Official title: GamePlan for PrEP: A Pilot Trial of a Web-based Intervention to Help High-risk Men on PrEP Adhere to Their Medication, Reduce Alcohol Use, and Encourage Safe Sex

NCT number: 04973267

Document date: 05/11/2021

Brown University
Application for Expedited / Full Board IRB Review

PART 1: Name(s) and Contact Information.

Protocol Title: Game Plan for PrEP: A pilot trial of a web-based intervention to help high-risk men on PrEP adhere to their medication, reduce alcohol use, and encourage safe sex

Principal Investigator: Chan, Philip A., Wray, Tyler B.

Department: Center for Alcohol & Addiction Studies

Phone number: Tyler Wray: (401) 863-6659, Philip Chan: (401) 793-2928

Email address: tyler_wray@brown.edu, philip_chan@brown.edu

Is this a graduate student project?* ☐ Yes ☒ No

If student PI, please provide the following:

Advisor: **Phone number:**

Department: **Email address:**

Is this an undergraduate student project?* ☐ Yes ☒ No

If yes, name of undergraduate student:

PART 2: Education Affirmation.

Human Subjects CITI training is complete (PI, advisor (if student PI)): ☒ Yes ☐ No

Good Clinical Practice (GCP) training is complete (clinical trials only): ☒ Yes ☐ No ☐ N/A

HIPAA training is complete (if using PHI): ☒ Yes ☐ No ☐ N/A

PART 3: Collaboration Information.

Are there multiple sites involved with this study? ☐ Yes ☒ No

If yes, list the site(s) involved:

- If "yes," review the Application for IRB Authorization Agreement

PART 4: Funding Information.

Funding Source(s):

- If externally funded, provide the following:

  Sponsor: National Institute on Alcohol Abuse and Alcoholism

Project title: Applying user-centered design strategies to develop a tablet-optimized intervention to help high-risk men starting PrEP reduce their heavy drinking and adhere to their medication

Grant / Contract #: R34AA027195

- If funded by a specific Brown program (e.g., Mellon Mays Fellowship, Royce Fellowship, UTRA, OVPR Seed funds, etc.) please specify**:** N/A
- If there is no funding for the study, write "Brown"

PART I. HUMAN SUBJECTS RESEARCH SCREENING

Expedited / Full Board studies must meet the federal definition of "Human Subjects Research." Answer the following questions to determine if your proposed study meets the federal definitions of both "Research" and "Human subjects."	
☒ Yes ☐ No	Is this study a systematic investigation?
☒ Yes ☐ No	Is the *primary design intent* of this study to contribute to generalizable knowledge?
☒ Yes ☐ No	Is the information being obtained *about* living individuals?
☒ Yes ☐ No	Will you collect information through some type of intervention or interaction? **OR** Will you have access to individually identifiable information? **OR** Will you have access to private information?
	If you answered "no" to any of the above questions, your study does not meet the definition of "Human Subjects Research." You are not required to submit an Application for IRB review to the Brown HRPP.

PART II. RISK ASSESSMENT & EXPEDITED ELIGIBILITY SCREENER

1. Minimal Risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests. **Using this definition, do you believe this research presents:**	
☐ Greater than minimal risk (**Full Board**)	Briefly justify this selection (and proceed to Part III): Click or tap here to enter text.
☒ No greater than minimal risk (**Expedited**)	Briefly justify this selection (and proceed to Question 2): Participants will be responding to online surveys and testing for STIs/HIV, which are both part of everyday life.
2. Below are Research Categories *eligible* for Expedited Review. Select one or more of the categories that are applicable to your proposed research, if any.	

☐ Category 1	Clinical studies of drugs and medical devices only when condition (a) or (b) is met (please select one): ☐ (a) research on drugs for which an IND application is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review); OR ☐ (b) research on medical devices for which (i) an IDE exemption application is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
☒ Category 2	Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: ☒ (a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these participants, the amounts drawn must not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; OR ☐ (b) from other adults and children, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.
☐ Category 3	Prospective collection of biological specimens for research purposes by noninvasive means. Examples may include: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicated a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue; (f) placenta removal at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routing prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
☐ Category 4	Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples may include: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging;

	(d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
☐ Category 5	Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). NOTE: Some research in this category may be Exempt. Review the categories for Exemption before selecting this option.
☒ Category 6	Collection of data from voice, video, digital, or image recordings made for research purposes.
☒ Category 7	Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. NOTE: Some research in this category may be Exempt. Review the categories for Exemption before selecting this option.

PART III. RESEARCH DESIGN & METHODS

THE BLUE TEXT IN THE FOLLOWING SECTIONS IS A GUIDE TO ENSURE ALL RELEVANT INFORMATION IS INCLUDED IN YOUR APPLICATION. YOU MAY DELETE THE BLUE TEXT BEFORE SUBMISSION

1. **Introduction and Background.** *In reviewing the protocol, the IRB must consider the rationale for the study and the importance of the knowledge that may reasonably be expected to result.*

Although the overall annual HIV incidence in the United States (US) has declined in recent years, the rate of new infections remains stable among men who have sex with men (MSM)1. If this trend continues, recent estimates show 1 in 6 MSM in the US will be diagnosed with HIV in their lifetimes2. However, new biomedical tools for HIV prevention could help achieve a sustained decline in new infections. A once-daily dose of the antiviral drug emtricitabine/tenofovir disoproxil fumarate has shown 99% efficacy in preventing HIV acquisition among adherent MSM in clinical trials3; 4. As a result, this approach, referred to as pre-exposure prophylaxis (PrEP), is being broadly implemented across the country5; 6. Despite its promise, concerns remain about PrEP's potential to prevent HIV in "real world" settings, since its effectiveness depends on sufficient adherence and persistence to the drug7; 8. Although follow-up analyses of clinical trial data suggest that adherence as low as 4 doses per week may be protective3; 4, several effectiveness studies (open-label extensions and demonstration projects) have reported adherence rates below this threshold among many MSM4; 9.

Alcohol use is a major risk factor for HIV infection among MSM10 and has harmful effects across the continuum of HIV care10-13. A robust literature also shows that heavy drinking affects adherence to antiviral medications when used to treat HIV, resulting in poorer health outcomes and increasing the potential for onward transmission12; 14-16. Although few published studies have explored alcohol's effects specifically on PrEP adherence4; 9, we have observed a similar pattern in our ongoing work. In a study of high-risk MSM on PrEP ($N = 40$), binge drinking days (5+ drinks on a single day) were three times more likely to occur during PrEP dose lapses of 4 or more days (a lapse length that may reduce PrEP's effectiveness4) than when adherence was more consistent. Our work also shows that nearly 50% of MSM prescribed PrEP at our clinic reported binge drinking in the past month, suggesting that this pattern of drinking is widespread. Together, these findings suggest that PrEP care would benefit from the integration of empirically-supported approaches to alcohol intervention.

Recent studies17-19 including our own work shows that brief alcohol interventions based on the principles of motivational interviewing (BMIs) help heavy drinking MSM and people living with HIV reduce their alcohol use, and that these reductions in turn improve medication adherence and decrease viral load. However, face-to-face BMIs are often difficult to implement and scale in many settings because of their reliance on highly-trained counselors. Internet-facilitated interventions inspired by face-to-face BMIs have also been shown to reduce heavy drinking among many at-risk groups20; 21, but no such tools have been developed for MSM on PrEP.

In our ongoing work22; 23, we developed Game Plan, a tablet-optimized web application designed to help heavy drinking, HIV-negative MSM reduce their alcohol use and sexual risk behavior. Based on our work on BMIs24, Game Plan was designed to go beyond many existing web-based interventions to provide much of the same content often provided in face-to-face BMIs, including personalized feedback about alcohol use and health risks, normative comparisons, reflective exercises to enhance motivation to change, and substantive change planning components. We also employed a thorough user-centered design process with the goal ofbuilding a tool that was interesting and engaging to its intended users. In an ongoing pilot study of nontreatment-seeking, heavy drinking MSM in an HIV testing clinic ($N = 40$), 74% of those who used Game Plan set a goal to reduce heavy drinking and reported 25% fewer binge drinking days compared to controls over 1.8 months of follow-up conducted

so far. These results are promising, and suggest that web-based BMIs could provide an efficacious, feasible, and scalable approach to alcohol intervention in resource-limited PrEP clinics.

2. **Specific Aims and Study Objectives.** *The IRB must evaluate the objectives of the research in order to determine whether the risks to participants are reasonable in relation to the importance of the knowledge that may be gained.*

The current study will explore the preliminary efficacy of Game Plan for PrEP, a web-based intervention to help high-risk men on PrEP adhere to their medication, reduce their alcohol use, and have safe sex. To accomplish this, we will randomize 100 of MSM to receive either (1) GP4PrEP or (2) an attention-matched control (AC). We will use self-report measures of alcohol use collected at 1-, 3-, and 6-months and changes in a biomarker of alcohol use collected at baseline, 3-, and 6-months to explore whether GP4PrEP reduces binge drinking compared with AC. We will also use data from a biomarker of PrEP adherence to explore whether GP4PrEP improves PrEP adherence vs. AC. Finally, we will also explore whether GP4PrEP reduces STI incidence compared to AC.

The aim is to explore preliminary evidence of GP4PrEP's efficacy in reducing heavy drinking and improving PrEP adherence/persistence, and sexually-transmitted infection (STI) incidence among heavy drinking MSM who are on PrEP, but who report a recent history of missing 3 or more consecutive doses.

If your study ONLY involves the use of identifiable secondary data / biospecimens, including coded data from which you may be able to ascertain participant identity, skip to PART V. Otherwise, please continue to next page.

3. **Materials, Methods and Analysis.** *The study design, methods and procedures must be adequately described in order for the IRB to understand all activities in which human subjects will participate. The IRB must also be able to differentiate those procedures that are performed for research purposes from those that are performed for routine care or evaluation.*

In order to explore its efficacy, 100 participants will be randomized to receive either the app or an attention-matched control (AC). We will use self-report measures of alcohol use collected at 1-, 3-, and 6-months and changes in a biomarker of alcohol use collected at baseline, 3-, and 6-months to explore whether GP4PrEP reduces binge drinking compared with AC. We will also use data from a biomarker of PrEP adherence to explore whether GP4PrEP improves PrEP adherence vs. AC. Finally, we will also test whether GP4PrEP participants showed lower rates of STI incidence across the study period compared to AC. A baseline assessment battery will be used to collect data on alcohol and other drug use and factors that can affect medication adherence such as attitudes towards PrEP, barriers and facilitators to taking PrEP, stigma, and beliefs. Follow-up assessments will also assess a number of covariates that may be relevant to PrEP adherence over time, including side effects, health insurance coverage, financial strain, health-related quality of life, and social support. STI incidence at each quarterly routine PrEP care visit will also be collected by extracting this data from participants' electronic medical records. At these visits, participants are tested for Chlamydia and Gonorrhea at genital, rectal, and oral sites, syphilis, and HIV. At-home kits to collect dried blood spot (DBS) samples will be sent to participants at baseline (immediately after they enroll), at 3-months, and 6-months post-enrollment, using procedures used by several national laboratories and in several past studies. DBS samples will be analyzed for TFV-DP levels, a biomarker for adherence to PrEP, as well as phosphatidylethanol (PEth), a biomarker of alcohol consumption. At the Miriam PrEP clinic, limited research staff who are co-located in the clinic will inquire about PrEP patients' potential interest in

participating in the study, or will provide them with a palm card (attached) with contact information for the study team. If patients request them to do so, research staff will also provide patients' first names and email addresses to the study team. The study team will email prospective participants a link to an online screening survey that will provide them with more information about the study and, if interested, will ask them to complete a brief survey (< 5 minutes) to assess their eligibility. All online surveys, including those used for screening, consent, baseline, and all follow-ups, will be collected in Qualtrics, which is currently approved to collect and store Level 3 data (e.g., personal health data, HIPAA-protected data, etc.) by Brown University's Computing and Information Systems office. The screening survey will provide real-time feedback about their eligibility, and if prospective participants are eligible and interested, will provide further study information and ask participants to provide informed consent by electronically signing in a provided field. Consent information will be provided in audio or text-based format to ensure participant understanding. Once they provide consent, participants will then be asked to complete a more detailed online baseline assessment, which will take about 30-45 minutes to complete. After they do so, research staff will mail a DBS collection kit to the addresses participants provide. These kits will include a Whatman protein saver card, two personal lancets, two alcohol pads, medical gauze, bandages, and thorough instructions about how to provide the dried blood spot sample. A link to video instructions will also be included in the kit. Once the DBS card has been prepared participants will be instructed to let it dry in ambient air for 4 hours before enclosing the card in a sealable foil biohazard bag, and then seal it in a self-addressed return mailer and drop it in any USPS mailbox to ship it back to the research offices. Once received, DBS cards will be stored in a -20 degree freezer until the end of the study, when they will be shipped on dry ice to the lab for analysis. DBS cards will be marked with that participants' study ID number prior to being shipped to participants so that no identifying information is included on any materials shared with the lab.

4. **Participant Population.** *In order to approve research, the IRB must determine that the selection of participants is equitable and reasonably related to the purpose and aims of the research. The IRB must also consider whether adequate safeguards are in place to minimize any risks that are unique to vulnerable populations. To make this determination, the IRB must review all methods and materials used to contact and recruit potential participants, including letters, flyers, emails, etc.*

Criteria for inclusion in this study are: (1) Current male gender, (2) 18+ years old, (3) able to speak and read in English fluently, (4) heavy alcohol use in the past month (>5 drinks on a single occasion or >14 drinks in a week), (5) currently prescribed and actively taking PrEP, and (6) report missing > 3 PrEP doses in a row at least once in the past 3 months. Those who have (1) injected drugs in the past year, (2) screen positive for drug-related disorders, (3) report a history or risk of complicated alcohol withdrawal, or (4) are currently receiving counseling or medications for alcohol or drug addiction will be excluded. Participants must be fluent in English to participate. The target number of participants to be included in the study is 100, 50 in each condition.

5. **Recruitment Methods**

Participants will be recruited a variety of ways, including social media advertisements, flyers and business cards, and from an existing database, in which potential participants previously expressed interest in participating in various research studies with Smash Labs. Examples of images and text used in online advertisements are attached, as well as advertising palm cards. Initial contact will involve participants completing an online screener to determine their eligibility for the study. If determined eligible, participants will consent online, and give contact info. Research staff will call to verify participants' enrollment, further explain the consent and what's expected of them in the study, and answer any questions the participant may have. Research staff will be trained by PI and project coordinator. Screening data will be destroyed after study completion.

6. **Compensation / Reimbursement**

Participants will be paid $20 for viewing/interacting with the GamePlan website or control videos, $50 for completing both the online survey and DBS kits ($15 and $35, respectively) at baseline, 3- and 6- months, $25 for and their 1-month online survey, with a bonus of $50 for completing all study procedures ($245 total possible). Participants will be paid via ClinCard. They will be mailed a ClinCard, and all study payment will be made within 3 business days of study activity completion.

Some of the services participants will receive are being performed only because they are participating in this research study. These 'research only' services include sampling a few drops of blood. This will be paid for by the study and will not be billed to the participant or their health insurance company.

Other services they will receive during this research study are considered "routine clinical services" that they would have received even if they were not in the research study. Examples include their PrEP medication and refills, follow-up visits with their doctor every 3 months, HIV and STD testing at these visits, and any other laboratory tests provided as a part of monitoring their health while on PrEP (for example, analysis of your urine and blood). These services will be billed to their health insurance company, but participants' will be responsible for paying any deductibles, co-payments, or co-insurance that are a normal part of their health insurance plan. If they do not have health insurance, they will be responsible for those costs.

7. **Potential Research Risks / Discomforts to Participants.** *In order to approve the research, the IRB must consider the risks posed to participants by the research and any efforts to mitigate those risks. The IRB needs to determine that the risks have been both minimized and are reasonable in relation to the anticipated benefits to participants, as well as to the importance of the knowledge that may be gained. The IRB will also consider whether the informed consent process provides potential participants with an accurate and fair description of the risks or discomforts.*

During this study, some of the questions we will ask are about sex, alcohol and drug use, and other sensitive behaviors. These questions might make participants uncomfortable or embarrassed. This discomfort is usually rare and very mild.

Participation in this study, as well as any information you provide us during the study, is confidential. To safeguard confidentiality, we store all data that participants provide us in secure locations and in password-protected and encrypted files, and after the study is over, we destroy any information that could identify participants (e.g., your name, phone, email). However, there is a risk that a data breach during the study may result in the loss of confidentiality. To minimize this risk, the systems we use to collect data throughout the study meet very high standards for security and are routinely checked for flaws. We also do not store any information that could identify participants in the programs we use to collect data from them online.

Participants may experience problems as a result of taking PrEP or while undergoing any medical procedure done as part of the typical course of monitoring their use of PrEP (e.g., HIV/STD testing/treatment). However, participants may experience these even if they chose not to join the study, since these are a result of taking PrEP and not the study procedures themselves. See data security assessment below.

8. **Potential Benefits of the Research. NOTE: Compensation for participation is not a benefit and should not be included in this section.** *In order to approve this research, the IRB must determine that the potential benefits to research participants are reasonable in relation to the potential risks. Very*

often, research at Brown does not include potential direct benefits to participants, but may only benefit society as a whole by helping researchers.

There are no direct benefits to participants, but this study will be contributing to general medical knowledge.

PART IV. INFORMED CONSENT

Informed consent is a *process*, not just a form. The IRB must ensure the informed consent process clearly discloses and facilitates the understanding of all information needed to make an informed decision to participate while promoting the voluntariness of participation.

Please use the Brown consent / assent templates and related guidance on the HRPP Forms & Templates page to develop your consent forms.

1. **Describe the informed consent process:**

Informed consent will be obtained online as part of the usual onboarding sequence for enrolled participants. This process will involve first providing the information contained in the consent in brief, bulleted segments, and providing the full consent information in audio format (for those who choose it). The full consent form will then be displayed and participants will be invited to download and/or save a copy for their records. Participants will then provide informed consent by electronically signing in a provided field.

2. **Facilitate Understanding**

Participants will be asked to read the bulleted list of consent items, before being shown the consent document in its entirety and given a downloadable copy. They will then be asked to digitally approve their consent. Participants can email, call, or text study staff at any time during the study with questions.

3. **Documentation**

Researchers will document all consent using an online Qualtrics survey, see measures document attached.

4. **Additional Considerations**

N/A

PART V. USE OF SECONDARY DATA / BIOSPECIMENS

For research that involves the use of identifiable secondary data / biospecimens, including coded data from which you may be able to ascertain participant identity.
If your research does not involve identifiable secondary data / biospecimens, proceed to PART VI. DATA SECURITY ASSESSMENT

1. From what source(s) will you acquire or access the data / biospecimens?

N/A

2. Describe the type(s) of data and date range(s) of the data you will use and the characteristics of the study research population (e.g., age range, sex, and any other pertinent demographic information.)

N/A

4. HIPAA and Protected Health Information (PHI):

- Please review the HIPAA Privacy Rule Guidance for Brown University Researchers.
- If the research involves the use of PHI from a HIPAA-covered entity, describe how authorization from participants to access and use their information will be obtained.
- Complete Appendix G. Use of Protected Health Information (PHI) for Research and include with this application.

5. Do any of the source(s) require a Data Use Agreement (DUA) or other Agreement that requires institutional signature to obtain, access or use the data / biospecimens? ☐ Yes ☒ No

If "yes," please include a copy of the Agreement(s) with this submission and also follow the Data Use Agreement review and signature processes.

PART VI. DATA SECURITY ASSESSMENT

1. Will you be collecting biospecimens?	
☒ Yes ☐ No	If "yes," please review the Institutional Biosafety Committee (IBC) webpage. A supplemental IBC review may be required.
2. Do the study data / biospecimens include identifiers? Video and audio recordings are considered identifiable.	
☒ No	If "no," I affirm that I have read and will abide by the Level 1 Risk Minimum Security Standards: ☒ Yes ☐ No Proceed to Question #3.
☐ Yes	If "yes," answer the following questions. A. Describe the identifiers associated with the data / biospecimens. B. Justify why identifiers are required to conduct the research. Click or tap here to enter text. C. Described the proposed research use of the identifiable data / biospecimens. Click or tap here to enter text. D. Self-classify the Risk Level of these data / biospecimens (select the *highest level of risk* for all data / biospecimens being collected). ☐ Level 2 Risk ☐ Level 3 Risk

3. How will study data / biospecimens be collected?

☐ Brown desktop
☐ Laptop
☒ Departmental server
☒ CIS managed server
☒ Brown Qualtrics
☐ REDCap; Please describe what instance of REDCap is being used (Brown does not have an instance of REDCap): Click or tap here to enter text.
☐ Amazon Mechanical Turk (MTurk)
☐ Text messaging → You must complete the Text messaging section after completing Qs 3 – 5.
☐ Mobile App (on tablet, iPad, Phone) → You must complete the Mobile App section after completing Qs 3-5.
☐ Zoom
☐ Digital records (audio / videoconferencing tools, digital photographs); please describe the tool: Click or tap here to enter text.
☐ Paper records (including physical photographs). Please describe, including how you will securely store the paper records: Click or tap here to enter text.
☐ Web-based site / survey / other tool not listed above → You must complete the Web-based Other section after completing Qs 3 – 5.

☐ Other; please describe:
Click or tap here to enter text.

4. Who will have access to the study data / biospecimens?

☐ A. Brown PI only. How will unauthorized access by others be prevented?
Click or tap here to enter text.

☒ B. Brown PI and other Brown research team members. How will unauthorized access by others be prevented?
Brown login credentials require the use of 2-step verification. Only approved staff will have access to study data.

☐ C. Data will be shared with research collaborators external to Brown. This data sharing intent **must** be described as part of your consent process / form. Please describe how you will securely share / transfer the data outside of Brown:
Click or tap here to enter text.

*Note that an Outgoing Data Use Agreement **is required when sharing identifiable data external to Brown**. Please follow the procedures outlined here. You do not need to submit a copy of a DUA to the HRPP. This will be linked by the ORI administratively.*

5. Where will the study data / biospecimens be stored?

☒ Departmental server
☒ CIS managed server
☐ Stronghold
☐ Campus file storage
☐ REDCap
☐ Other. Please describe: Click or tap here to enter text.

6. If traveling with your data, describe how your data will be secured.

N/A

7. For how long will you retain identifiable data / biospecimens? How will you destroy identifiers when no longer required?

Identifiers will be destroyed at the conclusion of study procedures.

8. Text Messaging (only complete if instructed above.)

A. Are you using the current text messaging service available on the device?

☐ Yes ☐ No	If "no," you must also complete the Mobile App section.

B. Whose device will be used? ☐ Participant's personal phone ☐ Brown-issued phone

C. Content of messaging: (If brief, insert here; otherwise, please provide as an attachment)

D. Is the communication one-way or two-way? ☐ One-way ☐ Two-way

9. Mobile App (only complete if instructed above.)

A. Name of the mobile app: Click or tap here to enter text.

B. Has this site / tool been reviewed by CIS IT Security?

☐ Yes ☐ No	If "no," answer the following: a) Who created the site / tool (vendor name or off the-shelf app creator name)? Click or tap here to enter text. b) Where is it hosted? Click or tap here to enter text. c) Is the site / tool scanned for security vulnerabilities? ☐ Yes ☐ No d) What version of software is being used, if applicable: ☐ N/A or Click or tap here to enter text. e) How are the data encrypted? Click or tap here to enter text.

C. Whose device will be used? ☐ Participant's personal phone ☐ Brown-issued phone
If Participant's person phone:

a. How is the app downloaded to the device?
Click or tap here to enter text.

b. Is a password or PIN required for the app? ☐ Yes ☐ No

D. Will data be stored on the device for any period of time?

☐ Yes ☐ No	a. If "yes," please describe (i.e., queue on phone and then transmitted to server): Click or tap here to enter text. b. Is the app data encrypted on the device? ☐ Yes ☐ No

E. Device features mobile app can access ☐ N/A

- ☐ Device ID and call information
- ☐ Identity
- ☐ Contacts
- ☐ Camera
- ☐ SMS or chat
- ☐ Storage
- ☐ Device and application history
- ☐ Phone
- ☐ Photo / media / files
- ☐ Microphone
- ☐ Location

☐ Other; please describe: Click or tap here to enter text.	
F. Will a third-party have access to research data through this app? ☐ Yes ☐ No	
G. Is data transmitted by the device?	
☐ Yes ☐ No	If "yes," how is it encrypted in transit? Click or tap here to enter text.
H. Are phone numbers or mobile identification numbers stored with the data? ☐ Yes ☐ No	
10. Web-based Other (only complete if instructed above.)	
A. Name of the site / tool: Click or tap here to enter text.	
B. Has this site / tool been reviewed by CIS IT Security?	
☐ Yes ☐ No	If "no," answer the following: a. Who created the site / tool (vendor name or off the-shelf app creator name)? Click or tap here to enter text. b. Where is it hosted? Click or tap here to enter text. c. Is the site / tool scanned for security vulnerabilities? ☐ Yes ☐ No d. What version of software is being used, if applicable: ☐ N/A or Click or tap here to enter text. e. How are the data encrypted? Click or tap here to enter text.
C. Is informed consent being obtained via this site / tool?	
☐ Yes ☐ No	If "yes," how is re-identification prevented? Click or tap here to enter text.
D. Does the technology allow for the explicit exclusion of the collection of IP address of the participant's connection?	
☐ Yes ☐ No	If "yes," will you use this option to exclude the collection of IP address? ☐ Yes ☐ No

Brown Qualtrics: CIS has pre-vetted Brown Qualtrics for collection/storage of up to Risk Level III data. Qualtrics is the preferred survey tool for all Brown research data collection.

REDCap: Brown does not currently have its own instance of REDCap. Access to REDCap through a Lifespan collaborator must be explicitly identified.

Data collection: The expectation is that data collection *devices* will only store data during active data collection. Data must then be transitioned to more secure long-term storage solutions.

Departmental/CIS managed servers: If data are collected/entered directly onto a Departmental or CIS managed server, **you must ensure** that the server meets the security standards described in the Minimum Security Standards for Servers based on the Risk Level of the data identified in 1D.

PART VII. APPENDICES

Please complete & attach the following Appendices to this Application, as applicable.

Incl.	N/A	
☐	☒	Appendix A. Children as Subjects *To be attached when minors are included as participants [please be aware of the age of majority for your specific research site(s)]*
☐	☒	Appendix B. Prisoners as Subjects *To be attached when prisoners are included as participants.*
☐	☒	Appendix C. Use of Drugs *To be attached when the research includes the use of FDA-regulated or unregulated drugs.*
☐	☒	Appendix D. Use of Devices *To be attached when the research includes the use of FDA-regulated or unregulated devices.*
☐	☒	Appendix E. Prescription Drug / Medication Management *To be attached when study procedures include administering prescription medications to study participants.*
☐	☒	Appendix F. Mental Health Safety Plan *To be attached when participants may experience significant emotional distress, or be at risk of themselves or others.*
☐	☒	Appendix G. Use of Protected Health Information (PHI) for Research *To be attached when study procedures include a plan to access, use or disclose Protected Health Information (PHI) of participants.*
☐	☒	Appendix H. International Research *To be attached when study involves human subjects research outside the United States.*
☐	☒	Appendix I. Advisor Appendix *To be attached when a graduate or medical student is the Principal Investigator.*

PART VIII. ATTACHMENTS

Please attach the following materials to this Application for Expedited / Full Board IRB Review, as applicable.

Incl.	N/A	
☐	☒	Additional Investigator COI
☐	☒	Application for IRB Authorization Agreement (IAA)
☒	☐	Data collection materials (questionnaires, surveys, interview scripts, etc.)
☐	☒	Data Safety Monitoring Plan
☐	☒	Data Use Agreement from data provider(s)
☐	☒	DSMB Charter Template
☐	☒	HIPAA Authorization
☒	☐	Informed consent documents / scripts
☐	☒	Permissions, approval documents, and/or support letters

☒	☐	Recruitment materials (emails, flyers, letters, scripts, posters, brochures, etc.)
☐	☒	Request for Approval to Serve as Principal Investigator on a Human Subjects Research Application
☐	☒	Other: Click or tap here to enter text.

PART IX. CONFLICT OF INTEREST

The *Brown University Conflict of Interest Policy for Officers of Instruction and Research* *("COI Policy")* defines the term "Investigator" as "the project director or principal investigator and any other person, regardless of title or position (e.g., full or part-time faculty member, staff member, student, trainee, collaborator, or consultant), who is **responsible** for the **design, conduct, or reporting** of sponsored research."

Using this definition of "Investigator," please ensure that all Investigators on this protocol answer questions (1) and (2) below. Attach additional sheets for any Investigators who are not the PI; additional sheets are available on the HRPP website.

☐	I am affiliated with Rhode Island School of Design and will abide by policies and procedures set forth by my institution.

1. Have you completed a conflict of interest disclosure (i.e. *COI Reporting Form*) within the past 12 months and is it accurate and up-to-date as of the time of this submission, as required by Brown's COI Policy? (If you have not completed this disclosure, access the InfoEd system here.)

☒ Yes ☐ No	If "no," please do so before submitting this Application

2. Do you have a significant financial interest (SFI) that is related to this research protocol?
"Related" could mean the research involves products, technology, intellectual property, or services made, owned, or provided by the entity/ies in which you have an SFI. It could also mean that the SFI could be affected by the proposed research or its results.

☐ Yes ☒ No	If "yes," please identify the SFI and explain the relatedness: Click or tap here to enter text.

3. Do you have a faculty advisor or other Brown investigators working on this study?

☐ Yes ☒ No	Additional COI sheets for Investigators are attached to this Application.

PART X. PRINCIPAL INVESTIGATOR AGREEMENTS & RESPONSIBILITIES

A. Conduct of the Research

1. I accept responsibility for the ethical conduct of this research and protection of participants as set forth in the Belmont Report, Common Rule, and Brown University policies.
2. I accept responsibility for ensuring this research is conducted in accordance with:
   a) Sound research design and methods;
   b) The parameters of the research plan and activities described in this Application;
   c) The applicable terms of the grant, contract, or other signed funding agreements;
   d) Applicable laws and regulations, including those protecting the rights, safety and welfare of human subjects.

3. I certify that I am, or my faculty advisor is, sufficiently qualified by education, training and experience to assume responsibility for the proper conduct of this research. I accept responsibility for ensuring that all member of the research team have or will complete human
4. subjects CITI training before any work with participants or identifiable data / biospecimens begins.
5. I accept responsibility to personally conduct and/or directly supervise this research. I certify that I have sufficient time and resources to properly conduct and/or supervise this research.

B. Ensuring and Maintaining Compliance

1. I will comply with relevant regulatory and institutional reporting requirements, including Brown University's *Reportable Events Policy*.
2. I understand that it is my responsibility to ensure that any research personnel, including myself, responsible for the design, conduct or reporting of the research declares any conflicts of interest related to this research. I will ensure that any changes that impact my or other research personnel's answers to the questions in PART IX. Conflict of Interest, are reported promptly to Brown's HRPP.
3. I will ensure that prospective agreement and/or informed consent is obtained and a copy is provided to participants, when appropriate.
4. If there are changes to the research described in this Application for Expedited / Full Board IRB Review that may impact the study's classification as Full Board or Expedited research, I will promptly notify the Brown HRPP of such changes.
5. I will notify the Brown HRPP when I have completed all activities involving human subjects or identifiable participant data or identifiable biospecimens.
6. I will maintain approval, as applicable, with collaborative parties, including approvals from other countries or jurisdictions.
7. I will cooperate with any post-approval monitoring or auditing of study activities and/or study records as requested and/or required by the Brown ORI, the Brown IRB, funding entities, sponsors, and/or any federal or state regulatory agencies.

C. Study records, Reports and Documentation

1. I will comply by Brown's *Research Data and Research Materials Management, Sharing and Retention Policy*.
2. I will maintain all research protocol materials and consent materials for the duration of this study.
3. I will maintain research records for at least three years following the end of this research, or for a longer length of time if specified in applicable regulations or sponsor requirements. I will take measures to prevent accidental or premature destruction of these records.
4. I will abide by all terms of any Data Use Agreement (or equivalent agreement) related to this study, including those agreed to electronically (through an online attestation).
5. I will ensure that the data security measures for acquisition, collection, transfer and use of study data described in PART VI. of this Application are adhered to by all members of the research team.

By my signature below, I certify that I have read and agree to uphold all of the Agreements and Responsibilities in PART X.

Principal Investigator signature: **Date:** 5/11/2021

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For IRB Use Only

Signature of the IRB:

Date of IRB approval: Click here to enter a date.