Submission Type: Initial Date: 4-8-2025

Getting Started

WP Human Subjects Review:

All projects involving Human Subjects Research (HSR) at William Paterson must have an Institutional Review Board (IRB) review. This review must be completed prior to recruiting participants or initiating data collection. Visit the WP IRB website to learn more about the WPIRB, and to view guidance on federal regulations and institutional policies.

Please review the How to Submit a Protocol for IRB Review. This page has information onrequired training and other important tasks investigators must complete before initiating a new application.

Using the Cayuse Human Ethics (HE) Module

Cayuse HE is an interactive web application. Cayuse will replace InfoReady for submissions to the WP IRB. Your responses will trigger new questions and sections to appear. All required fields must be completed. You do not need to finish the application in one sitting.

- Each submission must identify a **Principal Investigator (PI).** Applications submitted bystudent PIs (undergraduate or master students) must also list the student PI as the **Primary Contact**. More information is provided in the Key Personnel section.
- Read the Key Study Personnel section carefully to learn which individuals must be listed as study team members, and how roles in Cayuse HE impact individuals'access to the submission.
- Navigation: Click on the arrows at the bottom and top right corners of the application tomove from one section to the next. To navigate to a specific section, click on the section name on the left-hand menu.
- **Be sure to click "Save" frequently.** The "Save" button is in the top-right corner.

Types of Review Requested:

The Cayuse HE module uses one application to address different submission types. Click on the items below to learn how specific types of inquiries are handled within the Initial Submission form. Visit the IRB's Website to learn more about each category or review and email the IRBadministrator@wpunj.edu if you have any questions.

Oversight Determination

Exempt Research

Non-Exempt Research (Expedited and Full Board)

Submissions of Previously Approved Studies

Reliance on an External IRB

Attachments

Supporting documents (e.g., study instruments, consent forms, letters of support, etc.) can be uploaded to the attachment points that appear throughout the submission form. There isalso a summary Attachments page at the end of the application.

- Please ensure files are uploaded to the appropriate place (e.g., surveys uploaded to "Study Instruments," consent forms to "Consent Forms"). Multiple documents can beuploaded to each attachment point.
- Items should only be uploaded once. For instance, if a file contains both consent information and a survey, the preference is to upload the consent portion to the Consent attachment point and the survey to "Study Instruments." If this is not possible,upload the file containing both elements to one attachment point. Do not upload the same content more than once in an application.
- Submit recruitment materials, consent forms, and other files that may require revisions as Word Documents when possible. This allows the use of commentsand "Track Changes" during the review.

Completing the Submission

To complete the submission, you must:

- **Answer all required questions/Complete all sections.** Required questions are identifiedby a red asterisk(*). White checkmarks in the left-side menu indicate a section is complete. If a section is missing a white check mark, return to that section and complete all required questions.
- **COMPLETE SUBMISSION:** When all sections have been completed, the "COMPLETESUBMISSION" button will appear at the bottom of the left-hand menu. Click on the button to notify the PI that the submission is ready for their certification.
- **PI Certification:** The PI must certify every submission. To complete this step, the PImust click on the "CERTIFY" button. Note: **This button is found on the "Submission Details" page**, NOT within the submission.

Help and Support

There are several tools to assist users with their submission. Please consult the belowresources before contacting IRB for further support.

- Cayuse In-App Help Center: The large question mark icon at the bottom right cornerlinks to technical instructions on using the platform (e.g., how to make a new initial submission, how to complete a submission, etc.).
- WP Help Text: Small black question mark icons appear beside certain prompts. Click on those to view guidance on regulations and WP institutional policies, as well as examples and additional instructions. To make the text disappear, click the black iconagain.
- Hyperlinks: Click on the hyperlinks to access additional guidance on regulations andinstitutional policies.

If you continue to have questions or issues, contact IRBadministrator@wpunj.edu

Comments and Suggestions

The IRB appreciates comments and suggestions on the submission forms and processes. Ifyou encounter any problems or suggestions for improvement, please email IRBadministrator@wpunj.edu with "Feedback on Cayuse HE" as the subject line.

*required

I have read the information above and I am ready to begin my submission.

✓ **I Agree**

Key Study Personnel

Any individual who will interact with research subjects or have access to individually identifiable private information for research purposes must be listed on the Key StudyPersonnel page as a member of the study team.

- Required Entries: Every study must designate one **Principal Investigator** (PI) and one**Primary Contact**. The PI may serve as the Primary Contact.
- Student PI: Applications submitted by Undergraduate or Masters-level students mustlist the student PI as the **Primary Contact** and list the faculty advisor as the PrincipalInvestigator (PI).
- Primary Contact: To access/edit the application and receive system-generated notifications or other correspondence about study status from the IRB, an individual must be listed as a Primary Contact. A Primary Contact may be a project staff managerwho is not conducting human subjects research (HSR) but managing the IRB application and Cayuse workspace. A primary contact who is conducting HSR must also be listed as an investigator.
- Investigators: Individuals conducting Human Subject Research (HSR) activities who are not the PI must be listed as either a **Co-Principal Investigator** or an **Investigator**. These are Cayuse-defined terms that refer to system access and not to the roles/responsibilities of the individuals in the project. **Co-Principal Investigators** are able to edit the IRB application, while **Investigators** are not. Other than these Cayuse-specific distinctions, "investigator," "researcher," "study team member," and"study personnel" are used interchangeably by the IRB to refer to individuals conducting HSR activities.
- System notifications and Correspondence: Only the PI and the Primary Contact receivesystem-generated notifications and correspondence from IRB staff regarding the statusof IRB applications. Investigators who wish to receive communication about the application should be listed as a Primary Contact IN ADDITION TO being listed as either a Co-Principal Investigator or an Investigator.
- WP Researchers: WP-affiliated individuals conducting Human Subject Research activities should be added to the Key Study Personnel via the People Finder**. If youcannot find an individual in the People Finder, please email IRB Administrator**.
- Non-WP Researchers: If individuals NOT affiliated with WP are conducting Human Subject Research activities as part of this project, they must be identified using the text box fields provided below. Ethics training documentation for all non-WP investigators should be uploaded. If requested by the IRB, Individual Investigator Agreements (IIAs) for investigators not affiliated with an IRB should be uploaded here.

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*required

Principal Investigator: Add the Principal Investigator using the Person Finder below.

WP Policy: The Principal Investigator (PI) is ultimately responsible for the conduct of theentire study and all study team members.

- ***Each IRB submission must have one designated PI***
- To serve as PI, an individual must be a ***WP Faculty*** with an appropriate appointment or***WP Staff*** or be enrolled in a ***Doctoral Program at WP (e.g. PsyD, DNP, EdD students).*** Faculty Advisors for
- undergraduate or masters-level projects must be listed as PI. The student(s) will be listed below.

In Cayuse:

The PI is able to edit the IRB application and receive system-generated notifications and correspondence about the study from IRB staff.

Name:
Organization:
Address:
Phone:
Email:

Student Investigators

*required

Is the study student-driven (for the purpose of a thesis, class project, or other)?

Yes
✓ No

*required

Will other students be engaged in this human subjects research project?

Yes
✓ No

Faculty/Staff Investigators

Will other WP Faculty or Staff engage in this human subjects research?

✓ Yes

Check all that apply

Co-Principal Investigator
✓ Investigator

No

Investigators: Add WP Faculty/Staff Investigators using the Person Finder below.

Individuals designated "Investigator" are NOT able to edit the IRB application and do NOT receive system-generated notifications or other correspondence about the studyfrom IRB staff.
Name:
Organization:
Address:
Phone:
Email:

*required

Primary Contact

Is anyone else responsible for editing the IRB application and needs to receive system-generated notifications and correspondence about the study from the WP IRB staff?

Yes
✓ No

*required

Conflicts of Interest: Does a researcher or family member have a financial or other businessinterest in an entity that is supplying funding, materials, products, equipment, research participants, or the site of data collection for the current research project?

See Help Text for more information.

Yes
✓ No

*required

External Collaborators: Are non-WP-affiliated personnel conducting these human subjects research (HSR) activities?

- HSR activities include obtaining consent, interactions with human subjects for researchpurposes, and accessing private, identifiable data. For example, if data collection at an external site is administered by personnel from that site and involves direct interaction or intervention with human subjects, or access to identifiable private data, those individuals are considered external collaborators.
- Former students and employees who are not currently enrolled or employed at WP areconsidered not affiliated.

Select "YES" if they will be involved with this project.

Yes
✓ No

Commented [AL1]: When I reviewed the IRB protocol, I found that some PIs did not consider the external site admin (who manages data collection) as external collaborators. So what about explicitly mentioning like this here?

Ethics Training (CITI Certification)

Attachment

Please upload documentation for CITI certification of Human Subjects training or ethics training (CITI certificate or equivalent) completed for all team members, including the external collaborators. This applies in the absence of a reliance

Commented [AL2]: Suggestion: We should emphasize to submit the CITI certificates of external collaborators

agreement or oversight by another institution's IRB.

- Multiple documents can be uploaded here.

Study Summary

*required

Study Summary: Please provide a brief summary (150 words max) of your project.

- Include the reason for conducting this project and any study aims or research questionsyou will pursue
- Include a brief overview/description of your methods and proceduresInclude a brief
- description of your study population
- Include any plans for publishing or disseminating findings from the project

Please provide a brief summary (150 words max) of your project.

We are not looking for your entire thesis, just the details specific to the research project.

Period of Performance

Please provide the project start and end date.

*required

Start Date

This should be the anticipated start date. The project may not start until after IRBreview is completed, which typically takes 4 weeks to complete.

05/01/2025

*required

End Date

It is recommended that you allow enough time to collect and analyze your data.

04/30/2026

*required

Previous IRB Applications: Please select the statement that best describes this submission.

✓ This is a new IRB application.

This is a previously approved study submitted via InfoReady.

Funding and Support

Funding

*required

Is there funding for this project?

Select "yes" if external or internal funding for this project is pending or has beenawarded.

Yes

✓ No

External Support

*required

Is an external (non-WP) organization or company providing materials (non-monetarysupport of any kind), or equipment for this study?

Yes
✓ No

Oversight Determination

This section determines whether or not your project requires WP IRB oversight.

If your responses suggest that the project does not engage WP in HSR, the application will stop. However, you must still submit your protocol for review. Once you submit, an IRB staffwill review the form and if appropriate, issue an official determination as to whether your project requires oversight from the WP IRB.

*required

Research: Does this project involve a systematic investigation (including research development, testing and evaluation) intended to contribute to generalizable knowledge?

See Help Text for details and additional definitions.

✓ Yes
No

*required

Human Subjects: Does this study involve human subjects?

A "human subject" is a living individual about whom an investigator conducting research (1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; ***OR,*** (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

✓ Yes
No

Excluded activities at WP (45 CFR 46.102 (1) -(4)) Do ANY of the below apply to this study?

- Does the proposed activity include Scholarly and journalistic activities (e.g., oralhistory, journalism, biography, literary criticism, legal research, and historical scholarship)? **(45 CFR 46.102 (1)**
- Does the proposed activity include Public health surveillance activities, conducted, supported, requested, ordered, required, or authorized by a publichealth authority? **(45 CFR 46.102 (2)**
- Does the proposed activity include collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigativepurposes? **(45 CFR 46.102 (3)**
- Does the proposed activity include authorized operational activities (as determined by each agency) in support of intelligence, homeland security,defense, or other national security missions? **(45 CFR 46.102 (4)**
- Does the proposed activity meet WP's definition f a Quality Assurance/QualityImprovement activities?

If ANY of the above are true, then WP is NOT engaged in human subjects research.

Yes
✓ No

*required

Engagement:
Select "yes: if ***any*** of the following applies to this project:

- WP is the only institution participating in this studyWP is the
- primary awardee on the funding
- WP employees or students are obtaining consent from participants
- WP employees or students will have access to individually identifiable data or samples

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✓ Yes
No

Based on your responses to this section, your project appears to require oversight from theWP IRB. Please complete the sections that appear.

- If you feel your project does not engage WP in human subjects research, please reviseyour responses to one or more questions in this section.
- If you have any questions, please email IRBadministrator@wpunj.edu

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External Collaboration

This section asks about the involvement of institutions and/or personnel not affiliated withWP in this project and the nature of those collaborations.

Additional Information can be found in the help text.

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*required

Collaborative Research: Will non-WP individuals or institutions be involved in conducting HSR activities?

Select "yes" if any of the following apply to this project:

- Individuals not affiliated with WP will consent or interact with human subjects for research purposes, or access private, identifiable information. (Former students andemployees who are not currently enrolled or employed at WP are considered not affiliated.)
- One or more study team members are affiliated with WP as well as an externalinstitution
- Non-WP institutions are engaged in human subjects research (e.g., if data collection at an external site is administered by personnel from that site, those individuals are considered external collaborators.
- If the study is conducted at an external site (e.g., K-12 schools, research conducted as sites other than WP), please obtain a letter of support from the site and submit it later in the attachment section.

Yes
✓ No

Commented [AL4]: We can reiterate the example here)

Commented [AL5]: I found that some PIs did not submit the letter of support from the external site. What about emphasizing it here?

Exemption Eligibility

The questions in this section will help determine if your study may qualify for an exemptionunder the Common Rule.

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*required

Does this project include any of the following?

- Clinical Procedures
- Drug or Biologics
- Medical Devices
- Radiation (such as X-Ray Procedures, Radioactive Materials, Ionization/Radiation Emitting Interactions)
- Biological Samples
- Clinical Trials
- Involve the testing of a drug or device, or contain elements subject to FDA regulationsor oversight.

Click the help text to see definitions of these terms

Yes
✓ No

*required

Select from the following:

Please proceed with the Exemption Determination.

- Select this option if your study might be Exempt, or you are not sure.
- NOTE: Studies must pose no greater than minimal risk to human subjects to qualify for an exemption.

Please proceed with the Expedited/Full Board IRB application

✓
- Select this option for Protocols Requiring Expedited or Full Board Review
- Select this option if you already know that your study is NOT Exempt, or you have been instructed by IRB staff to complete the full application.

Study Overview

*required

Study Aims: Please describe your study aim(s) and/or hypotheses(es) being tested as part ofthis study.

Please describe your study aim(s) and/or hypotheses(es) being tested as part of this study.

*required

Rationale: Please provide background justification for your study.

Background justification should support the objectives of the research as well as theknowledge that is anticipated from the research results.

- Explain the need for the study and what gap in knowledge the results are expected tofill.
- Summarize relevant existing data, literature, past and ongoing studies, and explain howyour study is situated within this body of research.
- References may be uploaded to this application in the "Additional Documentation"attachment point found on the Attachments page at the end of this application.

Please provide background justification for your study.

Study Components

*required

Please indicate if your study involves any of the below.

Check all that apply.

Food or Beverage

Dietary Supplements

- Select if one or more dietary supplements are being studied;
- Including electrolytes

✓ Study is limited to analysis of pre-existing data sets or chart reviews
(No interactions or interventions with human subjects will be conducted.)

None of the above

Risks

*required

Risk Level: Please indicate the anticipated level of risk the study poses to participants.

See Help Text for additional information.

✓ Minimal Risk
Greater Than Minimal Risk

*required

Risks: Describe any risks posed to subjects from participating in this study.

- Include any potential physical and psychological risks.
- Include any potential legal, financial, social, or impacts on subjects of accidentaldata disclosure.

Describe any risks posed to subjects from participating in this study.

*required

Risk Mitigation: Describe all steps taken to minimize risks.

- Discuss any alternatives that were or will be considered, as well as anyalternatives that may not be feasible.

Describe all steps taken to minimize risks.

Benefits

*required

Direct Benefits: Describe any anticipated direct benefits to participants from participating in this study.

- Do not include compensation as a direct benefit.
- Contribution to science and/or society is considered as indirect (other) benefits, not direct benefits. If there are no direct benefits, state that.

Commented [AL6]: What about if we clarify this here?

Describe any anticipated direct benefits to participants from participating in this study.

- Do not include compensation as a direct benefit.
-

If there are no direct benefits, state that.

*required

Other Benefits: Describe any anticipated benefits to science and/or society fromconducting this study.

- List specific benefits.
- Do not overgeneralize.
- If there are no specific benefits, state that.

Methods and Procedures

This section asks about the procedures participants will undergo and how data will be collected and recorded.

*required

Research Procedures: Please describe ALL the study procedures participants will undergo.

- Provide details of any interactions, interventions or experiments with human subjectsInclude the
- number of study visits/sessions and the length for each (e.g., 30 minutes per week for 3 weeks for a total time of 1.5 hours), and the timetable for study completion.
- See Help text for more guidance

Describe ALL the study procedures participants will undergo.

Data collection

This section asks about the methods and procedures related to collecting and recording research data. Additional questions about managing, safeguarding, storing and sharing datawill be asked in other sections of the application.

Please describe the information that will be gathered and analyzed, as well as theproposed methods and instruments used to collect and record data.

See Help Text for more detailed guidance.
Describe the information that will be gathered and analyzed, as well as the proposed methods and instruments used to collect and record data.

*required

Audio-Visual Recording: Will participants be audio or video recorded?

- Please specify whether recordings will be audio-only, video-only, or both.
- If video recording is planned, provide a brief justification explaining why video is necessary beyond audio recording (e.g., analysis of nonverbal behavior).

Yes (put text box so they can add information for this response)

✓ No

*required

Education Records**:** Will you be accessing student grades, transcripts, or other education records for research purposes as part of your study?

Commented [AL7]: I found that some PIs failed to justify why video recording is necessary when audio would suffice.

So, somewhere near here, we should add:

- Please specify whether recordings will be audio-only, video-only, or both.
- If video recording is planned, provide a brief justification explaining why video is necessary beyond audio recording (e.g., analysis of nonverbal behavior).

Commented [SG8R7]: Put text box when yes selected

See Help Text for more information.

Yes

✓ No

*required

Setting: Please provide details about where data will be collected/where research will take place.

- Examples: Online, WP campus, K-12 classrooms, US parks, senior living communitiesin the rural south.
- ***International Research:*** ***If the study involves data collection outside of the US, review the guidance related to international research and include information about local context. All faculty, students and staff members are required to comply with the WP Travel Policy . For more information, see the Controller's Office's webpage on Travel.***
- Letters of support: Some studies may require special permission. Letters of support are required for certain external sites (such as research taking place in K-12 schools, research conducted as sites other than WP, etc.) For research taking place internationally, letters of support from local authorities or ethics review boards may berequested by the IRB to ensure methods are ethical and culturally appropriate. Uploadletters of support in the attachment point below.

Provide details about where data will be collected/where research will take place.

If it is a secondary dataset, state the specifics around the dataset. Do not describe the previous study setting as if you are conducting the research.

*required

Non-Research Activities: Are there any activities participants will be engaged in that would be taking place if research were not occurring?

See Help Text for examples.

Yes

✓ No

*required

Multi-Phase Study: Is the study designed to be implemented in phases, where fullydescribing one phase is dependent upon the outcome of another?

Yes

✓ No

*required

WP-Affiliated Research Subjects: Will the study enroll any of the following:

- students/advisees of any member of the study team employees supervised
- by any member of the study team?

Yes

✓ No

Study Instruments

Upload any study instruments here. These include:

Attachment

- Surveys/Questionnaires
- Interview guides
- Focus group prompts
- Tests/measures

Link to Survey Tool

Provide the link to your survey tool.

If data are collected via an online survey platform (e.g., Qualtrics), please ensure the following:

- The survey configuration must align with the informed consent. If the consent states that participants may skip questions, forced-response settings should not be used (in other words, use "Request Response" rather than "Force Response").
- Survey length and structure should be reasonable and consistent with the stated time commitment to minimize participant burden and attrition.
- Question formats (e.g., Likert scales, multiple choice) must be properly configured and functional to allow accurate responses.

Commented [AL9]: Many PIs made mistakes in their Qualtrics design, specifically:

•Forced responses contradicting consent language ("participants are allowed to skip questions").
•Excessively long survey even though the informed consent said 30 minutes to take.

•Inconsistent layouts across related surveys.

So what about adding these instructions?

Data Use Agreements

Attachment

If applicable, attach relevant documentation authorizing access/research use of data sets here. Documentation can take the form of a signed data use agreement, email correspondence, or other written documentation to confirm authorization and terms of use.

Letters of Support

If applicable, upload any letters of support from external sites of recruitment or research here. These include:

Attachment

- School district permission forms
- Letters of support from tribal authorities
- Letters from local organizations attesting to the feasibility or cultural appropriateness of international studies

Participants

This section asks questions about the participant population for this study and how researchers plan to enroll subjects.

PART I: Inclusion and Exclusion Criteria

Excluding certain categories of people may reduce generalizability and/or undermine the ethical principle of justice as described in the Belmont Report. Justification must be providedfor excluded populations.

The IRB will not approve a study that fails to provide adequate scientific and ethical justification for excluding persons who might directly benefit from the research, nor will theIRB approve a study that fails to provide scientific and ethical justification for targeting a category of participants who are vulnerable to coercion or

undue influence.

*required

Age

If the study is intended to be limited to adults, all enrolled participants must have attained the legal age to consent to research under the applicable law of the jurisdictionin which the research will be conducted. Not all states or countries consider 18 years tobe the age of majority; in New Jersey is 18.

*required

Eligibility: Please indicate the age range of study participants

indicate the age range of study participants

*required

Justification: Please provide a rationale/justification for limiting enrollment to this age range.

Please provide a rationale/justification for limiting enrollment to this age range.

*required

Sex and Gender Identity

*required

Are people of any sex and gender identity eligible to participate?

✓ Yes
No

*required

Race/Ethnicity

*required

Are people of any race or ethnicity eligible to participate?

✓ Yes
No

Non-English Speakers

*required

Will individuals who do not read or speak English be permitted to enroll?

Yes
✓ No

*required

Is enrollment limited to people who speak English fluently?

✓ Yes
No

*required

Special Populations

Please indicate if you will enroll individuals from the following populations:

- Pregnant Individuals/Fetuses/Neonates
- Minors
- Prisoners
- Adults lacking full capacity to consent
- Indigenous or Tribal Populations
- Economically or educationally disadvantaged persons
- Other vulnerable populations
- ✓ None of the above

*required

Inclusion Criteria: List/describe any inclusion criteria not indicated above. Explain how these criteria allow for a scientifically appropriate population for this study.

List/describe any inclusion criteria not indicated above.

*required

Exclusion Criteria: Please list any exclusion criteria not indicated above. Provide a reason for each exclusion.

Please list any exclusion criteria not indicated above if applicable.

PART II: Additional Information

The questions that follow ask about plans for recruitment, screening, and compensation, as well as costs that may be incurred by participants.

*required

Recruitment: Will you reach out to or contact potential participants in order to recruit them for the study?

- ✓ Yes
- No

*required

Screening: Will prospective participants be screened for eligibility?

- ✓ Yes
- No

*required

Compensation: Will compensation be offered for participating in research?

Yes

✓ No

*required

Costs: Describe any costs to participants that are associated with participating in thestudy (e.g., parking, travel, etc.).

Describe any costs to participants that are associated with participating in the study (e.g., parking, travel, etc.).

Part III. Target Enrollment

The target enrollment number refers to the total number of people that will sign a consentform or agree to participate in the research.

*required

Target Enrollment: Please provide the target enrollment number.

- For projects deemed to pose Greater Than Minimal Risk to participants, an exactnumber must be provided.
- The number cannot be exceeded without IRB approval.

Please provide the target enrollment number.

*required

Enrollment Breakdown:

Please provide the enrollment breakdown number for each participant population.

Please provide the enrollment breakdown number for each participant population.

*required

Scientific Justification: Please provide the scientific justification for the target enrollmentnumber.

Please provide the scientific justification for the target enrollment number.
Your sample size should be the least number of participants necessary to obtain the most accurate results.

Recruitment

*required

Recruitment Process: Please describe how you will recruit participants

- Specify method/channels for recruitment (e.g. flyers in WP dining halls, WPnewspapers, email listservs, Facebook, class presentations, etc.)
- Indicate if any of the requirements for recruitment will not be met and provide ajustification/explanation.
- Upload recruitment materials in the attachment point below.
- Specific recruitment methods (e.g., email, flyer, social media, listserv, in-person invitation), rather than general terms such as "word of mouth."

- The **exact text** to be used for recruitment (e.g., email draft, flyer language, social media post), uploaded as an attachment where applicable.
- Key participant-facing information, including **time commitment**, **compensation (or lack thereof)**, and **voluntary nature of participation**.
- If recruitment occurs in a workplace, classroom, or hierarchical setting, explain how **potential coercion or undue influence** will be minimized (e.g., no recruitment by supervisors, anonymous participation).

Please describe how you will recruit participants

*required

Privacy: Describe how privacy will be respected when identifying and recruiting potentialparticipants.

- Privacy refers to an individual's right to be free from unauthorized or unreasonable intrusion, including control over the extent, timing, and circumstances of obtaining personal information from or about them.

Describe how privacy will be respected when identifying and recruiting potential participants.

Recruitment

Attachment

- Upload all materials that will be used to recruit participants, including flyers advertising research, emails, verbal/phone scripts, website pages, social media posts, etc.)
- Recruitment materials should include: a) Study title b) Name of the Principal Investigator c) A clear statement that the project is research d) Contact information for study personnel.

Eligibility Screening

*required

Screening Process: Describe the process to screen potential participants for study eligibility.

Please ensure that:

- All eligibility criteria are **clearly stated and consistent** across the recruitment materials, informed consent form, and screening questions.
- If eligibility criteria apply, **screening questions must be implemented** (e.g., in Qualtrics or during initial contact) to prevent ineligible individuals from participating.
- Screening should occur **before** participants are presented with the informed consent form whenever possible.

Describe the process to screen potential participants for study eligibility.

*required

Consent for Screening: Will informed consent be obtained before eligibility screening takes place?

✓ Yes

No

Commented [AL10]: I found that several PIs used use vague language ("word of mouth) without detail (so, social media or email or in-person conversation?).

Also, when PIs provided the recruitment flyers, they omit details like eligibility, time commitment, compensation etc.

So, I suggest adding such instructions to prevent such mistakes.

Commented [AL11]: I found this part needs huge improvement.

- Many PIs repeatedly failed to include all eligibility criteria consistently across recruitment flyers, informed consent, and survey screening questions.
- Also, some of them did not include screening questions in Qualtrics despite requiring eligibility.
- Also, some PIs placed the eligibility questions AFTER the informed consent, which makes unqualified participants unnecessarily read the informed consent.

So I suggest including such instructions.

Commented [SG12R11]: Third point, as long as screening data before the study is to exclude and not use in data

*required

"Screen Fails": Describe what will be done with the data collected from participants if the individual is ineligible to proceed with the study.

Describe what will be done with the data collected from participants if the individual is ineligible to proceed with the study.

Eligibility Screening

Attachment

Upload instruments used for eligibility screening, such as screening questionnaires, verbal screening guides, or other document that describes the screening process.

Data

Identifiers

*required

identifiers: Please select ALL direct identifiers your study will collect.

Names

Home or mailing address

- Including street address, city, county, and zip code

Contact information

✓

- e.g. phone numbers, e-mail addresses, etc.

*required

Please select all that apply.

Telephone numbers
Fax numbers
✓ E-mail addresses
Other

Dates directly related to an individual

- e.g., birth dates, admission dates, discharge dates, etc.

Unique identifying numbers

- e.g. Social Security Numbers, student or employee ID numbers, account numbers etc.

Internet Protocol (IP) addresses

Photographic image, audio recording, or video recording

Biometric data

- e.g., finger prints, iris scans, facial scans

Any other data that can uniquely identify an individual.

My study will not collect direct identifiers.

Data Management

*required

Confidentiality: Describe the steps that will be taken to safeguard identifiable data andminimize the chance of a breach of confidentiality during and after data collection.

- If identifiable data will be linked to participants, describe how this will bepresented in any publications/presentations stemming from this study.
- If identifiable data will be coded, describe the method in which it will be coded andindicate who will have access to the key to the code.
- If data will be de-identified, describe who will conduct this process and how datawill be de-identified so participants cannot be identified by the research data.

Describe the steps that will be taken to safeguard identifiable data and minimize the chance of a breach of confidentiality during and after data collection.

*required

Data storage: Describe where and how you will store identifiable data during the study.

Describe where and how you will store identifiable data during the study.

*required

Coded data: Will a link between study code numbers and direct identifiers be retainedafter data collection is complete?

Yes
✓ No

N/A. My study does not access direct identifiers or identifiable information will never be linked to participant data.

Data Sharing

The following questions ask about plans to share research data beyond WP.

Any plans to share research data beyond the study team should be disclosed to participantsand described in the consent form.

*required

Please indicate if you will share research data or biological samples with any of the parties below.

Researchers/research organizations not affiliated with WP
Funding agency/sponsor
Regulating authority
Other
✓ Data/samples will not be shared with anyone outside the study team

*required

Publication: Could any of the participants be identifiable in publication or presentation?

- For instance, results will be reported using direct quotes, group or tribe name,company name and position title.

Yes
✓ No

*required

Participants' Records: Will a copy of the consent form, test results, or other researchstudy information be placed in the participants' records (e.g., medical, personnel, or education records)?

Yes
✓ No
N/A

Certificates of Confidentiality

The NIH issues Certificates of Confidentiality for certain research projects to protect theprivacy of research subjects by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research.

*required

Is this an NIH-funded study that includes individually identifiable data?

Yes
✓ No

*required

Has a Certificate of Confidentiality been obtained, or will one be sought, from theNIH for this study because it includes the collection of individually identifiable "sensitive" data?

Yes
✓ No

Data and Sample Transfer

*required

Do you intend to share data (transfer) this data to another entity?

Yes
✓ No

Records Retention

Records retention describes the methods and practices used to safeguard important recordsand maintain them for the required period of time until they need to be stored, redirected or otherwise disposed of.

Research Records

*required

PI: Will the PI store research records in a secure and audit accessible manner for aminimum of three years after the IRB application has been closed?

✓ Yes
No

*required

Please describe how research records will be stored post-study termination, and forhow long.

Please describe how research records will be stored post-study termination, and for how long.

*required

Student Researchers: Will student researchers store research records containing identifiable information after the study has closed?

Yes
✓ No
N/A. The study does not have student investigators.

*required

Data destruction: Describe your plans for the destruction of identifiable data.

- Specify when and how all forms of data (e.g., paper hardcopy, electronic, audio/video files/recordings, etc.) will be destroyed.

Describe your plans for the destruction of identifiable data.

Consent

This section will cover procedures for obtaining informed consent from participants.

*required

What population will your project engage?

Check all populations that apply

✓ Adult Participants (over 18 years of age)
Minors (under 18 years of age)

*required

Adult Consenting Procedures

Check the type(s) of consent or waiver of consent planned for this study: (check ALL that apply)

Written/signed consent (participants will sign an informed consent document)

Alteration of the elements of consent (participants will sign a consent document, but one or more of the basic required elements of consent will be altered or waived)

✓ **Waiver of signed informed consent** (informed consent document without the signature sections will be provided)

Describe how you are altering the consent process (e.g. not obtaining informed written consent)

WPU formerly called this Passive Consent, you are still obtaining consent, though participants will not sign it

Waiver of consent (participants will not be asked to sign or be given a consent document)

*required

Adult Participants: Justification for requesting a waiver or alteration of informed consent

Select one.

Wavier of Consent Requested: The research is no more than minimal risk of harm to subjects and does not involve any procedures for which written consent is normally required outside the research setting (for example, written consent is not needed for minimal risk surveys or non-invasive health measurements in everyday life).

Wavier of Consent Requested: The subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects, and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained

✓ **Waiver of Documentation of Consent Requested**: The only record linking the participant and the research data would be the signed consent document, and the main risk to participants would be breach of confidentiality (participants could suffer from social stigma or embarrassment or other harms if it became known that they participated in research that identified them as having issues including, but not limited to, risky sexual behaviors, drug use, HIV or mental health problems).

Alteration of Consent Requested: This project involves a methodology (e.g. deception), whereby obtaining written, informed consent would invalidate this methodologic approach or otherwise compromise the data collection process..

Other request for Alteration of Consent/Waiver of Consent Request:

Consent Forms

Upload consent materials here, including:

Attachment

- Written consent document
- Verbal consent guides
- Parental permission documents Assent documents
- Assessment Tools Debriefing protocols
- Translations of consent, assent, and parental permission document

Attachments

This section provides a summary of all attachment points relevant to your submission. Tofacilitate ease of review, please upload documents in the proper attachment points. If youhave already uploaded a file to the application, do not upload that same file again on this page.

Reliance on External IRB: Study documents reviewed and approved by an external IRB should be uploaded in the "External IRB Documents" attachment point, **not** in any other section (unless instructed by HRPP staff).

Additional Documents: Use the "Additional Documents" attachment point ***only if*** you cannot find an attachment point that describes your document, or you have been instructed to do soby HRPP staff.

Study Procedures and Components

Study Instruments

Upload any study instruments here. These include:

- Surveys/questionnaires
- Interview guides
- Focus group prompts
- Tests/measures

Authorizations and Special Permissions

Letters of Support

If applicable, upload any letters of support from external sites of recruitment or research here. These include:

- School district permission forms Letters of
- support from tribal authorities
- Letters from local organizations attesting to feasibility or cultural appropriatenessof international studies.

Data Use Agreements

If applicable, attach relevant documentation authorizing access/research use of data sets here. Documentation can take the form of a signed data use agreement, email correspondence, or other written documentation to confirm authorization and terms ofuse.

Participant Facing Documents

Recruitment

- Upload all materials that will be used to recruit participants, including flyers advertising research, emails, verbal/phone scripts, website pages, social mediaposts, etc.)
- Recruitment materials should include: a) Study title b) Name of the PrincipalInvestigator c) A clear statement that the project is research d) Contact information for study personnel.

Eligibility Screening

Upload instruments used for eligibility screening, such as screening questionnaires, verbal screening guides, or other document that describes the screening process.

Consent Forms

Upload consent materials here, including:

- Written consent documents
- Verbal consent guides
- Parental permission documents
- Assent documents
- Debriefing protocols
- Translations of consent, assent, and parental permission documents

Additional Documentation

Upload any other supporting documents here.