
Protocol Title:	Title of Research: Here
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Date Submitted:	Draft
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* * * Personnel Information * * *

Study Personnel Roles:
-Principal Investigator: accepts responsibility for study, can edit protocol, must submit to IRB
-Administrative Contact: additional study contact, can edit/prepare protocol, may or may not also be member of research team
-Key Personnel (Research Team): Pepperdine University member of research team, can view protocol (not edit)
-Non-Pepperdine Collaborator: member of research team from another institution or organization outside of Pepperdine University, has no access to system, must be provided with PDF of protocol.

IMPORTANT NOTE: Human Subjects Protection Training is mandatory for all research team personnel.

Principal Investigator Mandatory

PI must be Pepperdine University affiliate.

Name of Principal Investigator (Faculty, Staff or Student)	Degree (MD/PhD/Other)	Title
Jane Smith	MA	Student
Email	**Phone**	**Fax**
janesmith@pepperdine.edu	3109876543	
School	**Division**	
Graduate School of Education and Psychology	Psychology	

Please indicate your status	Student
Human Subjects Training Completed?	Y

If you have completed training that is not auto-populated below, upload a copy in the Attachments section.

No training data is available.

Faculty Chair / Sponsor - Mandatory for Investigators with Student Status

Name of Faculty Chair/Sponsor	Degree (MD/PhD/Other)	Title
Judy Ho		Ph.D.
Email	**Phone**	**Fax**
Judy.Ho@pepperdine.edu	310.568.2305	

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School	Division
Graduate School of Education and Psychology	Psychology

Human Subjects Training Completed? Y

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* * * Vulnerable Population * * *

Vulnerable Population(s) Checklist

Select All That Apply:

- Individuals with impaired decision-making capacity
- Fetuses
- Minors (under 18)
- Pregnant Women
- Prisoners
- X None of the above

If any of the vulnerable populations are selected above, explain using the space below why this vulnerable population is included in this study.

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* * * Study Location * * *

Study Location(s) Checklist

Indicate the location where the study will be conducted (e.g. where will the data will be collected?). Select all that apply:

- [ ] Pepperdine campus
- [ ] Other U.S. Location
- [X] Online
- [ ] Phone
- [ ] International Location
- [ ] Other (In the box below, list any off-campus institutions or locations and describe the activities being conducted there. Please provide letters of cooperation and/or IRB approvals from each location to document support/approval of the study.)

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* * * Review Type and General Checklist * * *

Review Type

Choose one of the review types below. You can determine which application to submit by reviewing the one-page handout entitled Exempt-Expedited Decision Tree. For more details on each type of application, check out the Exempt Research Guide and the Expedited Research Guide.If you believe your study may be eligible for full review, please select "expedited review" and carefully review the categories listed in the following section. The IRB will make the final "review type" determination.

- [ ] Study Eligible for Expedited Review
- [X] Study Eligible for Exempt Review

Non-human subjects research. If you believe your project does not constitute human subjects research, per Pepperdine University Institutional Review Board (IRB) guidelines, please review and complete the Non-Human Subjects Notification Form and submit to the IRB manager.

General Checklist

Select All That Apply :

- [X] Via E-Mail or The Internet
- [ ] Via Interviews
- [ ] Genetic Testing
- [ ] Human Blood, Cells, Tissues, or Body Fluids
- [ ] Investigational Drugs, Reagents, Chemicals, or Biologic Products
- [ ] Investigational Equipment (e.g. Spirometer, Sphygmomanometer, Portable Oxygen)
- [ ] Medical and/or Psychological Records
- [ ] Photography, Video, or Voice-Recording Subjects
- [X] Questionnaires, Surveys, and/or Tests
- [ ] Study of Existing Data
- [ ] Other (Clarify in Text Box to the Right)

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* * * Funding * * *

Funding Checklist

X **NONE**

NOTE: Applicable grant application, contract or subcontract, investigator's brochure, and sponsor's protocol (for all industry sponsored clinical trials) must be attached. Click "Add" to attach the documents.

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* * * Exempt Paragraphs(s) * * *

Federal regulations state that certain research is exempt from IRB oversight. However, a research protocol proposing the use of human subjects must be submitted to the IRB to determine if it qualifies for exempt status. EXEMPTIONS DO NOT APPLY TO RESEARCH INVOLVING PRISONERS.

45CFR46.101(b) Unless otherwise required by Department or Agency heads, research activities in which the ONLY involvement of human subjects will be in one or more of the following categories are exempt from this policy:

Select one or more of the following paragraph(s):

1. **Research conducted in established or commonly accepted educational settings, involving normal educational practices. This includes most:**

   i) Research on regular and special education instructional strategies, OR

   ii) Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

X 2. **Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior. Research involving these procedures is exempt, IF one of the following is correct:**

   i) Any information obtained is recorded in such a manner that subjects CANNOT be identified, directly or through identifiers linked to the subjects; OR

   ii) Any disclosure of the subjects' responses outside of the research could NOT reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, educational advancement, or reputation; OR

   iii) Any information obtained is recorded by the investigator in such a manner that the identity of the human subjects CAN readily be identified, directly or through identifiers linked to the subjects, AND an IRB conducts a Limited IRB review to make the determination required by 45 CFR 46.111(a)(7) and the research is not subject to 45 CFR 46 Subpart D.

   NOTE: Exemption for research involving survey or interview procedures or observation of public behavior does not apply to children as subjects except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.

3. **Research involving benign behavioral interventions in conjunction with the collection of information from adult subjects through verbal or written response (including data entry) or audiovisual recording, if the prospective subject agrees to the intervention and information collection, is exempt, IF**

   i) Any information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be identified, directly or through identifiers linked to the subjects, OR

   ii) Any disclosure of the subject's responses outside of the research could NOT reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation; OR

   iii) Any information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be identified, directly or through identifiers linked to the subjects, and an IRB conducts a Limited IRB review to make the determination required by 45 CFR 46.111(a)(7).

4. **Secondary Research involving collection or study of existing data, documents, records, or biospecimens, for which consent is not required is exempt, IF:**

   i) The identifiable private information or identifiable biospecimens are publicly available; OR

   ii) Information, which may include information about biospecimens, is recorded by the researcher in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify the subjects; OR

   iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subpart A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 1.512(b); OR

   iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private

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information that is or will be maintained on information technology that is subject to and in compliance with section 298(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 5521, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501et seq.

5. **RESEARCH AND DEMONSTRATION PROJECTS CONDUCTED BY OR SUBJECT TO THE APPROVAL OF DEPARTMENT OR AGENCY HEADS: This research is exempt IF it is designed to study, evaluate, or otherwise examine:**

   i) Public benefit or service programs;
   ii) Procedures for obtaining benefits or services under those programs; OR
   iii) Possible changes in or alternatives to those programs, OR
   iv) Changes in methods or levels of payment for benefits or services under those programs.

   Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts of consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 115A of the Social Security Act, as amended.

   Note: Each Federal department or agency conducting or supporting research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

6. **TASTE AND FOOD QUALITY EVALUATION AND CONSUMER ACCEPTANCE STUDIES: This research is exempt, IF:**

   i) Wholesome foods without additives are consumed; OR
   ii) A food is consumed that contains a food ingredient at or below the level and for a use found to be safe by the Food and Drug Administration (FDA) or approved by the Environmental Protection Agency (EPA) or the Food Safety and Inspection Service (FSIS) of the US Department of Agriculture (USDA); OR
   iii) A food is consumed that contains an agricultural chemical or environmental contaminant at or below the level found to be safe by the FDA or approved by the EPA or the FSIS of the USDA.

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* * * Purpose , Study Procedures * * *

Study Title

Title of Research: Here

Complete Sections 1 - 11. Specify N/A as appropriate. Do not leave any required sections blank.

1. Purpose of the study

a) Provide a brief (<200 words) explanation of the proposed research, including specific study hypothesis, objectives, and rationale. The lay summary should be readily understandable to the general public.

Hypothesis: We hypothesize that XYZ.

Objectives:

1. To deliver survey scales online via a Qualtrics study to participants of all ages 18+
2. To better understand XYZ
3. To better understand XYZ
4. To better understand XYZ
5. To understand the reasons why individuals XYZ
6. To ask questions related to XYZ to better understand the underlying causes of XYZ
7. To estimate the average amount of XYZ participants are XYZ

Rationale:
There are several XYZ scales or measures that research suggests show both reliability and validity in practical applications. The current study takes aim at a broad population of participants from all 18+ age demographics and backgrounds to determine the prevalence of XYZ in the U.S., and to determine an average of daily XYZ by different age groups. In a fully online Qualtrics survey that automatically deidentifies participant data, we will measure the XYZ scales, the XYZ, and other socio-environmental constructs to learn about the use of XYZ.

b) List your research questions. (Applicable only to full review)

c) Describe the study design (e.g., single/double blind, parallel, crossover, control, experimental, observational, etc.)

- N/A
- Quantitative
- Qualitative
- X Mix Methods (Quantitative + Qualitative)
- Observational
- Other (if selected, provide description in response box below)

2. Study Procedures

a) Is this project a multicenter study (i.e., same project is conducted elsewhere by a different investigator)? (Applicable only to expedited and full review)

Is Pepperdine University acting as a coordinating center for other sites?

Will the Pepperdine University site be participating in all parts/procedures/arms of the study?

If No, explain what Pepperdine University will NOT participate in:

b) Describe in chronological order of events how the research will be conducted, providing information about all study procedures and who will conduct each.If any interviews, questionnaires, surveys, or focus groups will be conducted for the study, explain and attach one copy each of all study instruments (standard and/or non-standard) in the "Attachments" section.

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Please see the "Attachments" section of this protocol for additional information.Indicate frequency and duration of visits/sessions, as well as total time commitment for participants in the study and an estimated time frame for when the study will be completed.If the proposed research involves use of existing data/specimens, describe how data/specimens will be acquired.

1. Subjects will receive and complete a survey issued via an email listserv, or social media (i.e LinkedIn, Facebook, etc.).
2. Subjects will click on the link which will lead them to a Qualtrics study
3. Subjects can access the survey on a computer, XYZ, or tablet.
4. Subjects will read the informed consent and select “I agree” if they want to continue the survey. If the subject does not want to participate, they can exit the survey, or select “I do not agree.” If they select “I do not agree”, the survey will end.
5. If the subject agrees to consent, they will progress through the survey. After the final question, the survey will end.
6. Estimated time commitment is 20-30 minutes, and will occur over one session.
7. The total length of the study is XYZ. The first six months of the study will be recruiting a high number of participants (XYZ +). The survey will be closed in July 2023. Three months will be spent analyzing data and summarizing results. The final publication will take approximately three months. The total time of the study is estimated to be completed by December 2023.
8. All surveys completed via Qualtrics will be automatically de-identified of participant data. De-identified data will be stored for 3 years and then destroyed.
9. All data will be held by the PI in a password-protected computer and with a password-protected file. PI's computer is in a locked office.

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* * * Subject Population(a-f) * * *

3. Subject Population - In the space below, please detail the participants that you are requesting to recruit (include description of each group requested)

a) Expected age range of subjects. (For example ? 18 yrs to 90 yrs). (Applicable only to full review)

b) Estimated total (maximum) number of subjects planned for the study (this should include recruitment numbers). N/A: 1000

c) If applicable, state the rationale for involvement of potentially vulnerable subjects to be entered into the study, including minors, pregnant women, prisoners, or decisionally impaired individuals. (Applicable only to full review and Expedited)

d) If women, minorities, or minors are excluded, a clear compelling rationale must be provided. Examples for not including minors: disease does not occur in children; drug or device would interfere with normal growth and development; etc.

Minors are excluded from the study because minors are shown to exhibit greater compulsive behavior. Women and minorities are not excluded from the study as PI is looking to learn about the use of XYZ across the life span and developmental stages.

e) Are any of the specifically targeted subjects a Pepperdine student or a Pepperdine employee? Please note that if targeted subjects are either a Pepperdine student or a Pepperdine employee, you will be required to provide risk mitigation steps (specifically risks of coercion) in the "Risk" section of this protocol.

- [ ] Student
- [ ] Employees
- [X] Both of the above
- [ ] None

f) Describe how potential subjects will be identified for recruitment (e.g., chart review, referral from individual's treating physician, those individuals answering an ad). How will potential participants learn about the research, and how will they be recruited (e.g., flyer, e-mail, web posting, telephone, etc.)? State where recruitment materials will be located. Click "Add" to upload recruitment materials document.

Important to remember: potential subjects cannot be contacted before IRB approval.

1. Subjects will be recruited via social media and via email listservs using the recruiting template enclosed in the attachments section.
2. Subjects will only need to click on the link that will take them to the Qualtrics survey.
3. The first step of the Qualtrics link will deliver the Informed Consent, and subjects will need to read the informed consent and select “I agree” if they want to continue the survey.
4. If the subject does not want to participate, they can exit the survey, or select “I do not agree.” If they select “I do not agree”, the survey will end.
5. If the subject agrees to consent, they will progress through the survey. After the final question, the survey will end.
6. The estimated time commitment is 20-30 minutes, and will occur over one online Qualtrics survey session.

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* * * Subject Population(g-i) * * *

3. Subject Population (continued)

g) **Inclusion and Exclusion Criteria.**

Identify Inclusion Criteria. Inclusion criteria are characteristics that the prospective subjects must have if they are to be included in the study, or the key features of the target population that the investigators will use to answer their research question. Typical inclusion criteria include demographic, clinical, and geographic characteristics such as age, gender, race, ethnicity, marital status, educational experience, language, type of occupation, physical activity, medical conditions, and the presence of medical, psychosocial, or emotional conditions. For additional guidance and examples of inclusion and exclusion criteria please click here.

You are over the age of 18 and you have/are XYZ

Identify Exclusion Criteria. Exclusion criteria are defined as features of the potential study participants who meet the inclusion criteria but present with additional characteristics that could interfere with the success of the study or increase their risk for an unfavorable outcome. Common exclusion criteria include characteristics of eligible individuals that make them highly likely to be lost to follow-up, miss scheduled appointments to collect data, provide inaccurate data, have comorbidities that could bias the results of the study, or increase their risk for adverse events such as side effects (most relevant in studies testing interventions). For additional guidance and examples of inclusion and exclusion criteria please click "https://community.pepperdine.edu/irb/content/inclusionexclusioncriteria.pdf" target="_blank"here.

You are under the age of 18, or you do not have/are XYZ

N/A

h) **Compensation. Explain any compensation for study subjects, including dispensing gift cards or drawings for prizes.**

After the participant completes the Qualtrics survey, they will have the option to click on another link and enter their information for a drawing to win an Amazon gift card for $25, there will be two drawings.

i) **Estimate the probable duration of the entire study including:- Subject recruitment- Include the total time each subject is to be involved- Any subject follow-up- Data analysis and publication**

The total length of the study is one year. The first six months of the study will be recruiting a high number of participants (1000+). The survey will be closed in July 2023. Three months will be spent analyzing data and summarizing results. The final publication will take approximately three months. The total time of the study is estimated to be completed by December 2023.

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* * * Risks and Discomforts * * *

4. Risks and Discomforts

There is no research that can be considered totally risk free (e.g., a potential risk of breach of confidentiality). Therefore, when describing the risk, the lowest level of risk is "no more than minimal risk". For the following categories remember to consider scientific estimate of the frequency, severity, and reversibility of potential risks. In describing these risks to subjects in the consent form, it is helpful to use comparisons which are meaningful to persons unfamiliar with medical terminology.

For examples of types of risk, click link here.

a) Please check the appropriate box for level of risk that applies to your study:

X No greater than minimal risk - The probability and magnitude of harms or discomforts anticipated in the research protocol are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological exams or tests. Examples of "Minimal Risk" activities include: Study poses no more risk than expected in daily life (e.g., blood draw, physical exam, routine psychological testing). Non-interventional studies (e.g., observational studies of behavior or nutrition). Survey/Questionnaire studies of a non-sensitive nature. Electrophysiological studies in healthy subjects or clinical populations (surface recordings such as EEG, ERP, MEG) Genomic studies Non-invasive imaging (e.g., MRI and fMRI) in healthy subjects or clinical populations to investigate basic mechanisms of brain function. Research involving the collection or meta-analysis of existing data, documents, records, pathological specimens, or diagnostic specimens to understand basic bio-behavioral processes.

Greater than minimal risk - The probability and magnitude of harm or discomfort anticipated in the research protocol are greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological exams or tests, but these risks are considered to be acceptable when weighed against the anticipated benefits and the importance of the knowledge to be gained from the research. Examples of "Greater than Minimal Risk" activities:Monitored by the Principal Investigator and IRB: Some imaging studies (e.g. PET scan) Studies using transcranial magnetic stimulation Post-approval studies of FDA-approved drugs or devices (may require an independent safety monitor if the PI is blinded to randomization)Monitored by an Independent Safety Monitor (in addition to the PI and IRB): Studies involving treatment delays or medication washouts or placebo-controlled studies in clinical populations Subjects with serious mental illness in a treatment study (may require an independent DSMB) Some first-in-human or Phase I investigational intervention (may require an independent DSMB based on preclinical findings)

b) Please describe any reproductive risk associated with any part of the research study. Include any data from other studies (animal or human). (Applicable only to expedited and full review)

c) Describe any risks related to the study procedures and include the ways you will reduce the risk in the space below. Examples include: provide breaks to reduce fatigue, provide resources for emotional distress.Note that even if the study is no greater than minimal risk, you must complete this section.

- No study is completely risk-free, and this study poses no more risk than expected in daily life using a XYZ. We do not anticipate that the participants will be harmed or distressed during this study.
- The participants may stop being in the study at any time if they become uncomfortable with the survey questions.
- Potential risks to participants include the risk of boredom or fatigue. There is a small possibility that responses could be viewed by unauthorized parties (e.g., computer hackers).
- The collection of such data is not expected to present any greater risk than the participant would encounter in everyday life when sending and/or receiving information over the internet or XYZ.
- Data will be deidentified and use Qualtrics. Qualtrics encrypts all data in transit using Hypertext Transfer Protocol Secure (HTTPS) and enforces HTTP Strict Transport Security (HSTS) to prevent attacks, eavesdropping, and session hijacking.

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* * * Benefits/Alternatives, Procedures to Maintain Confidentiality * * *

5. Benefits/Alternatives

a) **Benefits. Describe any potential benefits to the individual subject, group of subjects, and society in general. If subjects will not benefit directly from study procedures, this should be stated.NOTE: Do not include compensation/payment of subjects in this section, as remuneration is not considered a "benefit" of participation in research.**

Being a participant in this study will not help the individual. Information from this study might help researchers better understand the populations with the highest prevalence of XYZ.

b) **Alternatives. Describe any alternative treatments and procedures available to the subjects should they choose not to participate in the study. If no such alternatives exist, please state that "the alternative is nonparticipation". For some studies, such as record reviews, a description of alternatives would not be applicable.**

The alternative is nonparticipation.

6. Procedures to Maintain Confidentiality

Federal regulations require that study data and consent documents be kept for a minimum of three (3) years, and HIPAA documents be kept for a minimum of six (6) years after the completion of the study by the PI. For longitudinal or sponsored projects, the PI may be required to keep the data and documents for a longer time period.

Data Security

All information must be stored using at least two of the following safeguards and must be kept in accordance with the Pepperdine University Information Security Policies. (If you are using both electronic data and hard copy data, you will need two safeguards for each type).

Electronic Data

> Password access

> Coded, with a master list kept as a hardcopy or on a secure network (confidential)

> Data collected anonymously

> Secure network (e.g. firewall)

> Data are de-identified by PI or research team

Hardcopy Data

> Locked suite

> Locked office

> Locked file cabinet

> Coded, with a master list kept secured and separately (confidential)

> Data collected anonymously

> 24 hour personnel supervision

> Data are de-identified by PI or research team

For example document, click link here.

a) If applicable, how will you maintain anonymity of participants and data? Explain the specific steps you are taking to ensure anonymity of participants (in 6 sentences or less). A response to this question is required, but if appropriate you may indicate the question is "not applicable" for your study.Anonymity is a condition in which the identity of individual subjects is not known to researchers.

All surveys completed are entirely anonymous since they are delivered via Qualtrics which automatically de-identifies participant data. All participant information will be kept completely anonymous.

b) How will you maintain confidentiality of participants and data? Explain the specific steps you are taking to ensure confidentiality of participants (in 6 sentences or less).Confidentiality refers to a condition in which the researcher knows the identity of a research subject, but takes steps to protect that identity from being discovered by others.

- Data will be deidentified through the use of Qualtrics. Qualtrics encrypts all data in transit using Hypertext Transfer Protocol Secure (HTTPS) and enforces HTTP Strict Transport Security (HSTS) to prevent attacks, eavesdropping, and session hijacking.
- No identifying information will be taken, unless participants want to enter to win a $25 Amazon gift card. Those names will be kept separate from the data. Once the raffle is completed, all of these names/emails will be deleted.

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- Digital data will have password encryption in the PI's cloud storage and computer. The de-identified data collected via Qualtrics will be stored on a password-protected computer for three years and then destroyed.

c) If data or specimens are being shared outside of the research team, indicate who will receive the materials and specifically what they will receive (data or specimen). Describe specific measures to protect shared participant data (in 6 sentences or less).

N/A

d) Y Secure Data Transport - I acknowledge that I will secure data during all applicable transport to the best of my ability using best practices for my field.

e) Y Paper Data Security - I acknowledge that I will securely store any paper data in a locked location with access only to the researcher for at least 3 years after the date of collection.

f) Y Electronic Data Security - I acknowledge that I will securely store any electronic data (this includes audio/video recordings and photography files) to the best of my ability, using best practices for my field, for at least 3 years from the date of collection.

g) Y Data Destruction - I acknowledge that after at least 3 years of secure storage, I will destroy my data in a manner that renders it irretrievable. (If you have electronic data, please make sure to digitally erase it rather than simply deleting it.)

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* * * Potential Conflict of Interest * * *

7. Potential Conflict of Interest

Indicate whether you, your spouse or dependent children, or any investigator participating in the study have, or anticipate having, any income from or financial interest in a sponsor of this protocol, or a company that owns/licenses the technology being studied or any other entity which may affect the outcome of this research? Financial Interest includes but is not limited to: consulting; speaking or other fees; honoraria; gifts; licensing revenues; other research agreements; equity interests (including stock, stock options, warrants, partnership and other equitable ownership interests). For questions regarding Conflict of Interest consult the Conflict of Interest in Research Policy.

Check one of the following:

a) X No Financial Interest or Financial interest less than or equal to $5K

b) Potential Financial Conflict of Interest (You must submit a Conflict of Interest Disclosure form in the "Attachments" section of this IRB protocol.)

Note to Investigator(s) Reporting a Potential Conflict of Interest

Investigator(s) must have:

a) Current, up-to-date Conflict of Interest Disclosure form attached to this IRB protocol that describes any financial relationship indicated above.

. This information must be disclosed on the Pepperdine University Confidential Conflict of Interest Disclosure Form (found on the IRB website, under the Special Circumstances section) and reviewed by the necessary signatories before accruing research subjects in this study. If your current Disclosure Form does not contain this information, you are required to submit an updated Disclosure Form to the IRB Manager.

b) Financial disclosure statement incorporated into the consent document.

c) You may not begin your study until your disclosure form has been reviewed and any required management plan has been approved by the appropriate signatories.

Does any member of the study team, members' spouses, or members' dependent children have any significant financial interests related to the work to be conducted as part of the above-referenced project? N

Name of Personnel with Financial Conflict of Interest

Other research staff that may have a conflict. Please specify below.

A staff person will contact any researcher listed above to obtain additional information regarding the specific financial interest(s).

I certify that all members of the study team have answered the financial interests question and only those individuals listed in the box above have disclosed any financial interest related to this study. Y

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* * * Informed Consent * * *

8. Informed Consent

Federal regulations require that informed consent be obtained from individuals prior to their participation in research unless the IRB grants a waiver of consent. Answer the questions, below, then click Add to provide the necessary consent documents and information regarding subject consent. Multiple consents/waivers may be added, but they must be uploaded one at a time.

NOTE: You may refer to the Pepperdine University IRB Guidance for Obtaining Informed Consent for considerations regarding the consent/assent process.

State N/A if not applicable.

a) **How is consent being obtained? When and where will the communication take place?**

- Informed Consent will be delivered within the Qualtrics survey and it will be first.
- There will be a statement Participants will have to click "I agree" before beginning the survey. After reading the informed consent, participants will agree/disagree to:

-By clicking the link below you agree to the following statements:
I have read this form, and I voluntarily agree to be in this study.
I have not given up any of my legal rights as a research participant. I will print a copy of this consent information for my records.

-If they disagree the survey will end.

b) **If the study involves a cognitively impaired population, what steps are you taking to determine that potential subjects are competent to participate in the decision-making process? If you may need to seek surrogate consent, please explain how you will obtain surrogate consent.**

c) **If a study involves non-English speakers, what steps are you taking to provide translation of consent documents, who will obtain informed consent? Will translation sources be provided for the duration of the study? NOTE: If a study involves non-English speakers, then Investigator must provide professional translation of consent documents.**

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* * * Assent * * *

9. Assent

Complete this section if your study includes minors. An assent document should be used if subjects are 6 to 17 years of age. The Assent Form Template provides guidelines for writing assent documents.

a) Will minors be asked to give assent? If not, please justify.

b) If minors are asked to assent and do not wish to participate, will they still be accrued in the study? If yes, justify.

c) How will the minor's ability to give assent be assessed? (Consider the age and maturity of the minors as well as their physical or mental condition).

Note: For studies that require a discussion about reproductive risks, note that the conversation with the minor should take place separately from the parents. Also, if a minor will reach adulthood (18 in Missouri) during the course of the study, they will need to be asked to consent as an adult at that time to continue in the study.

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* * * HIPAA * * *

10. HIPAA

Studies that receive or create protected health information (PHI) are subject to HIPAA regulations. PHI is health information with one or more personal identifiers. For more information see: http://community.pepperdine.edu/irb/investigator-resources/

a) Will health information be accessed, received or collected?

X No health information. HIPAA does not apply.

Yes (continue to question 2).

b) Which personal identifiers will be accessed, received or collected?

No identifiers. I certify that no identifiers from the list below will be received or collected and linked to health information. HIPAA does not apply (skip remainder of page).

Names

Social Security numbers

Telephone numbers

Linkable code or any other unique identifying number (note this does not mean the unique code assigned by the Investigator(s) to code the research data)

All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if, according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000

All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older

Fax numbers

Electronic mail addresses

Medical record numbers

Health plan beneficiary numbers

Account numbers

Certificate/license numbers

Vehicle identifiers and serial numbers, including license plate numbers

Device identifiers and serial numbers

Web Universal Resource Locations (URLs)

Internet Protocol (IP) address numbers

Biometric identifiers, including finger and voice prints

Full face photographic images and any comparable images

c) Sources of Protected Health Information:

Hospital/medical records for in or out patients

Physician/clinic records

Laboratory, pathology and/or radiology results

Biological samples

Interviews or questionnaires/health histories

Mental health records

Data previously collected for research purposes

Billing records

Otherr Please describe:

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d) **If data will be shared outside the research team and the study involves PHI indicate how the research team will share the information.**

Not applicable (continue to question 5).

Only linkable code that can link data to the identity of the subject. A code access agreement or business associate agreement may be needed when data are shared with other non-Pepperdine University entities. If necessary, the agreement can be added and uploaded in item #5, below.

Limited identifiers: Zip codes, dates of birth, or other dates only. The study qualifies as a Limited Data Set. A data use agreement may be needed when data are shared with other non-Pepperdine University entities. If necessary, the agreement can be added and uploaded in item #5, below.

With unlimited identifiers. The consent document and HIPAA Authorization form must describe how the information will be disclosed.

e) **A HIPAA Authorization Form or Waiver of HIPAA Authorization is required for this study. You must upload HIPAA Documents for your study in the "Attachments" section of this protocol. If you are accessing medical records, or other health records that include PHI, you must complete a waiver of HIPAA authorization.**

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* * * Attachments * * *

11. Attachments

In this section, please upload additional documents associated with your protocol. Failure to attach files associated with the protocol may result in the protocol being returned to you. Templates can be found on Pepperdine's IRB Forms page.

To update or revise any attachments, please delete the existing attachment and upload the revised document to replace it.

Possible documents for this protocol could include:

Accessing Capacity to Consent Form
Confidentiality Form
Cooperating Institution's IRB Approval
Cooperating Authorization Agreement
Data Collection Sheet
Data Protection Plan
Debriefing Consent Form
Debriefing Information Sheet
Debriefing Script
Dissertation (Ch. 1-3)
FERPA Form
Grant Proposal/Sub-Contract
Human Subjects Training Certificate/Proof of Training (required for all protocols)
Information Sheet
Interview/Focus Group Questions
Investigator's Brochure
Medical Consent Form
Parental Notification Form (Minors)
Questionnaire/Survey
Recruitment Material (e.g., flyers, ads, e-mail text)
Research Proposal
Research Consultant Non-Engagement Agreement
Short-Form Consent for Non-English Speakers to Participate in Research
Site Approval
Unaffiliated Outside Investigator Agreement
Verbal Consent Form
Other files associated with the protocol (most standard formats accepted: pdf, jpg, tif, mp3, wmv, etc.)

Document Type	Document Name	Attached Date	Submitted Date
Human Subjects Training Certificate/Proof of Training	2Detailed CITI IRB Scores - citiCompletionReport10616719	12/20/2022	

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* * * PI Obligations * * *

PI Obligations

By clicking the box below you indicate that you accept responsibility for and will follow the ethical guidelines set forth by the Belmont Report, Declaration of Helsinki, the Nuremberg Code, and the Ethical Principles of the American Psychological Association (if applicable) for the research described. Modifications to the research described will be submitted for further review.

Submission by the Principal Investigator (PI) indicates that the PI and any co-investigators and/or research personnel has reviewed and will follow the Pepperdine IRB PI Checklist, has the requisite funding, credentials, training, and any necessary hospital privileges, if needed, to carry out all procedures and treatments involved in the protocol. Additionally, the PI certifies that the IRB PI checklist has been reviewed and guidance will be reviewed with all Key Personnel.

Clicking the box also affirms that the activities involving human subjects will not begin without prior review and approval by the Institutional Review Board, and that all activities will be performed in accordance with state and federal regulations and Pepperdine University's assurance with the Department of Health and Human Services. The PI assures that if members of the Pepperdine University research team access protected health information (PHI) from a Pepperdine University covered entity in order to seek consent/ authorization for research, such access is necessary for the research, is solely for that purpose, and the information will not be removed from the covered entity without IRB authorization or approved waiver.

I accept this responsibility.

By submitting this form, the PRINCIPAL INVESTIGATOR certifies that he/she has read the University's Conflict of Interest Research Policy and has checked the appropriate box in the 'Potential Conflict of Interest' section of the application. In addition, the PRINCIPAL INVESTIGATOR certifies that, to the best of his/her knowledge, no person working on this project at Pepperdine University has a conflict of interest or if a conflict of interest does exist, that an appropriate management plan is in place.

The Principal Investigator has read and agrees to abide by the above obligations.

The Faculty Chair/Sponsor has read and agrees to abide by the above obligations.

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* * * Event History * * *

Event History

Date	Status	View Attachments	Letters
12/20/2022	NEW FORM PROTOCOL CLONED (22-12-2055)		