed?**

☐Yes
☐No ***(see below)***

***If "No" explain the circumstances why you would not be able to let participants know they are being observed.***

**5.15 If permission to observe participants is obtained, how will you ascertain whether there are individuals who do not want to participate, and how you will manage such a situation?**

## AUDIO-RECORDING/VIDEO-RECORDING/PHOTOGRAPHS

*Skip this section if not applicable.*

**5.16 What type of recording will take place? (check all that apply)**

☒Audio-Recording
☐Video-Recording
☐Photography
☐Other ***(see below)***

***If "Other" describe:***

**5.17 Explain what types of data will be recorded or photographed.**

Individual interviews with a subset of students who have (a) used the StriveWeekly platform at least once, (b) completed all study surveys, and (c) either identify as LGBTQ+ or want to provide feedback about program inclusivity for the LGBTQ+ community will conducted via Harvard Zoom. Each student will participate in a single interview lasting approximately 30 to 60 minutes. Interviews will be audio-recorded and only audio files will be sent out to the research team for transcription and subsequent coding for analysis.

**5.18 If you will be collecting sensitive data, will you use any procedures to de-identify or anonymize the recordings or photographs?**

Participants will be identified during the telemeeting in which the interview will take place using the same participant ID assigned to them for primary data analyses, per the Qualtrics ID key. Data will be automatically transcribed by Harvard Zoom software and reviewed for accuracy by Shayna Greenberg. Transcripts will additionally be thoroughly reviewed and any names or identifying information will be removed from the transcriptions immediately. All recordings will be deleted after they have been transcribed and analyzed.

**5.19 Explain what will happen to the recordings/photographs at the end of the study.**

Recordings will be stored in the encrypted Harvard Zoom cloud and as password-protected files on the PI's Harvard OneDrive. All recordings will be deleted after transcription is complete, files have been reviewed, and the analyses completed. While the transcribing process is underway, all transcripts will be saved on Harvard OneDrive. Transcripts will be retained for study record keeping purposes per institutional policy and future research use.

## DECEPTION AND INCOMPLETE DISCLOSURE

*Skip this section if not applicable.*

***Deception is the intentional misleading of a subject about the nature of the study. While withholding of full information is known as incomplete disclosure.***

**5.20 Describe what information will be withheld from participants or what misinformation will be provided to participants.**

**5.21 Explain why this research involves no more than minimal risk to participants and why it would be impracticable to carry out the research without the use of deception or incomplete disclosure.**

**5.22 Describe the plans for debriefing participants after their participation. If you do not plan to debrief participants, explain why.**

***Please be sure to attach a copy of the debriefing script (if applicable) to the "Local Sites Documents" section in the ESTR SmartForm.***

## DATA FROM OTHER SOURCES

*Please complete this section if you are receiving data that is coming from other sources, for example, from a repository, medical record, institutional data, etc. This section does not pertain to data that is being collected through interaction or intervention as part of this study. Skip this section if not applicable.*

**5.23When was the data collected?**

☐The data has already been collected to date (retrospective data).
☒The data will be collected (prospective data)
☐The data will include both types (retrospective and prospective)

**5.24 Indicate the identifiability of the data when you collect and/or receive it:**

☐Will not contain any direct or indirect identifiers; will be anonymous.
☐Will not be directly identifiable, but there will be a code held by the data source that links to the identities; will be coded.
☒Will contain direct or indirect identifiers, but this research team will remove them upon receipt; will be de-identified data.

☐Will contain direct identifiers; will be identifiable.

**5.25 Describe which data sets you plan to analyze, who is providing the data to you, and whether the data are public use data sets, restricted access datasets, or another type of dataset.**

Data will be collected via the app (StriveWeekly) being tested in this intervention study. As the owner of StriveWeekly, Leslie Rith-Najarian has been collaborating with developers from Harvard University Information Technology (HUIT) to duplicate the platform onto a Harvard-hosted instance. HUIT will provide Leslie Rith-Najarian with access to the Harvard-hosted StriveWeekly app and its associated database. Students will have been informed about this data collection and transfer during the electronic consent procedure. Once all data collection is complete, Leslie Rith-Najarian (StriveWeekly owner) will download the StriveWeekly user database onto a personal work laptop (due to remote work set-up) while logged into Harvard's network via Cisco VPN. Once it is downloaded as an Excel file, email addresses in the StriveWeekly user database will be linked and replaced by assigned participant IDs per the Qualtrics ID key, to which Leslie Rith-Najarian in her role as the study PI has access. The platform database and Qualtrics surveys data will then all be merged into a password-protected master dataset using these participant IDs. This master file will thus have no identifying data within it. See 12.18 for details of StriveWeekly data storage. Also see corresponding DAT20-0492.

**5.26 Provide an overview of the types of variables that are contained in the dataset.**

The app's user database collects the following information, all based on user self-reported information:

Users Collection

1. User ID (randomly assigned by platform)
2. Name
3. Email (Harvard email addresses only)
4. Race / ethnicity
5. Gender
6. Year in college
7. Email timing preferences* (e.g., "On what days would you like to receive reminder emails?"
8. Personal program goals* (see examples: https://s3.amazonaws.com/documents.striveweekly.com/ExampleGoalPlans.pdf)
9. Weekly check-ins* (e.g., "When you imagine your Life 2.0, did this week move you closer, further, or about the same?")

Logs / Histories Collections

10. User ID
11. Practice date
12. Virtual medals earned*
13. Practice activity logs* (drop-down list of skills for each week, e.g., "Practiced Yoga")
14. Self-reported stress and mood ratings 1-10*

**The only variables that will be used for this research study are #7, 8, 9, 12, 13, & 14.** The other variables will thus not be merged into the master dataset. Adherence and program completion will be defined *post hoc* based on spread of variables 13-14. Qualitative feedback from #9 may be reviewed for assessing individual program modules

**5.27 Was the data you plan to analyze collected in a previous research study?**

☐Yes ***(see below)***

☒No

***If "Yes" provide the title/name of the previous research study and which institution and researcher collected the data for the previous study. If the data were collected in a previous Harvard University research study, provide the ESTR number assigned to that study.***

**5.28 Will any of your data be obtained from internet sites (including data mining and data scraping activities)?**

☒Yes ***(see question below)***

☐No

***If "Yes" what websites will you access to obtain the data?***

***Please know that it is your responsibility to check the terms of service of any websites from which you plan to collect data to determine whether your planned data collection is compatible with the terms of service.***

striveweekly.fas.harvard.edu

**5.29 Is the data publicly available on the internet (i.e., freely available without permission, sign-in, or other restrictions)?**

☐Yes
☒No

**5.30 Do you plan to access any data that is Protected Health Information (PHI) under the HIPAA law (for example, data held by a hospital or other healthcare provider or insurer)?**

☐Yes ***(see question below)***
☒No

***If "Yes", which organization will provide the HIPAA PHI to you?***

Per email from Kae Audette (assigned DAT reviewer): "I ran your use case for StriveWeekly by my colleagues and we reached consensus that there's no direct FERPA coverage or any other regulatory aspect of concern where your registration or non-sensitive data collection within the platform goes."

***How will permission to allow the use/disclosure of individual's protected health information (PHI) be obtained?***

***HRP-330 WORKSHEET: HIPAA, which may be found in the ESTR library, provides an overview of items pertaining to HIPAA that may be helpful to the study team.***

**5.31Do you plan to access any data that is FERPA protected (data that are held as education records by an educational institution)?**

☐Yes
☒No

***HRP-331 WORKSHEET: FERPA COMPLIANCE which may be found in the ESTR library provides an overview of items pertaining to FERPA that may be helpful to the study team.***

**5.32 Do you plan to obtain data that has been obtained under "Broad Consent" (as part of the 2018 Requirements)?**

☐Yes
☒No
☐ Uncertain

## BIOLOGICAL MATERIALS FROM OTHER SOURCES

*Please complete this section if you are receiving biological material from other sources, for example, from a biorepository, pathology department, commercial provider, etc. This section does not pertain to biological material that is being collected through interaction or intervention as part of this study. Skip this section if not applicable.*

**5.33When was the biological material collected?**

☐The biological material has already been collected to date (retrospective).
☐The biological material will be collected (prospective)
☐The biological material will include both types (retrospective and prospective)

**5.34Indicate the identifiability of the biological materials when you collect and/or receive it:**

☐Will not contain any direct or indirect identifiers; will be anonymous.
☐Will not be identifiable, but there will be a code held by the data source that links to the identities; will be coded.
☐Will contain direct or indirect identifiers, but this research team will remove them upon receipt; will be de-identified data.
☐Will contain direct identifiers; will be identifiable.

**5.35How will you obtain the material? (check all that apply)**

☐Residual clinical material
☐Material obtained from a vendor
☐Material that was collected as part of another research study ***(please see below)***
☐Other – ***(see below)***

***If you chose "another research study" provide the title/name of the previous research study and which institution and researcher collected the specimens for the previous study. If the specimens were collected in a previous Harvard University research study, provide the ESTR number assigned to that study.***

***If "another research study" or "Other" please specify:***

**5.36 Will the material consist of any of the following? (check all that apply)**

☐Embryonic tissue
☐Embryonic stem cells
☐Stem cells
☐Fresh human fetal tissue
☐None of the above

**5.37 Provide an overview of the types of variables that will accompany the biological materials (for example, identifiable data such as names, date of birth, addresses, or any data that are considered sensitive).**

## DEVICES

*Skip this section if not applicable.*

**5.38 List the device(s) that you plan to use in this study (add additional lines as necessary):**

| Device Brand Name | Generic/Common Name | Manufacturer | Purpose | Function/Operation |
|---|---|---|---|---|
| | | | | |

**5.39 Is the device(s) that you plan to use FDA-approved/cleared?**

☐Yes
☐No

**5.40 If any of the devices that you plan to use require a certified professional to operate, please explain who is certified to operate this device and whether they are on your study team.**

***Please complete HRP-307 WORKSHEET: DEVICES which may be found in the ESTR library and attach to the "Local Site Documents" section in the ESTR SmartForm.***

## DRUGS

*Skip this section if not applicable.*

**5.41 List the drug(s) or biologic(s) that you plan to use in this study (add additional lines as necessary):**

| Drug/Biologic Brand Name | Generic/Common Name | Manufacturer | Purpose | Function/Operation |
|---|---|---|---|---|
| | | | | |

**5.42 Is the drug(s)/biologic(s) that you plan to use FDA-approved/cleared?**

☐Yes
☐No

**5.43 Please explain who is qualified to dispense this drug/biologic and whether they are on your study team.**

***Please complete HRP-306 WORKSHEET: DRUGS which may be found in the ESTR library and attach to the "Local Site Documents" section in the ESTR SmartForm.***

# 6. RISK AND BENEFIT ASSESSMENT

**6.1 Describe the foreseeable risks associated with your study. Please include discussion of any physical risks and non-physical risks, such as economic, psychological, social, and legal harms.**

**Loss of confidentiality** is always a risk in studies using human subjects.

Participants may experience **mild discomforts** such as:
-mild boredom or fatigue when completing surveys
-mild annoyance for receiving survey reminder emails
-mild discomfort upon self-reflection about emotional functioning as prompted by surveys

Although we will not be prompting for sensitive data in our surveys, students may of their own volition self-report **potentially sensitive risk data** within open-ended response fields in posttest and follow-up surveys. We do not anticipate such cases being common though, given that the two open-ended questions that we are posing is unlikely to prompt sensitive date. For reference the two questions are: (1) "Overall, what was the most helpful part of this program? What did you like best? What most encouraged you to complete the program?" and (2) "And what was/were the biggest barrier(s) to completing the program? What would need to change to make this program better?"

We do not anticipate any serious risks. Supporting this claim, in a prior open trial and a prior randomized controlled trial there were no students reporting adverse events due to the intervention (as documented by open-ended responses in posttest feedback surveys).

**6.2 Describe the steps that you will take to minimize risks to your participants (for example, using pseudonyms or a coding system, etc.)**

**Loss of confidentiality** will be minimized by the following procedures:

1. All consent/assent forms and surveys will be electronic via the Harvard Qualtrics, which is encrypted and will only be accessible by the PI.
2. The Harvard Qualtrics surveys will be configured to use an auto-generated participant ID, kept separate from the ID key (which is associated with their Harvard Key email address)
3. All datasets downloaded on the PI's laptop for analyses (over a secure wifi connection) will have all identifying data (e.g., names, emails) removed.
4. See DAT20-0492 uploaded documentation for platform security info.
5. The master dataset will be password-protected and stored on the PI's Harvard OneDrive.
6. Any qualitative findings will be presented in an aggregated and de-identified way. Selected quotes will be accordingly redacted as necessary.

**Mild discomforts due to survey fatigue** will be reduced by optimizing Qualtrics surveys to be easy to answer and minimizing the number of reminder emails sent. Mild discomforts due to self-reflection about psychological symptoms and stressful experiences will be mitigated by provided resource referral info (more info in next item).

**Regarding potential sensitive risk data:** We will not be asking any questions that prompt students to report on intent to harm themselves or others. Our consent form will warn students (see the "Clinically-Relevant Results" section of consent form) that their individual responses on their StriveWeekly user accounts or in open-ended survey responses will not be monitored during the study, and thus they should not use such text fields to communicate to the research team or Harvard admin about any health concerns. We will also remind students within the posttest and follow-up survey instructions that they are discouraged from entering sensitive data. Nevertheless, we will provide students with referral information to mental health services (e.g., crisis hotlines, counseling center services) in (A) the auto-email sent after a respondent completes a survey, and (b) under the "campus" section of StriveWeekly's platform.

**6.3 Are provisions needed for medical and/or psychological support resources (for example, in the event of research-related distress or incidental findings)?**

☐Yes

☒No

**6.4 If applicable, what steps will you take if a participant becomes distressed during your study or reports intent to harm themselves or others?**

We will not be asking any questions that prompt students to report on intent to harm themselves or others. Our consent form will warn students (see the "Clinically-Relevant Results" section) that their

individual responses on their StriveWeekly user accounts or in open-ended survey responses will not be monitored during the study, and thus they should not use such text fields to communicate to the research team or Harvard admin about any health concerns. Nevertheless, we will provide students with referral information to mental health services (e.g., crisis hotlines, counseling center services) in (A) the auto-email sent after a respondent completes a survey, and (b) under the "campus" section of StriveWeekly's platform.

**6.5 Describe any potential direct benefits to participants in the study. If there are no individual benefits, indicate as such.**

Students may benefit psychologically from the StriveWeekly program, as supported by the demonstrated small effect sizes of anxiety and depression symptom improvement in the prior RCT testing StriveWeekly. Given that two of the skill weeks encourage physical exercise, sleep hygiene, and social skills, students may experience physical health and social life benefits if the intervention helps them to engage in more of such activities.

**6.6 Describe any potential benefits to society.**

The results of the research may advance our knowledge about disseminating effective lifestyle programming on university campuses. With the rise of personalized medicine, understanding individual differences in prevention program response will help us better tailor programs to engage and help more individuals. With many universities feeling uncertain about how they can support their students emotionally during remote learning and the COVID-19 pandemic, this trial may demonstrate if such online mental health skills programs are a worthwhile service.

## 7. CHARACTERISTICS OF THE STUDY POPULATION

**7.1 Indicate the estimated number of participants, by subgroup if applicable. *If it is not possible to estimate the number of participants (e.g., open online survey), please indicate that it is not possible and provide an explanation of why it is not possible.***

It is not possible to estimate how many participants will enroll, as it will be open to all Harvard undergraduate students who are interested in enrolling. The maximum sample size therefore cannot exceed the size of the undergraduate student body (~6000). By contrast, the randomized controlled trial at UCLA enrolled 1600+ students from an entire student body of 40,000+. This programming was not centrally sponsored by an equivalent to the Dean of Students Office though, so we expect the relative enrollment rate to be higher by percentage of enrolling students relative to total student body. The secondary analyses on a subset of survey data is estimated to include approx. 125 students endorsing identification with the LGBTQ+ community. We expect to conduct follow up interviews with approximately 20 to 30 participants to achieve saturation.

**7.2 Describe the criteria for enrollment – Will you be limiting your enrollment to a certain age range, gender, people with certain health conditions, etc.? Please also describe any criteria that will exclude people from enrollment.**

We will recruit undergraduate students who are currently enrolled as fulltime students at Harvard as of the time of recruitment. There are no *a priori* exclusion criteria. *Post hoc* exclusion procedures will remove students with invalid data reporting (e.g., straight-lined responses to surveys, high inconsistency in responses to cross-validation item pairs selected based on content similarity). Additionally, inclusion criteria for secondary analyses assessing outcomes among sexual and gender minority subgroups will include endorsement of belonging to the LGBTQ+ community. Students eligible to participant in the follow up interviews will be those who (a) used the StriveWeekly platform at least

once, (b) completed all study surveys, and (c) either identify as LGBTQ+ or want to provide feedback about program inclusivity for this community.

**7.3 Are there any potential vulnerable populations or individuals proposed for involvement in the research? (check all that apply)**

☒Children
☐Wards of the State
☐Prisoners/Detainees
☐Pregnant Women
☐Adults not Competent to Consent
☐Non-English Speaking
☐Employees of Harvard University (as a focus of the study)
☒Undergraduate Students of Harvard University (as a focus of the study)
☐Staff or students that are part of your lab or for whom you provide oversight
☐ Other – ***(see below):***

***If "Other" please specify:***

## *CHILDREN*

*Skip this section if not applicable.*

**7.4 What is the age range of children participating in your study?**

The vast majority of Harvard students are 18+, however some may be as young as 16 or 17.

**7.5 Are there any special considerations that need to be taken into account? For example, do the children have a learning disability?**

N/A

## *PRISONERS*

*Skip this section if not applicable.*

**7.6 Describe any advantages that prisoners may accrue through their participation in the research, especially in comparison to the general living conditions, medical care, quality of food, amenities, and earning opportunities in the prison.**

**7.7 Explain whether the risks of the research are commensurate with risks that would be accepted by non-prisoner research participants.**

### *EMPLOYEES OR STUDENTS OF HARVARD UNIVERSITY*

*Skip this section if not applicable.*

**7.8 Explain how you will minimize the potential for employees and/or students of Harvard University to feel coerced or experience undue influence to participate in the research.**

There will be no direct recruitment, as all recruitment will be completed via email, and no one will be monitoring which individual students do or do not enroll. The PI will direct any students whom she supervises/teaches to the contacts listed in the study consent form. The PI will not ask students to indicate their study participation, but rather simply notify them of this procedure. If any students happen to be enrolled in this study, they can direct questions/concerns accordingly to Dr. McLaughlin or the IRB.

## 8. RECRUITMENT

**8.1 Will potential participants be provided with information about the study?**

☒Yes ***(see below)***
☐No ***(skip to next section)***

***If "Yes" indicate how, when, where, and by whom participants will be recruited. If you are recruiting from a Harvard University Study Pool, describe how you meet their requirements.***

Recruitment will take place in via emails sent from the Dean of Students Office and participating Residential Life Staff.

*Please be aware that the Telephone Consumer Protection Act prevents recruitment through auto-generated SMS/text messages as well as other restrictions.*

**8.2 Are there any materials that will be used to recruit participants (e.g., websites, emails, posters, oral scripts)?**

☒Yes ***(see below)***
☐No

***If yes, list the materials by document name here, and be sure to attach copies to the "Consent and Recruitment Materials" portion of the "Local Site Documents" section in the ESTR SmartForm.***

A recruitment email draft has been uploaded in ESTR supporting documents section.

***HRP-315 WORKSHEET: ADVERTISEMENTS which may be found in the ESTR library provides an overview of items pertaining to advertisements that may be helpful to the study team.***

## 9. SCREENING

**9.1 Will you be screening participants for eligibility? *Note that If you are using inclusion or exclusion criteria, you will be "screening" individuals in order to determine who is eligible.***

☒Yes

☐No ***(skip to next section)***

**9.2 Explain what your screening criteria will be and how you will conduct the screening process.**

Participants will automatically be screened for current enrollment status using survey logic on Qualtrics. The Qualtrics consent form is configured to only be accessed by people with active HarvardKey access. Moreover, the electronic consent process will ask students to select their current residential affiliation, and if a participant does not select one, they will be redirected to a page informing them that they are not eligible.

**9.3 Do you plan to destroy the data from people who participate in the screening process and do not qualify to be in the study as soon as the screening process is over?**

☒Yes

☐No ***(see below)***

***If "No" explain why you will keep the data collected in the screening process for people who are not eligible to participate in this study.***

## 10. INFORMED CONSENT PROCESS

***If you plan on having more than one consent process (such as signed, written consent for one population and use of an online "click" consent script for another population), please explain which variations of the study will use which types of consent process with each of these questions.***

### ADULT PARTICIPANTS

*If you will not include adults in your study, please skip this section.*

**10.1 Will you be obtaining informed consent or an agreement to participate (for Exempt studies) from participants that take part in your study?**

☒ Yes, I will be obtaining informed consent or an agreement to participate.

☐ No, I will not be obtaining consent or an agreement to participate **(skip to next section after answering below)**

***If you will not be obtaining consent or an agreement to participate, please explain:***

- ***why this research involves no more than minimal risk to participants and***
- ***why it would be impracticable to carry out the research with consent or an agreement to participate***

**10.2 Will the consenting or an agreement to participate process involve obtaining a signature?**

☒ Yes

☐ No ***(see below)***

***If a signature is not obtained, explain why:***

**10.3 What type of signature will you obtain?**

☐Inked
☒Electronic ***(Refer to the HUA Investigator Manual (HRP-103) for electronic signature requirements)***
☐Other ***(see below)***

***If other, please describe:***

**10.4Where will the consent or an agreement to participate process take place?**

☐In-person
☒Online
☐Over the telephone
☐Other ***(see below)***

***If other, please describe:***

**10.5 Who will obtain consent or an agreement to participate from participants? *Will the Principal Investigator, other members of the Harvard University research team, collaborating researchers from other institutions, or another third party (such as a survey firm) obtain consent?***

Harvard Qualtrics

**10.6 Describe the process that will be used to obtain consent or an agreement to participate.**

The consent form will be completed electronically using the signature feature on Qualtrics. Participants will be required to login to Qualtrics via HarvardKey Shibboleth, which requires dual authentication. The consent survey will be configured to capture the embedded data of the student's first and last name. Students will also need to type their name along with the electronic signature field, and this name can be compared to embedded name data for confirmation. If a student does not complete the electronic consent form within 7 days, their "in progress" response will be permanently deleted along with any personally identifying information. At the time we invite participants to the optional interviews (see 5.7 above), those wo are interested in signing up will be directed to a new consent form for interview procedures. This consent form will additionally be completed using similar processes for obtaining consent to the full study.

**10.7 Describe how you will assess comprehension of the research and what it means to participate, including understanding of the voluntary nature of participating.**

After reading the consent form and before completing the signature field, there will be some quiz comprehension questions to ensure that participants actually read the consent form, including voluntary participation info. Participants will also be emailed a copy of their consent form (to their embedded HarvardKey email address), so they can reference it later as needed.

## CHILDREN PARTICIPANTS

*If you will not include children in your study, please skip this section.*

***If you are including children in your research study, know that consenting or requesting an agreement to participate from a child is comprised of two parts: child assent and parent permission.***

**10.8 Will you be obtaining assent or an agreement to participate (for Exempt studies) from child participants that take part in your study?**

☐ Yes, I will be obtaining assent or an agreement to participate.
☒ No, I will not be obtaining assent or an agreement to participate ***(skip to next section after answering below)***

***If you will not be obtaining assent or an agreement to participate, please explain:***

- ***Why this research involves no more than minimal risk to participants and***
- ***Why it would be impracticable to carry out the research with assent or an agreement to participate:***

Rather than obtaining assent, enrolled Harvard students who are under age 18 will be invited to complete the same electronic consent form described for "Adult Participants" above in Section 10.1-10.7. See further justification below in section 10.15 for why these participants should consent on their own behalf, along with a waiver of parental consent.

**10.9 Will the assenting or an agreement to participate process involve obtaining a signature?**

☐ Yes
☐ No ***(see below)***

***If a signature is not obtained, explain why:***

**10.10 What type of signature will you obtain?**

☐Inked
☐Electronic ***(Refer to the HUA Investigator Manual (HRP-103) for electronic signature requirements)***
☐Other ***(see below)***

***If other, please describe:***

**10.11 Where will the assent or an agreement to participate process take place?**

☐In-person
☐Online
☐Over the telephone
☐Other ***(see below)***

***If other, please describe:***

**10.12 Who will obtain assent or an agreement to participate from child participants? *Will the Principal Investigator, other members of the Harvard University research team, collaborating researchers from other institutions, or another third party (such as a survey firm) obtain the assent?***

**10.13 Describe the process that will be used to obtain assent or an agreement to participate from children.**

**10.14 Describe how you will assess comprehension of the research and what it means to participate, including understanding of the voluntary nature of participating.**

## PARENT PERMISSION

*If you will not be including children in your research, please skip this section.*

**10.15 Will you be obtaining parent permission or an agreement to participate (for Exempt studies) from parents whose child takes part in your study?**

☐ Yes, I will be obtaining parent permission or an agreement to participate.

☒ No, I will not be obtaining parent permission or an agreement to participate ***(skip to next section after answering below)***

***If you will not be obtaining parent permission or an agreement to participate, please explain:***

- ***Why this research involves no more than minimal risk to participants and***
- ***Why it would be impracticable to carry out the research with parent permission or an agreement to participate:***

**Responses based on HRP-416-CHECKLIST-Children Waiver of Parental Permission**

1. **This research is not FDA-regulated. (section 8 and 9)**
2. **This research does not involve non-viable neonates. (section 8 and 9)**
3. **The research protocol is designed for conditions for which parental or guardian permission is not a reasonable requirement to protect the subjects. (section 8).**
    a. This study is designed to test an online prevention program for anxiety and depression prevention.
    b. First, Massachusetts Law acknowledges the “mature minor” rule, which accepts than an unemancipated minor who possess sufficient intelligence to understand and appreciate the consequences of choosing or rejecting a health service should be permitted to do so, even without parental consent. It is reasonable to assume that if an individual possesses enough intellectual capacity to perform as a Harvard

undergraduate student, then they have enough maturity to elect for a program that might benefit their mental health.

c. Moreover, requiring parental consent is not necessarily in the best interests of participants under age 18. Anxiety and depression symptoms are very personal experiences, and participants who are legally minors should be allowed to consent to a study testing a program that might prevent such symptoms. Given that stigma is a common barrier for seeking mental health services, requiring parental consent could prevent otherwise eligible research participants from enrolling in a study that could provide them with psychological benefits.

d. Finally, parents/guardians of college students are not necessarily physically accessible to the student. Therefore, for some students under age 18 a parental consent form would need to be sent to the parent, either virtually by email or physical by mail. In either case, not only would such a procedure be cumbersome, it also would not guarantee that parental consent form is delivered and/or returned. Moreover, such procedures to obtain the signed parental consent form would actually increase the risk of confidentiality breach, as an email with an attachment or letter in the mail could be delivered to the wrong recipient.

4. **An appropriate mechanism for protecting the children who will participate as subjects in the research is substituted. (section 8)**
    a. Invited participants who are under age 18 will complete the same electronic consent form on their own behalf.
5. **The waiver is not inconsistent with Federal, State, or local law. (section 8)**
    a. M.G.L.A. c. 112 § 12F - 3.3.1.4; establishes that minors may seek health care services without parental consent if the minor is living separate and apart from parents or a legal guardian and is managing his or her own financial affairs.
    b. M.G.L.A. c. 123 § 10; A minor who is at least 16 years old may commit himself or herself for mental health treatment without parental consent.
    c. 45 CFR §46.408 allows a waiver of parental consent when it is not a reasonable requirement to protect subjects
6. **The research involves no more than Minimal Risk to the subjects. (section 9)**
    a. See HUA Protocol sections 6.1-6.4.
7. **The research could not practicably be carried out without the waiver or alteration (section 9)**
    - Again, parents/guardians of college students are not necessarily physically accessible to the student, so the same concerns outlined above in response 3d apply.
    - If students under age 18 are prevented from participating in this study due barriers for obtaining parental consent (outlined in responses 3c and 3d above), then some students are unfairly being denied access to a program that is being offered and tested with the support of the Dean of Students Office. This study aims to evaluate how effective the online intervention is for university students during COVID-19 and remote learning, so to functionally preclude some students from enrolling as participants would render findings less generalizable to “all students”.

- 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. (section 9)
    - All research survey responses will be collected on the Harvard Qualtrics and will include the participant’s official email address. This procedure is necessary in order to link responses from the same participants across all surveys. Other procedures such as asking participants to enter a unique identifier code could risk participants forgetting or mistyping their random identifier, rending their survey response impossible to link across assessment times.

**10.16 Will the parent permission or an agreement to participate process involve obtaining a signature?**

☐ Yes
☐ No (see below)

***If a signature is not obtained, explain why:***

**10.17 What type of signature will you obtain?**

☐Inked
☐Electronic ***(Refer to the HUA Investigator Manual (HRP-103) for electronic signature requirements)***
☐Other ***(see below)***

***If other, please describe:***

**10.18 Where will the parent permission or an agreement to participate process take place?**

☐In-person
☐Online
☐Over the telephone
☐Other ***(see below)***

***If other, please describe:***

**10.19 Who will obtain parent permission or an agreement to participate from the parents? *Will the Principal Investigator, other members of the Harvard University research team, collaborating researchers from other institutions, or another third party (such as a survey firm) obtain the permission?***

**10.20 Describe the process that will be used to obtain parent permission or an agreement to participate from parents.**

**10.21 Describe how you will assess comprehension of the research and what it means to participate, including understanding of the voluntary nature of participating.**

## OTHER TYPES OF PARTICIPANTS

*If this section is not applicable, skip to next section.*

**10.22 If you will be including Wards of the State, explain how consent of legal guardian(s) of ward(s) will be obtained. How will you ensure that the appropriate person granted permission for each ward to participate?**

**10.23 If you will be obtaining consent from special populations such as non-English speaking participants, illiterate participants, or adults not competent to consent, please explain how you will obtain consent from those individuals.**

**10.24 Describe how you will assess comprehension of the research and what it means to participate, including understanding of the voluntary nature of participating.**

***Please be sure to attach copies of all informed consent/parent permission/assent materials to the "Local Site Documents" section in the ESTR SmartForm.***

## 11. PARTICIPANT COMPENSATION AND FINANCIAL OBLIGATION

**11.1 Will your study offer any compensation/incentive to participants (including cash, gift cards, course credit, etc.)? *Please refer to the* Harvard University Financial Policy on Human Subject Payments.**

☒Yes
☐No ***(skip to #11.6)***

**11.2 What type of compensation will you provide to participants?**

☐Cash
☐Check
☒Gift Card/Gift Certificate
☐Course Credit
☐Lottery/Raffle ***(see below)***
☒Other ***(see below)***

***If you chose "Lottery/Raffle":***

***What is the amount and total number of payments to be awarded?***

$5 Amazon gift card guaranteed for every survey. Pending approval, we may also give students the option of payment via CrimsonCash instead of Amazon.com gift card

**For the full RCT**, there will also be a an additional raffle of x10 extra $50 gift card for every survey. Participants can only win the raffle once. 4 surveys x 10 winners each time = 40 students earning the additional raffle gift card

For follow up interviews, participants who have met inclusion criteria and completed an individual interview will be guaranteed an additional $15 Amazon gift card.

***What are the odds of winning (if known)?***

Odds of winning will depend on how many total participants complete each survey, and are expected to improve over time at each survey assessment. We estimate that odds of winning a bonus $50 gift cards over the course of the study is 1:10 to 1:25.

***What is the approximate timing of the drawing?***

Winners will be notified and receive this gift card electronically within two weeks of submitting their respective full survey response, for each survey.

***How will participants who are awarded be notified?***

Email sent from Qualtrics or directly from Amazon.com, with PI's contact info provided

***If you chose "Other" please specify:***

Participants will have opportunities to earn prizes through StriveWeekly program participation during either Fall or Spring semester. Conceptually, these prize incentives are for supporting students' participation in the intervention. These prize drawings are <u>not</u> connected with the research surveys, so not all research participants would be entered. Therefore, these prizes are <u>not</u> counted within a participant's total research compensation payment amount.

Rather, these drawings are additional opportunities to earn prizes by those students who are actively participating in the StriveWeekly program. A random number generator will be used to select winners from the pool of eligible participants, according to these requirements:
**Weekly Prizes** are items worth ~$20 and will be randomly given out weekly to 1-5 students. Who is entered into prize drawing: everyone who logs at least one activity on their StriveWeekly user account that week and completes the Weekly Check-In (see the "Progress" tab on your dashboard) by Sunday at midnight of the respective week. Winners will be notified by an email sent via the StriveWeekly platform within seven days of the drawing.
**Finalist Prizes** are worth <$100 and will be randomly given to 3-10 students at the end of the 7 weeks of StriveWeekly programming each semester. Who is entered into prize drawing: everyone who logs at least one activity every week on their StriveWeekly user account. Winner will be notified by an email sent via the StriveWeekly platform within seven days of the drawing. Of these 3-10 winners, they will get priority of prize choice based on total number of logged activities.

Statement from the DSO: "The DSO is aware that research payments may be made to participants, under the supervision of Leslie Rith-Najarian. The DSO will not have any involvement with research payments nor will they be responsible for their distribution. The DSO will purchase and administer incentive prizes which will not exceed $100 in value, so as to comply with Harvard University gift policy. It is possible that students may receive both a research payment and a participation incentive. Participation incentives will be administered and tracked separately from research payments."

**11.3 What amount will the compensation be worth?**

Needs Assessment survey = $5

Pilot program feedback survey = $5

Full RCT study = Total amount of Amazon gift cards per participant will vary based on number of Qualtrics surveys completed, with a minimum of $5 and a maximum of $70.

- Only one survey = $5
- two surveys = $10
- three surveys = $15
- four surveys = $20
- one survey + one raffle win = $55
- two surveys + one raffle win = $60
- three surveys + one raffle win = $65
- four surveys + one raffle win = $70

***Note:*** No individual participants will earn $100+ in total research compensation. Even if a participant completed all research surveys from the Needs Assessment survey through the final RCT survey, their max total compensation would be $80.

If additional data collection and research compensation opportunities are added to this study in the future, our research study team will ensure that we never pay a single participant $100+ within a calendar year. For example, we could add a focus group opportunity for $20 after the pilot and before the RCT. In theory, one participant who completes ALL possible research components could then earn exactly $100 over the course of the full study. If instead, we offered $25 for the focus group, then this hypothetical participant could earn $105. However, in this example, we would only offer such compensation if (A) the Needs Assessment, pilot feedback survey, focus group, baseline survey, and posttest survey took place in 2021, and (B) the follow-up surveys took place in 2022. This hypothetical participant would then have earned a max of $95 in 2021 and a max of $10 in 2022.

**11.4 Describe which participants will receive compensation and when the compensation will be given.**

We are only compensating participants who complete each respective survey. For each survey, participants will receive this gift card within two weeks of submitting their full survey response (incomplete response will not be eligible for compensation). Participants will be provided with a gift card redemption instructions either through Qualtrics or directly from the Amazon.com website.

**11.5 Will you provide partial compensation for participants who do not complete all the study procedures?**

☐Yes **(see below)**
☒No

***If "Yes" please explain how partial compensation will be managed:***

Participants get based per survey, regardless of their participation at other points during the study.

***HRP-316 WORKSHEET: PAYMENT which may be found in the ESTR library provides an overview of items pertaining to payment that may be helpful to the study team.***

**11.6Will participants be compensated for injuries caused by study procedures, if applicable?**

☐Yes ***(see below)***
☒No

***If "Yes" please explain.***

**11.7 Will participants incur any financial costs by taking part in this study?**

☐Yes ***(see below)***
☒No

***If "Yes" please explain.***

## DATA COLLECTION

### INITIAL COLLECTION

**12.1 Describe the identifiability of the data when first obtained/collected:**

☐Will not contain any direct or indirect identifiers (Anonymous)
☒Will not be directly identifiable but there will be a code held by the data source that links to the identities (Coded) – *i.e., if receiving data from another site*
☐Will contain direct identifiers (Identifiable)

**12.2 In what format will the research data be collected?**

☐Paper
☒Electronic
☐Other – ***(see below)***

***If "Other" please specify:.***

**12.3 Do you plan to obtain data from individuals located in the European Economic Area (EEA)*?**

☐Yes
☒No

***If "YES" the data you obtain may be subject to the E.U. General Data Protection Regulation (GDPR). Click here for more information.***

**** The EEA includes the 28 states of the European Union and four additional countries: Iceland, Liechtenstein, Norway, and Switzerland. Note that this regulation may also apply to data obtained over the internet.***

**12.4 Will data collected from individuals located in the EEA include any of the following? (mark all that apply)**

☐Information about a Subject's Health
☐Racial or Ethnic Origin
☐Political Opinions
☐Religious or Philosophical Beliefs
☐Trade Union Membership

☐Sexual Orientation
☐Data concerning a person's sex life
☐Biometric Data
☐Genetic Data
☐None

**12.09 Will the study require the use of Mobile Apps?**

☐ Yes
☒ No

***List the names of each Mobile App:***

StriveWeekly

**12.10 Will the study use a web-based survey tool?**

☒ Yes
☐ No

***List the names of each web-based tool:***

https://harvard.az1.qualtrics.com/

**12.11 Select any personal device that will collect study data:**

☒ Laptop
☒ Tablet & Smartphone
☐ None

**12.12 Will the study involve study subjects using wearable technology as part of the study?**

☐ Yes
☒ No

***List the names of the wearable technology:***

**12.13 Will the data be managed by Harvard researchers either remotely or housed at Harvard (e.g., physically or Harvard Cloud Storage)?**

☒Yes
☐No

**12.14 Describe the identifiability of the data when stored:**

☒Will be directly labeled with personal identifying information (identifiable)

☐Will be labeled with a code that the research team can link to personal identifying information *This refers to when the research team is using a crosswalk document to link identifiable data to research data and each dataset is kept separately.*
☐Will not be directly identifiable but there will be a code held by the data source that links to the identities (Coded) – *i.e., if receiving data from another site*
☐Will not be labeled with any personal identifying information, nor with a code that the research team can link to personal identifying information (Anonymous or De-identified)
☐Other – ***(see below)***

***If "Other" please specify:.***

**12.15 In what format will the research data be stored?**

☐Paper
☒Electronic
☐Other – ***(see below)***

***If "Other" please specify:.***

**12.16 How will the consent forms be collected and stored?**

☐ Paper
☒ Electronic

**12.17 Will subject contact information or other individually identifiable subject information be stored in the data set?**

☒ No
☐ Yes

**12.18 Explain where the research data will be stored while the study is active (e.g., personal laptop, thumb drive, departmental computer server, office file cabinet, etc.).**

During the study, documentation of identifying information within consent forms and participant ID key will be stored on Harvard Qualtrics, which will be accessible only by the PI of this study. The Harvard Qualtrics site login requires HarvardKey dual authentication. The electronic consent forms will be stored separately from survey responses. The Harvard Qualtrics surveys will be configured to use an auto-generated participant ID, matched to email addresses in the separate ID key.

The StriveWeekly Platform User Database for the Harvard-hosted instance will be stored on a HUIT-managed AWS EC2 instance. HUIT will provide Leslie Rith-Najarian with access to this database.

Once all data collection is complete, Leslie Rith-Najarian (StriveWeekly owner) will download the StriveWeekly user database onto a personal work laptop (due to remote work set-up) while logged into Harvard's network via Cisco VPN. At the same time, Leslie Rith-Najarian in her role as the Harvard-affiliated study PI will download all the survey datasets from Qualtrics. Once all these datasets are downloaded as Excel files, email addresses in the StriveWeekly user database will be used to link all assigned participant IDs per the Qualtrics ID key. The datasets (platform database and Qualtrics surveys) will then all be merged into a password-protected master dataset using these participant IDs. This master file will thus have no identifying data within it. The password for the master data will be known only by the PI, and anyone listed in the IRB for the corresponding study (currently or in the

future). All downloaded files will be permanently deleted from the laptop, and the master dataset will be saved within the PI's Harvard O365 OneDrive. Kevin Shani (Graduate Assistant) and Shayna Greenberg (Graduate Assistant) will help with management of the resulting dataset.

**12.19 What will happen to the data at the conclusion of the study? (check all that apply)**

☐Direct identifiers* and/or the key to the codes will be destroyed upon completion of the research (all data will be stripped of identifying information and/or the key to codes destroyed, identifiable paper documents shredded, identifiable electronic files purged, Identifiable electronic media securely erased).
☒Retained for study record keeping purposes per institutional policy.
☒Retained by the investigator for future research use.
☒Retained for future research use (create repository/bank).
☐Restricted use data will be destroyed or will be returned to the source.
☐No direct or indirect identifiers* are being collected. This anonymous data will be retained at the discretion of the investigator.
☐This research is a clinical trial conducted under FDA regulations. Direct identifiers* and/or the key to the codes will be destroyed as directed by the sponsor (IND/IDE holder) in accordance with FDA regulations.
☒Other – ***(see below)***

***If "Other" please specify:.***

Direct identifiers will still be stored on the Harvard Qualtrics. A copy of the Qualtrics ID key will be stored on the PI's Harvard OneDrive, password-protected by a password known by no one else. When the PI's affiliation with Harvard is terminated (June 2024), the PI will lose access to all of these direct identifiers.

Before PI loses access to these services, Dr. Rith-Najarian will download a password-protected version of the master dataset that includes no direct identifiers. This version will include participants' responses to all study questions and their merge StriveWeekly platform data, including open-ended responses. See 13.2 for more information on sharing of de-identified datasets. The PI has already consulted with the Dean of Students Office, and received permission to retain de-identified copies of research datasets.

**** Direct identifiers.*** *These are variables that point explicitly to particular individuals or units. Examples include: names, addresses, including ZIP and other postal codes, telephone numbers, including area codes, Social Security numbers, other linkable numbers such as driver's license numbers, certification numbers, etc.*

***Indirect identifiers.*** *These are variables that can be problematic as they may be used together or in conjunction with other information to identify individual respondents. Examples include: detailed geographic information (e.g., state, county, province, or census tract of residence), organizations to which the respondent belongs, educational institutions (from which the respondent graduated and year of graduation), detailed occupational titles, place where respondent grew up, exact dates of events (birth, death, marriage, divorce), detailed income, offices or posts held by respondent.*

## DATA TRANSFER

**12.20 Do you anticipate that the research data will be transferred or transported from your possession to another at any time?**

☒Yes
☐No ***(skip to question #12.22)***

**12.21 Explain what methods you will use to transfer/transport the data and how you will minimize the risks of a data breach during the transmission process.**

Shayna Greenberg will be provided access to the Qualtrics data collection during the study, as well as access to payment tracking files in Harvard OneDrive. This folder will be shared to Shayna Greenberg's email address, and the share settings will not allow anyone else to access the files. Once the study is over, Shayna Greenberg will have access to any identifiable data revoked.

Shayna Greenberg will be provided de-identified data files after the study is complete. This transfer will be coordinated by the study PI. Two types of data will be provided:

1. A subsample of the data derived from students endorsing identification with the LGBTQ+ community for secondary data analyses.
2. Transcripts of individual interviews for qualitative data analysis procedures.

This de-identified data files will be placed into a folder on the PI's Harvard OneDrive. This folder will be shared to Shayna Greenberg's LLU email address, and the share settings will not allow anyone else to access the files. Once Shayna Greenberg has confirmed that all de-identified files are downloaded on their end, the folder will be deleted from OneDrive.

**12.22 Will data be transferred from the EEA* to Harvard or another non-EEA location?**

☐Yes

☒No

**** The EEA includes the 28 states of the European Union and four additional countries: Iceland, Liechtenstein, Norway and Switzerland.***

## DATA CONTROLS

**12.23 Will (or has) a Certificate of Confidentiality (CoC) be (been) obtained for this study?** ***If your study meets the definition of a clinical trial according to the NIH, a CoC will be automatically issued with your funding.***

☐Yes

☒No

**12.24 Does your protocol have a Data Use Agreement?**

☒ Yes

☐ No

## 13. SHARING DATA WITH OTHERS

**13.1 Will the data be released to anyone who is not on the Harvard University Area research team?**

☒Yes

☐No ***(skip to question #13.4)***

**13.2 Other than the Harvard University Area research team, who will have access to the data?**

☒Colleagues/Collaborators at other institutions

☐Transcribers/coders hired by the research team

☐Sponsor/Funding Agency

☒OpenScience or other framework (Specify: https://osf.io/8dvjq/)

☒Other ***(see below)***

***If "Other" please specify:.***

Collaborators at other institutions: While the data is being collected, Shayna Greenberg will be helping collect and process data via Harvard Qualtrics, the StriveWeekly platform, Harvard OneDrive, and Harvard Zoom. After the data collection is complete, Shayna Greenberg's access to these services will be revoked. At that time Shayna Greenberg will then be provided de-identified data files. See details in 12.21 above.
OpenScience: a de-identified copy of main study variables (e.g., condition assignment, outcome measure total scores) will be uploaded to the PI's OSF profile. This copy of the dataset will contain none of the qualitative open-ended response data. In future published manuscripts, the PI will offer de-identified versions of other variables should other researchers wish to verify study results, or use study data for secondary analysis or meta-analysis research.

Other: See 5.25 and 12.18 for explanation of Leslie Rith-Najarian's external role as StriveWeekly website owner

**13.3 How will the data be shared/disclosed beyond the Harvard University Area research team?**

☐Without any identifiers
☒Coded
☐With Identifiers

**13.4 Will you be sharing research findings with study participants?**

☐Yes ***(see below)***
☒No

***If "Yes" please describe which findings will be shared, when they will be shared, and how they will be shared with participants (in-person, over the telephone, etc.):***

**13.5 Does the study include establishing a repository for sharing data or specimens with other researchers?**

☐Yes ***(If so, please know that a separate IRB submission will be needed if a data or specimen repository will be created)***
☒No

## GENOMIC DATA SHARING

**13.6 Will you be submitting data to a national data repository (dbGaP, GEO, etc.) or other type of repository for broad sharing of data?**

☐Yes
☒No

**13.7 Will you require a Genomic Data Sharing (GDS) Institutional Certification per NIH GDS policy?**

☐Yes
☒No

**13.8 Include a description of all fields to be submitted to the repository:**

**13.9 Describe the plan for de-identifying data for inclusion in the repository, including how the key linking the identity of participants will be maintained and who will have access:**

***If data will be prospectively collected, specific elements are required to be included in the informed consent form that you will be using in this study. Please see the NIH guidance document.***

***If data that will be submitted have already been collected under another IRB or other collection protocol, please be sure to attach a copy of the IRB approval and approved consent form(s) used to collect the underlying data/specimens to the "Local Site Documents" section in the ESTR SmartForm.***