**DO NOT DELETE OR ALTER ANY PART OF THIS FORM**

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| --- |
| **HRPP USE ONLY** |
| **IRB #:** |  |
| **Rec. Log:** |  |

|  |
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| **NON-EXEMPT HUMAN SUBJECT RESEARCH APPLICATION** |

**Application instructions:**

* Do not begin data collection **prior** to IRB approval.
* Do not leave questions/[REQUIRED FIELD] blank; write or check "**N/A**" if not applicable.

**Before submitting, please ensure the following applicable supporting materials are complete and included in your submission:**

* **Application**
* **Addenda**

*For index of all HRPP addenda, please click* [*here*](https://irb.wsu.edu/forms/)*.*

* **Recruitment materials**

*For guidance on recruitment materials, please click* [*here*](https://irb.wsu.edu/documents/2021/01/recruitment-and-advertising-guidance.pdf)*.*

* **Informed consent materials/permission/assent materials**

*For guidance on consent, please click* [*here*](https://irb.wsu.edu/consent-form-guidance/)*.*

* **Data collection materials** (e.g., surveys, questionnaires, interview scripts, tools, measures, etc.)
* **Letters of institutional support/approval**
* **Debriefing scripts**
* **CITI training course certificates**

*For guidance on CITI training requirements and registration, please click* [*here*](https://irb.wsu.edu/training/)*.*

**How to submit:**

* All submissions must be emailed to irb@wsu.edu.
* Please have the subject line read as: **“Human Subject Application, for Non-Exempt review submission.”**
* Submissions **must** be sent from a WSU email account.
* Submissions should be sent by the **PI**. If someone other than the PI (e.g., a graduate student, post doc, co-PI, or staff) is submitting the application on behalf of PI, the PI **must** be copied as a recipient and the PI must provide a signature in section 13.1.
* If you are requesting rush review due to funding disbursements, please indicate this in your submission email so that our office can make the appropriate considerations in assigning review dates. Rush review requests do not guarantee that the review will be completed early, and accommodations are dependent on reviewer availability.
* When submitting, please submit all supporting material attachments as **PDF** or **Word** documents only.

**Do not submit:**

* Links (e.g., social media sites, etc.)
* Documents via cloud sharing platforms (e.g., SharePoint, Google Drive, etc.)
* Zip files
* Documents with tracked changes or comments.

**Please note:**

* Applications are processed in the order in which they are received.
* Submissions that include an incomplete application or that are missing supporting materials **cannot** be sent out for review and may result in a delay in your data collection. In the case of this event, you will receive an “Addition Materials Request (AMR)” notice indicating the corrective action needed.

|  |
| --- |
| **SECTION 1. GENERAL INFORMATION**  |

1. **Indicate level of review:**

[ ]  **Minimal risk**

The probability and magnitude of harm or discomfort anticipated in the research arenot greater in and of themselves from those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests;

[ ]  **More than minimal risk**

The probability and magnitude of harm or discomfort anticipated in the research **are greater in and of themselves from those ordinarily encountered in daily life** or during the performance of routine physical or psychological examination or tests, or are not in a category allowed for Expedited Research; [45 CFR 46.109](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.109).

1. **If the study is minimal risk, please indicate which category best fits the research:**

[ ]  **Clinical studies of drugs and medical devices** **only when either of the following conditions are met.**

* Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required.

***PLEASE 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*

* Research on medical devices for which:
	+ an investigational device exemption application (21 CFR Part 812) is not required; or
	+ the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling

[ ]  **Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:**

* From healthy, non-pregnant adults who weigh at least 110 pounds. For these participants, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or
* From other adults and children considering the age, weight, and health of the subjects, 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.

[ ]  **Prospective collection of biological specimens** **for research purposes by noninvasive means. Examples include:**

* Hair and nail clippings in a non-disfiguring manner
* Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction
* Permanent teeth if routine patient care indicates a need for extraction
* Excreta and external secretions (including sweat)
* Un-cannulated 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
* Placenta removed at delivery
* Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor
* Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques
* Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings
* Sputum collected after saline mist nebulization

[ ]  **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 include:**

* 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;
* weighing or testing sensory acuity;
* magnetic resonance imaging;
* electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
* moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

[ ]  **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).**

***PLEASE NOTE:***

*Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.*

[ ]  **Collection of data from voice, video, digital, or image recordings made for research purposes.**

[ ]  **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.**

***PLEASE NOTE:***

*Some research in this category may be exempt from the HHS regulations for the protection of human subjects 45 CFR 46.101 (b)(2) and (b)(3). This listing refers only to research that is not exempt*.

[ ]  **N/A**

1. **Provide principal investigator (PI) contact information (a-h).** **The PI must be WSU faculty or staff and will be the study supervisor at WSU. Students, post-doctoral researchers, and visiting faculty may not serve as PI, but may be listed as co-investigators. All correspondence will be directed to the PI listed below.**
2. **PI Name:** [REQUIRED FIELD]
3. **WSU ID #:** [REQUIRED FIELD]
4. **College campus:** [REQUIRED FIELD]
5. **College area:** [REQUIRED FIELD]
6. **College department:** [REQUIRED FIELD]
7. **Address/mail code:** [REQUIRED FIELD]
8. **Phone:** [REQUIRED FIELD]
9. **Email:** [REQUIRED FIELD]
10. **Provide study information (a-b).**
11. **Study title:** [REQUIRED FIELD]
12. **Estimated Start date:** [REQUIRED FIELD]
13. **Is this a student’s project in which you are serving as a mentor?**

[ ]  **No**

[ ]  **Yes**

1. **In the table below, provide the required information for all WSU key personnel involved in this research. Include all persons who will be directly responsible for the study management, data collection, consent process, data analysis, transcription, participant recruitment, or follow up. If additional lines are needed, submit on a separate page and reference “Continuation of Section 1.6.”**

***PLEASE NOTE:***

*The application will not be* ***approved*** *until all study personnel have completed* [*CITI training*](http://www.citiprogram.org)*. For more information on CITI requirements and registration guidance, please click* [*here*](https://irb.wsu.edu/training/)*. WSU personnel should follow the “Registration & Enrollment for CITI Training With an SSO” guidance steps.*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Name:** | **WSU Email:** | **WSU ID#:** | **CITI Complete:** | **Role****(PI, Co-PI, Research assistant, Coordinator):** | **Delegated by PI to obtain informed consent:** |
| [REQUIRED FIELD] | [REQUIRED FIELD] | [REQUIRED FIELD] | [ ]  **Yes** [ ]  **No** | PI | [ ]  **Yes** [ ]  **No** |
|  |  |  | [ ]  **Yes** [ ]  **No** |  | [ ]  **Yes** [ ]  **No** |
|  |  |  | [ ]  **Yes** [ ]  **No** |  | [ ]  **Yes** [ ]  **No** |
|  |  |  | [ ]  **Yes** [ ]  **No** |  | [ ]  **Yes** [ ]  **No** |
|  |  |  | [ ]  **Yes** [ ]  **No** |  | [ ]  **Yes** [ ]  **No** |
|  |  |  | [ ]  **Yes** [ ]  **No** |  | [ ]  **Yes** [ ]  **No** |
|  |  |  | [ ]  **Yes** [ ]  **No** |  | [ ]  **Yes** [ ]  **No** |
|  |  |  | [ ]  **Yes** [ ]  **No** |  | [ ]  **Yes** [ ]  **No** |
|  |  |  | [ ]  **Yes** [ ]  **No** |  | [ ]  **Yes** [ ]  **No** |
|  |  |  | [ ]  **Yes** [ ]  **No** |  | [ ]  **Yes** [ ]  **No** |
|  |  |  | [ ]  **Yes** [ ]  **No** |  | [ ]  **Yes** [ ]  **No** |
|  |  |  | [ ]  **Yes** [ ]  **No** |  | [ ]  **Yes** [ ]  **No** |
|  |  |  | [ ]  **Yes** [ ]  **No** |  | [ ]  **Yes** [ ]  **No** |
|  |  |  | [ ]  **Yes** [ ]  **No** |  | [ ]  **Yes** [ ]  **No** |
|  |  |  | [ ]  **Yes** [ ]  **No** |  | [ ]  **Yes** [ ]  **No** |

1. **In the table below, provide the required information for all non-WSU key personnel involved in this research. Include all persons who will be directly responsible for the study management, data collection, consent process, data analysis, transcription, participant recruitment, or follow up. If additional lines are needed, submit on a separate page and reference “Continuation of Section 1.7.”**

***PLEASE NOTE:***

*The application will not be* ***approved*** *until all study personnel have completed* [*CITI training*](http://www.citiprogram.org)*. For more information on CITI requirements and registration guidance, please click* [*here*](https://irb.wsu.edu/training/)*. Non-WSU personnel should follow the “Registration & Enrollment for CITI Training Without an SSO” guidance steps.*

*Review and approval of this protocol* ***does not constitute approval of non-WSU collaborators****. If non-WSU collaborators are added in Section 1.8, they will not be covered under WSU IRB review unless a collaborative agreement is executed. For more information about collaborative agreements, please click* [*here*](file:///%5C%5Corfileserver.or.wsu.edu%5Cdepartment_ora%24%5CFiles%5CHuman%20Subjects%5CIRB%20ADMINISTRATION%5CForms%2C%20Checklists%2C%20%26%20Templates%5C2.%20Non-Exempt%20Application%5Cagreements%2C%20please%20visit%3A%20https%3A%5Cirb.wsu.edu%5Cexternal-collaborations%5C)*.*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name:** | **Email:** | **CITI Complete:** | **Role****(PI, Co-PI, Research assistant, Coordinator):** | **Delegated by PI to obtain subject informed consent:** |
| [REQUIRED FIELD] | [REQUIRED FIELD] | [ ]  **Yes** [ ]  **No** | [REQUIRED FIELD] | [ ]  **Yes** [ ]  **No** |
|  |  | [ ]  **Yes** [ ]  **No** |  | [ ]  **Yes** [ ]  **No** |
|  |  | [ ]  **Yes** [ ]  **No** |  | [ ]  **Yes** [ ]  **No** |
|  |  | [ ]  **Yes** [ ]  **No** |  | [ ]  **Yes** [ ]  **No** |
|  |  | [ ]  **Yes** [ ]  **No** |  | [ ]  **Yes** [ ]  **No** |
|  |  | **☐ Yes ☐ No** |  | [ ]  **Yes** [ ]  **No** |
|  |  | **☐ Yes ☐ No** |  | [ ]  **Yes** [ ]  **No** |
|  |  | **☐ Yes ☐ No** |  | [ ]  **Yes** [ ]  **No** |
|  |  | **☐ Yes ☐ No** |  | [ ]  **Yes** [ ]  **No** |

1. **Is this research supported in whole or in part by a grant or contract (federal or non-federal)?**

[ ]  **No**

[ ]  **Yes**

***If yes****,* ***complete (a-e).***

1. **Funding source:** [REQUIRED FIELD]
2. **ORSO #:** [REQUIRED FIELD]
3. **Grant title:** [REQUIRED FIELD]
4. **PI name on grant:** [REQUIRED FIELD]
5. **List all additional funding, if applicable:** [REQUIRED FIELD]
6. **Is the proposed research classified as a** [**clinical trial**](https://www.clinicaltrials.gov/about-site/about-ctg)**?**

[ ]  **No**

[ ]  **Yes**

***If yes, complete (a-c).***

***PLEASE NOTE:***

***If yes****, complete and include* [*ADDENDUM: FDA Drugs, Devices, Biologics, & Biospecimens*](https://irb.wsu.edu/forms/) *with your submission and ensure* ***all*** *research personnel have completed the* ***Good Clinical Practice*** *course on* [*http://citiprogram.org*](http://citiprogram.org)*.*

1. **Has registration been completed with** [**clinicaltrials.gov**](https://irb.wsu.edu/forms/)**?**

[ ]  **No**

[ ]  **Yes**

1. **Registration # or equivalent:** [REQUIRED FIELD]
2. **If registration has not been completed, please provide expiation:** [REQUIRED FIELD]
3. **Does the research require another IRB’s review?**

[ ]  **No**

[ ]  **Yes**

***If yes, complete (a-c).***

***PLEASE NOTE:***

***If yes****, include the* ***approval or exemption determination from the outside IRB*** *with your application submission. The PI is responsible for securing approval and keeping a copy of the documentation.**Please review the information regarding* [*external collaborations*](https://irb.wsu.edu/external-collaborations/) *and contact our office prior to submission if unsure if external IRB review is needed.*

1. **Name of the non-WSU IRB:** [REQUIRED FIELD]
2. **FWA# or equivalent:** [REQUIRED FIELD]
3. **List all additional IRB’s:** [REQUIRED FIELD]
4. **Is the proposed research study conducted at an outside (non-WSU) facilities or entities such as hospitals, clinics, schools, school districts, factories, offices, etc.?**

[ ]  **No**

[ ]  **Yes**

***If yes, complete (a).***

***PLEASE NOTE:***

*The researcher has an obligation to ensure that the outside entity is aware of the proposed research study and has no objections (e.g., agrees to participate). In order to respect the rights of entities, research to be conducted at these locations* ***may*** *require a letter from an authorized representative to submitted to the WSU IRB or researcher acknowledging the research study and their willingness to allow the proposed research.* *Please include all* ***letters of support*** *with your application submission if available.*

1. **List name(s) and of location(s) where research will be conducted:** [REQUIRED FIELD]
2. **Is the proposed research study specifically targeting Alaska Natives/Native Americans as a subject population?**

[ ]  **No**

[ ]  **Yes**

***PLEASE NOTE:***

***If yes****, in order to respect the sovereign governments, research to be conducted on Native American tribal lands will* ***require*** *a letter from the Tribal Council (or equivalent authorized signatory) to the WSU IRB acknowledging the research study and their willingness to allow the proposed research.*

*This includes tribes that have* [*signed an MOU*](https://native.wsu.edu/tribalrelations/) *with Washington State University.*

*Please include all* ***tribal******letters of support*** *with your application submission.*

1. **Does the research require approval from other WSU compliance committees such as the Radiation Safety Committee (RSC), Institutional Animal Care and Use Committee (IACUC), or Institutional Biosafety Committee (IBC)?**

[ ]  **No**

[ ]  **Yes**

***PLEASE NOTE:***

***If yes,*** *the PI has responsibility to seek approval from the other committees required for this research. Work cannot start until final approval is received from* ***all*** *appropriate committees.*

1. **Has any PI, Co-PI, or any other person responsible for the design, conduct, or reporting of the research received, or will receive, any personal considerations or financial assistance (other than a WSU grant or WSU award) including, but not limited to: equipment, staff, data transfers, proprietary information, or financial help? Does anyone involved in the design, conduct or reporting of research have a potential non-financial conflict of interest?**

[ ]  **No**

[ ]  **Yes**

***If yes****,* ***complete (a-b).***

1. **Does a non-financial conflict of interest (COI) exist?**

[ ]  **No**

[ ]  **Yes**

***If yes****,* ***complete (i-iii).***

* + 1. **Name of the individual(s) with a non-financial conflict:** [REQUIRED FIELD]
		2. **Explain the assistance or potential non-financial conflict:** [REQUIRED FIELD]
		3. **Explain how the potential COI will be managed:** [REQUIRED FIELD]
1. **Does a financial conflict of interest (COI) exist?**

[ ]  **No**

[ ]  **Yes**

***If yes****,* ***complete (i-iii).***

1. **Name of the individual(s) with a financial conflict:** [REQUIRED FIELD]
2. **Explain the assistance or potential financial conflict:** [REQUIRED FIELD]
3. **Explain how the potential COI will be managed:** [REQUIRED FIELD]

***PLEASE NOTE:***

*If the economic interest is “a significant economic interest” as defined in* [*WSU’s Executive Policy #27*](https://policies.wsu.edu/prf/index/manuals/executive-policy-manual-contents/ep27-ethics-conflict-interest-technology-transfer/)*, you will need to obtain a* ***management plan*** *with the Conflict of Interest Committee.*

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| **SECTION 2. STUDY DESCRIPTION** |

1. **Provide a brief summary of the proposed research (a-e).** **Use lay language and avoid technical terms. IRB members not familiar with the area of research must understand the nature of the research. The application will be returned without further review if summary is too technical.**
2. **Study purpose:** [REQUIRED FIELD]
3. **Study design (e.g., descriptive, correlational, causal-comparative/quasi-experimental, and experimental research, mixed-methods):** [REQUIRED FIELD]
4. **Study procedures**. **Provide a complete description of the study procedures, including the sequence, intervention, or manipulation (if any), drug dosing information (if any), use of records, and subject time required:** [REQUIRED FIELD]
5. **Participant role/expectations. What will each participant be asked to do in their role as a participant? For longer studies with multiple visits or extensive procedures, please include tables, flowcharts, or other visual aids:** [REQUIRED FIELD]
6. **Cultural competency. For projects involving vulnerable or select populations, provide the researchers’ qualifications for working with the subjects:** [REQUIRED FIELD]

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| **SECTION 3. DATA COLLECTION METHODS** |

1. **Select all methods of data collection to be used (a-h).**

***PLEASE NOTE:***

*Submit* ***all study tools/measures*** *to be used with* ***translated*** *versions, if applicable (e.g., surveys, questionnaires, scripts.)*

*If participants will be shown* ***media*** *(such as a video or images), provide a copy of the media, or a thorough description of the material contents to the IRB.*

1. **Survey/questionnaire:**

[ ]  **Phone** [ ]  **In-Person** [ ]  **Internet** [ ]  **Email ☐ Postal Mail** [ ]  **N/A**

***PLEASE NOTE:***

*Use a secure system for digital methods, such as* ***Qualtrics****, which is WSU approved.*

1. **Interview:**

[ ]  **One-on-one** [ ]  **Focus group** [ ]  **Internet ☐ Other** [ ]  **N/A**

***If other, complete (i).***

1. **Describe the other interview method:** [REQUIRED FIELD]
2. **Observation of public behavior:**

[ ]  **Yes** [ ]  **N/A**

***If yes, complete (i).***

1. **Provide description of the planned observation of public behavior:** [REQUIRED FIELD]

***PLEASE NOTE:***

***Public behavior*** *refers to behavior taking place in a publicly accessible location in which the participant does not have an expectation of privacy (e.g., a public plaza or park, a street, a building lobby, a government building).*

***A public school is not considered a public location****.*

1. **Examination of Archived Data/Secondary or Records that contain any of the direct or indirect identifiers listed under HIPAA or FERPA:**

**☐ Yes ☐ N/A**

***If yes, complete (i-iii).***

1. **Briefly describe who will provide the record and what it will contain:** [REQUIRED FIELD]
2. **List all fields that the researchers will receive:** [REQUIRED FIELD]
3. **If data is being de-identified before it is sent to the researchers, state who will do this and when, and what fields will be removed:** [REQUIRED FIELD]

***PLEASE NOTE:***

*For the examination of Archived Data/Secondary or Records that contain any of the direct or indirect identifiers listed under HIPAA, please submit the* ***A***[***DDENDUM: Informed Consent Alteration/Waiver – Minimal Risk***](https://irb.wsu.edu/forms/) *and the* [***ADDENDUM: HIPAA Authorization***](https://irb.wsu.edu/forms/)*.*

*If the research has a* ***Memorandum of Understanding (MOU) or Data Sharing Agreement (DSA)*** *with the entity providing the data or records, please include a copy of the* ***MOU or DSA*** *with your application submission.*

1. **Taste evaluation:**

[ ]  **Wine/alcohol\*** [ ]  **Non-Wholesome food** [ ]  **Wholesome food without additives** [ ]  **N/A**

***PLEASE NOTE:***

*Wholesome foods are foods* ***without additives*** *and contain a food* ***ingredients at or below the level*** *found to be safe (or agricultural chemical or environmental contaminant at or below the level found to be safe), by the* ***Food and Drug Administration*** *or approved by the* ***Environmental Protection Agency*** *or* ***the Food Safety and Inspection Service*** *of the U.S. Department of Agriculture.*

\*If you check the box for administration of wine/alcohol, please specifically address this risk to participants in the risk/benefit section. Also, be sure that your research design complies with WSU alcohol policies (EP20 and BPPM 70.22 and 70.29)

1. **Examination of human pathological or diagnostic tissue specimens (e.g., blood, tissue, bodily fluids, or other biological specimens):**

**☐ Yes ☐ N/A**

***If yes, complete (i-iv).***

1. **Provide a description of the Human Pathological or Diagnostic Tissue Specimens to be examined:** [REQUIRED FIELD]
2. **Will any of the blood, tissue, bodily fluids, or other biological specimens be used for genetic testing? If so, please describe:** [REQUIRED FIELD]
3. **Will your studies involve the analysis of genes known to be implicated in the disorder(s), syndrome(s) or condition(s) you are studying? If so, please describe what genes will you be studying:** [REQUIRED FIELD]
4. **Will your studies involve finding the gene(s) that may cause the condition or genetic markers that co-segregate with this condition? If so, please describe:** [REQUIRED FIELD]
5. **Recordings:**

**☐ Voice ☐ Video ☐ Image ☐ Other ☐ N/A**

***If other, complete (i-ii).***

1. **Describe other recording method (e.g., GPS, accelerometer recordings):** [REQUIRED FIELD]
2. **Describe the purpose of other recording method (e.g., for speech pattern analysis, archiving purposes, presentation at the meetings etc.) Include this information in Section (2.c): [**REQUIRED FIELD]
3. **Describe all data collection tool/measures that do not fit into categories listed in section (a-g), if any:** [REQUIRED FIELD]

|  |
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| **SECTION 4. CONFIDENTIALITY AND PROTECTION OF DATA** |

**Please review the following guidance before answering the questions and completing this section.**

* Identify all the types of data you will be analyzing for your research (e.g., online surveys, questionnaires, one-one-interviews, focus group interviews, audio/video recordings, and digital images).
* Determine the level of confidentiality you will have at each stage of the data (e.g., collection, analysis, storage, and dissemination). When this is completed, then fill in the table below.

**Example:**

* If a researcher was conducting a survey and collecting an email address to conduct follow-up focus groups and individual interviews, then transcribing the interviews without identifiers for analysis, and later deleting the recordings, the data would move through different stages of confidentiality. The researcher would have five types of data: (1) survey, (2) focus group recording, (3) interview recording (4) focus group transcription, and (5) interview transcription.
* **Survey:** Collected with an email address so this is Intentionally Identified. However, after receipt, the researcher assigns a Confidential Unlinked code to the survey. Later, after conducting interviews and focus group interviews, the researcher transcribes the interviews and links them which creates a Confidential Unlinked code to connect the three data points from the subject.
* **Interviews and Focus group interviews**: These are being audio-recorded so they are considered Intentionally Identified. Then the researcher transcribes the interviews and assigns the transcriptions a Confidential Unlinked code to connect them to the other three data points. The original recordings are stored but are not analyzed or disseminated.
* **The researcher then analyzes all data together with the confidential unlinked code**: The researcher distributes it with a pseudonym rendering it either Anonymous or Confidential Unlinked, depending on whether the information disseminated could lead back to a potential subject, or whether the researcher used a small or large subject pool (i.e., **all** WSU college students versus **only** female WSU college students taking one course, from one professor, during one semester, etc.)
* **Table completion**: See example of surveys, interviews, focus groups, recordings, and transcriptions completed in the table below.

|  |  |
| --- | --- |
| **Stages of Data** | **Level of Confidentiality** |
|  | **Anonymous***No identifiers that link the data to a specific subject* | **Confidential****Unlinked***Collected with identifier, but all identifiers & codes are removed* | **Confidential****Coded***Linked to a specific subject by a code, not by a direct identifier)* | **Intentionally Identified:***Linked to a specific subject by personal identifiers* |
| **Collection** |  |  | EXAMPLE | **1. Survey****2. Focus Group Recording****3. Interview Recording** |
| **Initial Storage** |  |  |  | **1. Survey****2. Focus Group Recording****3. Interview Recording** |
| **Analysis** |  | **1. Survey****4. Focus Group Transcription****5. Interview Transcription** |  |  |
| **Long-Term Storage** |  | **1. Survey****4. Focus Group Transcription****5. Interview Transcription** |  |  |
| **Dissemination** | **1. Survey****4. Focus Group Transcription****5. Interview Transcription** |  |  |  |

***PLEASE NOTE:***

*Anonymous and confidential are* ***not*** *the same thing;* ***confidential*** *means that data collected could identify participants but is being kept secure.* ***Anonymous*** *means that identifiers are not collected, or few enough identifiers are collected that re-identification is not possible.*

[*Executive Policy #8*](https://policies.wsu.edu/prf/documents/2017/06/ep8-university-data-policies.pdf/) *describes university data policies that apply to all research projects.*

1. **Complete the confidentiality table to display how the data will be stored at each stage:**

|  |  |
| --- | --- |
| **Stages of Data** | **Level of Confidentiality** |
|  | **Anonymous***~~Collected with~~ no identifiers that link the data to a specific subject* | **De-Identified***~~Collected with identifier, but~~ all identifiers & codes are removed such that no link exists* | **Confidential****Coded***Linked to a specific subject by a code, not by a direct identifier)* | **Intentionally Identified:***Linked to a specific subject by personal identifiers* |
| **Collection** | [REQUIRED FIELD] |  | [REQUIRED FIELD] | [REQUIRED FIELD] |
| **Initial Storage** |  |  |  |  |
| **Analysis** |  |  |  |  |
| **Long-Term Storage** |  |  |  |  |
| **Dissemination** |  | [REQUIRED FIELD] |  |  |

***PLEASE NOTE:***

*If* ***HIPAA data*** *is being used, increased data protections are required for all systems and IT services that store, process, and/or transmit the data, to include researcher computer endpoints and data collection devices.* ***A signed Business Associates Agreement is required with all third-party vendors*** *that store, process, and/or transmit HIPAA protected data.*

1. **The level of data protection is dependent on the type of data collected and stored by researchers. Common methods of data protection include:**
* **Locked Office (not private)**
* **Locked Private Office**
* **Locked Cabinet**
* **Restricted Computer**
* **Password Protected Computer**
* **Cloud Storage**
* **Master list stored separately from the data (for Confidential Coded or Confidential Unlinked)**
* **Encrypted Data (This requirement is from** [**WSU’s Executive Policy #8**](file:///%5C%5Corfileserver.or.wsu.edu%5Cdepartment_ora%24%5Cfiles%5CHuman%20Subjects%5CIRB%20ADMINISTRATION%5CForms%2C%20Checklists%2C%20%26%20Templates%5CApplications%5CWSU%E2%80%99s%20Executive%20Policy%20#8)**. All data must be encrypted at all stages of storage and transfer. Usage of WSU OneDrive complies with this policy)**

**Describe how the data will be protected by the researchers:** [REQUIRED FIELD]

1. **Data** Administration **(a-c). Include responsible parties name, title, WSU affiliation, and contact information per the guidelines in** [**WSU’s Executive Policy #8**](https://policies.wsu.edu/prf/index/manuals/executive-policy-manual-contents/ep8-university-data-policies/)**.**
2. **Secondary access person:** [REQUIRED FIELD]
3. **Data custodian:** [REQUIRED FIELD]

***PLEASE NOTE:***

*If your college or department does not have anyone identified as Data Custodian, the Primary Investigator (PI) can act as the Data Custodian for the systems and data they are responsible for. However, the PI should consult with their Area Technology Officer or their IT department on how to comply with applicable information security and privacy requirements.*

1. **Data Users****:** [REQUIRED FIELD]
2. **Data Location (a-b).**
3. **List all countries data may be collected from:** [REQUIRED FIELD]

***PLEASE NOTE:***

*Countries that have adopted the General Data Protection Regulation (*[*GDPR*](https://ec.europa.eu/info/law/law-topic/data-protection_en)*) of the European Union have additional data security requirements.*

*At this time, WSU does not have the capability to store data regulated by the European Union’s General Data Protection Regulations. If identifiable data is collected from countries in the European Economic Area, a third-party service will be required to house this data.*

***Your department/college/area IT professionals will need to evaluate the 3rd party storage option and their approval must be submitted with this application.***

1. **Will any service be storing, processing, or transmitting WSU Confidential or Regulated data at a 3rd party facility (e.g., Microsoft Azure, Dropbox, Box or other vendor or 3rd party site)?**

**☐ Yes ☐ No**

***If yes, complete (i-iii).***

1. **List the names of all vendors or 3rd party services that will be used to store and process WSU data:** [REQUIRED FIELD]

***PLEASE NOTE:***

*WSU-licensed OneDrive,* [*Qualtrics*](https://surveys.wsu.edu/surveys/qualtrics/)*, Zoom, or* [*REDCap*](https://surveys.wsu.edu/surveys/redcap/)*, these are not considered third-party vendors.* [*WSU prohibits*](https://surveys.wsu.edu/) *the use of products such as SurveyMonkey, Zoomerang, or other online survey tools that require a click through agreement. Please reference the* [*Cloud Acceptable Use Matrix*](https://its.wsu.edu/information-security/)*for reference on approved platforms.*

1. **List data elements that will be stored, processed, or transmitted by the service(s):** [REQUIRED FIELD]
2. **Describe the location of data storage at each stage in the research process. Include WSU campus locations (with building and room numbers), off-campus sites, international sites, and cloud storage locations:** [REQUIRED FIELD]

***PLEASE NOTE****:*

*If identifiable research data will be stored in your home, please describe additional data security protections (locked box, locked home office). If personal devices will be used to store identifiable research data, these devices (e.g. computers, phones) must also meet data security policies in in* [*WSU’s Executive Policy #8*](https://policies.wsu.edu/prf/index/manuals/executive-policy-manual-contents/ep8-university-data-policies/)*.*

*Personal devices should not be used for storage of identifiable research data.*

1. **Types of Data (a-c).**
2. **Select the categories that describe your data, per the guidelines** **in** [**WSU’s Executive Policy #8**](https://policies.wsu.edu/prf/index/manuals/executive-policy-manual-contents/ep8-university-data-policies/)**:**

[ ]  **Public** [ ]  **Internal** [ ]  **Confidential** [ ]  **Regulated**

1. **Will the data elements will contain any information that contains identifiers and could be used to link confidential or regulated information to an individual?**

[ ]  **Yes** [ ]  **No**

1. **Will there involve receipt of data or “big data”?**

[ ]  **Yes** [ ]  **No**

***If yes, complete (i-ii).***

1. **Include a list of all fields and/or overlapping source layers (e.g., combining newspaper accident reports, police reports, and medical charts that will be received):** [REQUIRED FIELD]
2. **Explain who will strip unnecessary data, and how this will be completed:** [REQUIRED FIELD]
3. **Data Storage, Retention and Disposition, select all that apply:**

[ ]  **De-identified or anonymous data will be retained indefinitely.**

[ ]  **Identifiable data will be retained securely for at least 3 years after the completion of the research and then destroyed/deleted.**

[ ]  **Identifiable data will be retained indefinitely or for a defined period.**

* **Indicate the retention period or write “indefinitely” (IRB approval may be required for any future use of identifiable data that is retained.):** [REQUIRED FIELD]

[ ]  **The data retention schedule is different than** [**BPPM 90.01**](https://policies.wsu.edu/prf/index/manuals/90-00-records/90-01-research-sponsored-project-records/)**.**

* **How long will the data be retained?** [REQUIRED FIELD]
* **What identifiers will be removed to make data anonymized?** [REQUIRED FIELD]
* **When will identifiers be removed?** [REQUIRED FIELD]
* **What will be the final disposition of the data?** [REQUIRED FIELD]
* **If data will be destroyed, please describe the method(s) to be used:** [REQUIRED FIELD]

***PLEASE NOTE:***

*WSU’s Business Policy & Procedures Manual requires that all identifiable research materials (e.g., consent forms, surveys, voice/video/images, etc.) be kept for a minimum of three years after completion of the study. See*[*WSU BPPM 90.01*](https://policies.wsu.edu/prf/index/manuals/90-00-records/)*.*

*It is recommended that paper records be shredded, physical tapes be erased, or physically destroyed, and electronic media be scrubbed after files are deleted. Entirely de-identified data (links to individual identity including any information that could identify participants) may be retained.* ***Simply deleting files from a computer is not considered data destruction****. See* [*BPPM 90.01*](https://policies.wsu.edu/prf/index/manuals/90-00-records/90-01-research-sponsored-project-records/)*.*

|  |
| --- |
| **SECTION 5. HUMAN SUBJECT POPULATION** |

1. **List approximate number of subjects to be enrolled, including totals for each subgroup (e.g., minors #, elderly #, students #, parents #):** [REQUIRED FIELD]

***PLEASE NOTE:***

*For* ***expedited and minimal risk studies****, you are allowed actual enrollment can vary* ***by +/-10%****. If your enrollment is anticipated to vary outside of this range post approval, you must submit an amendment request.*

*For* ***full board studies with greater than minimal risk*** *– If your enrollment post approval is* ***greater*** *than what is stated, please contact our office. If you anticipate enrolling more subjects post approval, please submit an amendment request.*

1. **For more than minimal risk studies (as determined in Section 8.3) or studies including vulnerable populations, a sample size calculation or justification is required. If a power analysis or statistical assessment has been completed to determine how many subjects are needed to have a meaningful result, provide the information below. If a power analysis or statistical assessment has not been completed, explain why not:** [REQUIRED FIELD]
2. **Identify subjects that will be recruited (a-b). Submit applicable additional materials indicated.**
3. **Target age of subjects, select all that apply:**

|  |  |
| --- | --- |
| **Age** | **Additional materials required** |
| [ ]  **Birth to 3 years** | [**Parental Permission Form**](https://irb.wsu.edu/forms/) |
| [ ]  **4-7 years** | [**Parental Permission Form and Child's Assent**](https://irb.wsu.edu/forms/) |
| [ ]  **8-17 years** | [**Parental Permission Form and Child's Written Assent**](https://irb.wsu.edu/forms/) |
| [ ]  **18 & over** | [**Written Consent**](https://irb.wsu.edu/forms/) |

1. **Priority population of subjects, select all that apply:**

|  |  |
| --- | --- |
| **Population** | **Additional materials required** |
| [ ]  **College students** | **N/A** |
| [ ]  **Adults, aged 18 and older** | **N/A** |
| [ ]  **Specific gender identity/expression** | **N/A** |
| [ ]  **Neonates/fetuses** | [**Research with Children Addendum**](https://irb.wsu.edu/forms/) |
| [ ]  **Children** | [**Research with Children Addendum**](https://irb.wsu.edu/forms/) |
| [ ]  **Wards of the state aged 17 and younger** | [**Research with Children Addendum**](https://irb.wsu.edu/forms/) |
| [ ]  **Pregnant women** | [**Pregnancy Addendum**](https://irb.wsu.edu/forms/) |
| [ ]  **Prisoners** | [**Prisoners Addendum**](https://irb.wsu.edu/forms/) |
| [ ]  **Substance abusers** | **N/A** |
| [ ] [**Institutionalized individuals**](https://www.law.cornell.edu/cfr/text/42/435.1010) | **N/A** |
| [ ]  **Decisionally impaired** | **N/A** |
| [ ]  **Crime victims** | **N/A** |
| [ ]  **HIV/AIDS patients** | **N/A** |
| [ ]  **Terminally ill** | **N/A** |
| [ ]  **Native American Tribes with whom WSU has agreement** | **N/A** |
| [ ]  **Persons living outside the U.S.** | **N/A** |
| [ ]  **Non-English speaking** | **N/A** |
| [ ]  **Other (please specify):** [REQUIRED FIELD] |

1. **Are there groups of people you are purposefully excluding?**

[ ]  **No**

[ ]  **Yes**

***If yes, complete (a-b).***

1. **Indicate which groups will be excluded, select all that apply:**

[ ]  **Adults, 65 or older**

[ ]  **Children, 17 and younger**

[ ]  **Pregnant women**

[ ]  **Specific gender identity/expression**

[ ]  **Specific sexual orientation**

[ ]  **Marital status**

[ ]  **Ethnic groups**

[ ]  **Race**

[ ]  **Non-English speaking**

[ ]  **Religion**

[ ]  **Other (please specify):** [REQUIRED FIELD]

1. **Provide justification for the exclusion criteria:** [REQUIRED FIELD]

|  |
| --- |
| **SECTION 6. HUMAN SUBJECT RECRUITMENT** |

1. **Select all recruitment/advertising methods that apply and submit all recruitment materials to be used:**

[ ]  **None (e.g., for studies using existing specimens or secondary data)**

[ ]  **Person to person solicitation**

[ ]  **Snowball sampling**

[ ]  **Phone**

[ ]  **Postal mail**

[ ]  **E-mail**

[ ]  **Poster**

[ ]  **Media (e.g., TV, newspaper, radio, web site, social media****) (please specify):** [REQUIRED FIELD]

[ ]  **Subject Pool or Recruitment Pool (please specify):** [REQUIRED FIELD]

[ ]  **Other** **(please specify):** [REQUIRED FIELD]

1. **How will potential subjects be identified? How will potential subjects be approached? Explain in detail for each subject group****:** [REQUIRED FIELD]
2. **Describe any screening tools/procedures in detail for each subject group:** [REQUIRED FIELD]
3. **Special considerations (a-b).**
4. **If you be specifically targeting WSU students for recruitment, please describe how you will avoid undue influence and refer to available guidance for acceptable methods**: [REQUIRED FIELD]
5. **If patients in a hospital or healthcare facility will be recruited, they must first be approached by a member of their healthcare team. Describe how you will introduce the study to the healthcare staff to avoid the common misconception that the research is in any way connected to treatment:** [REQUIRED FIELD]
6. **Will subjects be compensated (including extra credit)?**

[ ]  **No**

[ ]  **Yes**

***If yes, complete (a-d).***

1. **Specify the monetary compensation to be offered (e.g. extra credit, money, cash, gift card)****, how much will the subject be offered, and how/when they will receive it:** [REQUIRED FIELD]
2. **If compensation interferes with subject confidentiality, explain how this will be resolved:** [REQUIRED FIELD]

***PLEASE NOTE:***

*You must collect social security numbers if you are offering cash, cash cards or gift certificates in excess of $250. Payments exceeding $600 per year from WSU (including cash cards or gift certificates) require reporting to the IRS as taxable income (*[*BPPM 45.53*](http://public.wsu.edu/~forms/HTML/BPPM/45_Research/45.53_Incentive_Payments_Research_Participants.htm#Tax_Reporting)*).*

1. **Specify if extra credit is being offered, how much will the subject be offered, and how will they receive it:** [REQUIRED FIELD]

***PLEASE NOTE:***

*If students will be receiving extra credit for participation, they must be able to complete an alternative assignment for the same amount of credit should they choose not to participate. This assignment must be comparable, with respect to time and effort, to participation in the research.*

1. **When will the participants be compensated?**

[ ]  **Before the study**

[ ]  **Installments during the study**

[ ]  **Withdraw/complete the study**

|  |
| --- |
| **SECTION 7. INFORMED CONSENT/PARENTAL PERMISSION/ASSENT PROCESS** |

1. **Select all informed consent/parental permission/assent processes that apply to be used for:**

[ ]  **Adults** [ ]  **Parents** [ ]  **Guardians** [ ]  **N/A**

|  |  |
| --- | --- |
| **Type/Description** | **Additional materials required** |
| [ ]  **Written:** A consent or permission form that contains all the [required elements of informed consent](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.116). | * [Consent form](https://irb.wsu.edu/forms/)
* [Permission form](https://irb.wsu.edu/forms/)
 |
| **☐ Alteration of informed consent process:** Requesting IRB approval for waiver of some or all the elements of informed consent or permission (e.g., medical record review, deception research, or collection of biological specimens). | * [ADDENDUM: Informed Consent Alteration/Waiver – Minimal Risk](https://irb.wsu.edu/forms/)
 |
| [ ]  **Waiver of documentation of informed consent:**Requesting IRB approval for waiver of the requirement for documentation of informed consent or permission (e.g., telephone survey or mailed survey, internet research, or certain international research). | * [ADDENDUM: Informed Consent Alteration/Waiver – Minimal Risk](https://irb.wsu.edu/forms/)

**or*** [ADDENDUM: Informed Consent Waiver – More Than Minimal Risk](https://irb.wsu.edu/forms/)
 |
| [ ]  **Waiver of informed consent process:**Requesting IRB approval for waiver of the requirement for the informed consent or permission process (e.g., medical record review, deception research, or collection of biological specimens). | * [ADDENDUM: Informed Consent Alteration/Waiver – Minimal Risk](https://irb.wsu.edu/forms/)
* For the examination of Archived Data/Secondary or Records that contain any of the direct or indirect identifiers listed under HIPAA, please also submit the [ADDENDUM: HIPAA Authorization](https://irb.wsu.edu/forms/)
 |

1. **Select all informed consent/parental permission/assent processes that apply to be used for:**

[ ]  **Children**[ ]  **Vulnerable population****s** [ ]  **N/A**

|  |  |
| --- | --- |
| **Type/Description** | **Additional materials required** |
| [ ]  **Written:**An assent or consent form that contains all the [required elements of informed consent](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.116). | • [Assent form](https://irb.wsu.edu/forms/)• [Consent form](https://irb.wsu.edu/forms/) |
| **☐ Alteration of informed consent process:**Requesting IRB approval for waiver of some or all the elements of informed consent or permission (e.g., medical record review, deception research, or collection of biological specimens). | * [ADDENDUM: Informed Consent Alteration/Waiver – Minimal Risk](https://irb.wsu.edu/forms/)
 |
| **☐ Waiver of documentation of informed consent:**Requesting IRB approval for waiver of the requirement for documentation of informed consent (e.g., telephone survey or mailed survey, internet research, or certain international research). | * [ADDENDUM: Informed Consent Alteration/Waiver – Minimal Risk](https://irb.wsu.edu/forms/)

**or*** [ADDENDUM: Informed Consent Waiver – More Than Minimal Risk](https://irb.wsu.edu/forms/)
 |
| **☐ Waiver of informed consent process:**Requesting IRB approval for waiver of the requirement for the informed consent process (e.g., medical record review, deception research, or collection of biological specimens). | * [ADDENDUM: Informed Consent Alteration/Waiver – Minimal Risk](https://irb.wsu.edu/forms/)
* For the examination of Archived Data/Secondary or Records that contain any of the direct or indirect identifiers listed under HIPAA, please also submit the [ADDENDUM: HIPAA Authorization](https://irb.wsu.edu/forms/)
 |

1. **Describe how will informed consent information will be presented to participants (e.g., consent form, orally, information sheet):** [REQUIRED FIELD]
2. **For each subject group, explain who, when, and how consent/assent/permission will be obtained:** [REQUIRED FIELD]
3. **If there will be a waiting period between informing a prospective participant about the research and obtaining consent, please describe how long the prospective participant will be given to consider participation. If there will not be a waiting period and the research poses more than minimal risk, please justify (e.g. emergency research):** [REQUIRED FIELD]

1. **Describe how will you determine whether the participants or their legally authorized representatives understand the information presented:** [REQUIRED FIELD]
2. **If participants do not understand English, describe how will translation be provided:** [REQUIRED FIELD]
3. **If participants are unable to read the consent form, describe how will their consent be documented:** [REQUIRED FIELD]
4. **Describe in detail what steps you have taken to prevent potential coercion or undue influence in obtaining consent, permission, or assent:** [REQUIRED FIELD]
5. **Describe what circumstances participants can be withdrawn by the investigator from the research without their consent:** [REQUIRED FIELD]
6. **Describe what procedures will be followed when participants are withdrawn by an investigator or withdraw voluntarily:** [REQUIRED FIELD]

|  |
| --- |
| **SECTION 8. RISK AND BENEFIT ASSESSMENT** |

1. **Select all potential risks to participants that apply:**

[ ]  **Invasion of privacy to the subject or family**

[ ]  **Breach of confidentiality**

[ ]  **Physical harm or discomfort**

[ ]  **Psychological/emotional discomfort or distress**

[ ]  **Psychological effect that is more than discomfort or distress**

[ ]  **Social stigmatization**

[ ]  **Economic (e.g., employment, insurability)**

[ ]  **Legal**

[ ]  **Any study related activity which subjects might consider sensitive, offensive, threatening, or degrading?**

[ ]  **Withholding standard care and procedures**

[ ]  **Other** **(please specify):** [REQUIRED FIELD]

***PLEASE NOTE:***

*These risks* ***must*** *also match the risks listed in the* ***consent/assent/permission documents*** *as well as mitigation strategies in* ***Section 8.4 and 8.5****.*

1. **Does the study pose risk to individuals other than the participants?**

[ ]  **No**

[ ]  **Yes**

***If yes, complete (a).***

1. **Describe in detail the risk to individuals other than the participants:** [REQUIRED FIELD]
2. **Indicate one category listed below that accurately describes the specific potential risk level based on all items in Section 8.1:**

[ ]  No more than minimal risk to participants

[ ]  More than minimal risk to participants.

[ ]  Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of subjects (usually emergency research).

***PLEASE NOTE:***

***Minimal risk*** *means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves from those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests. 45 CFR 46.102(i).*

1. **Describe in detail how you will minimize each potential risk in order to protect participants’ rights and welfare:** [REQUIRED FIELD]
2. **If any of the above-mentioned potential risks occur, describe how it will be handled (e.g., compensation, counseling, etc.):** [REQUIRED FIELD]
3. **Is it possible that you will discover a subject's previously** **unknown physical or psychological condition (e.g., disease, depression, suicidal ideation, genetic predisposition, etc.) as a result of your procedures?**

[ ]  **No**

[ ]  **Yes**

***If yes, complete (a-b).***

1. **Describe what the potential discoveries would be and how you will handle these situations if they were to occur and state if will results be returned to participants:** [REQUIRED FIELD]
2. **Describe any risks and benefits associated with returning results to participants:** [REQUIRED FIELD]
3. **Describe the expected benefits of this project (a-c).**

***PLEASE NOTE:***

*Compensation is* ***not*** *considered a benefit for participation in research. Participating in the research itself (e.g., “experiencing the research process,” or “reflecting on one’s experiences”) is not considered a benefit either. Research does not have to benefit the individual participants.*

1. **Benefits to the individual participants:** [REQUIRED FIELD]
2. **Benefits to society:** [REQUIRED FIELD]
3. **Describe how the benefits of this study outweigh the risks:** [REQUIRED FIELD]
4. **Data Safety Monitoring and the Data Safety Monitoring Board (DSMB) (a-c). If applicable, describe the plan for monitoring data to ensure participant safety.**

***PLEASE NOTE:***

*For many projects involving* ***clinical interventions*** *(behavioral or biomedical interventions regardless of FDA status) or projects that are determined to be* ***more than minimal risk****, a plan must be in place for monitoring data throughout the project to ensure continuing participant safety.*

* 1. **Clearly indicate who will monitor the data (e.g., a DSMB, the PI, the PI and an independent consultant):** [REQUIRED FIELD]
	2. **Describe what actions will be taken if data indicate a potential for increased risk to participants:** [REQUIRED FIELD]
	3. **Describe what actions will be taken to safely stop the study should the monitor(s) or DSMB determine that the risks of continuation outweigh any potential benefits (e.g., stopping rules):** [REQUIRED FIELD]

|  |
| --- |
| **SECTION 9. RESEARCH INVOLVING POTENTIAL REPORTABLE ACTIVITY** |

1. **Will the project involve the potential discovery of child abuse?**

[ ]  **No**

[ ]  **Yes**

***PLEASE NOTE:***

***If yes,*** *there are legal obligations to disclose to the proper authorities certain information about reportable activities obtained during research.* ***This obligation and intended course of action must be communicated to the participants in the consent form.***

|  |
| --- |
| **SECTION 10. RESEARCH INVOLVING DECEPTION** |

1. **Will any information be purposely withheld from the participants, or will they be given any misinformation?**

[ ]  **No**

[ ]  **Yes**

***PLEASE NOTE:***

***If yes,*** this will require alteration of informed consent process. Please complete and submit [*ADDENDUM: Informed Consent Alteration/Waiver – Minimal Risk or ADDENDUM: Informed Consent Waiver – More Than Minimal Risk*](https://irb.wsu.edu/forms/)with your application materials.

1. **Describe why the deception is necessary:** [REQUIRED FIELD]
2. **Describe how/when subjects will be debriefed after the project:** [REQUIRED FIELD]

***PLEASE NOTE:***

*If deception will be used, please include a* ***debriefing script*** *in your application submission.*

|  |
| --- |
| **SECTION 11. RESEARCH INVOLVING HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)** |

1. **Will health information be obtained from a covered entity (a health care provider who bills health insurers e.g., WSU Cougar Health Services)?**

[ ]  **No**

[ ]  **Yes**

1. **Does the research involve the provision of healthcare in a covered entity, such as WSU Cougar Health Services?**

[ ]  **No**

[ ]  **Yes**

1. **If the study involves the provision of healthcare, will a health insurer or billing agency be contacted for billing or eligibility?**

[ ]  **No**

[ ]  **Yes**

1. **Does the research involve use or creation of protected health information?**

[ ]  **No**

[ ]  **Yes**

***PLEASE NOTE:***

***If no to all*** *the questions above, you are not subject to HIPAA****.***

***If yes to any*** *of the questions above, complete the* [*ADDENDUM: HIPAA Authorization*](https://irb.wsu.edu/forms/) *and submit with the application.*

***For HIPAA compliant storage options, please see*** [***Cloud Acceptable Use Matrix***](https://its.wsu.edu/information-security/)***.***

|  |
| --- |
| **SECTION 12. RESEARCH INVOLVING** FDA **DRUGS/DEVICES/BIOLOGICS** |

***PLEASE NOTE:***

***If your research does not involve administration of drugs or other compounds, please select N/A for question 1 and skip the rest of this section*****.**

1. **Will you be using an FDA approved drug, device or biologic but only as approved by the FDA (e.g., no off-label use of device and doses only within approved range for drugs)? If you selected Expedited category 2, please check “yes” here.**

[ ]  **N/A (If selected, skip questions 2-4 and go to section 13)**

[ ]  **No**

[ ]  **Yes**

1. **Will any investigational new drug (IND) be used. Please note that this includes any proposed off-label use of an approved drug (e.g., different indication, dosing, or route of administration) and/or any use of a non-food article intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease?**

[ ]  **No**

[ ]  **Yes *(If selected, please complete, and submit the*** [***ADDENDUM FDA Drugs, Devices, Biologics***](https://irb.wsu.edu/forms/)***)***

1. **Will any other drugs (non-IND, including off-label use of an approved drug) or biologics be used? Note: Unlike typical small molecule drugs, “biologics” are typically larger (and of a biological source), such as blood components or vaccines?**

[ ]  **No**

[ ]  **Yes *(If selected, please complete, and submit the*** [***ADDENDUM FDA Drugs, Devices, Biologics***](https://irb.wsu.edu/forms/)***)***

1. **Will any investigational device (IDE) be used. Please note: This includes any device where an IDE Exemption will be sought from the FDA, any device used in an experimental way that the sponsor determines to be exempt from IDE requirements but that may still require compliance with abbreviated IDE requirements, or the experimental use of an FDA approved device in a manner that is not currently approved by the FDA (sometimes referred to as off-label use).?**

[ ]  **No**

[ ]  **Yes** ***(If selected, please complete, and submit the*** [***ADDENDUM FDA Drugs, Devices, Biologics***](https://irb.wsu.edu/forms/)***)***

|  |
| --- |
| **SECTION 13. INVESTIGATOR’S RESPONSIBILITIES AND ASSURANCES** |

1. **Indicate that you have read and will comply with each statement by checking the boxes and signing below.**

[ ]  **I certify that the information provided in this application, and in all attachments, is complete and correct.**

[ ]  **I understand that I have ultimate responsibility for the protection of the rights and welfare of human participants, the conduct of this study, and the ethical performance of this research.**

[ ]  **I agree to comply with all WSU policies and procedures, the terms of its Federal Wide Assurance, and all applicable federal, state, and local laws regarding eh protection of human participants in research.**

[ ]  **I agree that legally effective informed consent, permission and/or assent will be obtained from human subjects as required and documented using the IRB approved forms, unless waived by the IRB.**

[ ]  **I understand that my research is subject to post-approval review by HRPP staff on behalf of the IRB.**

[ ]  **I certify and agree that:**

* The project will be performed by qualified personnel according to the WSU IRB-approved application.
* The equipment, facilities, and procedures to be used in this research meet recognized standards for safety.
* All data collected for this research is the property of Washington State University (WSU) , which retains rights of access and ownership both during my association with and after my separation from WSU.
* Unless otherwise prohibited by a data sharing agreement or other contract signed by WSU, I will retain an appropriately secured back up copy of all data in a manner compliant with WSU policies, with two WSU personnel having access to it.
* WSU-owned data held on non-WSU devices and WSU devices will be destroyed in accordance with Executive Policy 8. Note: Refer to the “data retention and disposition” section in the policy.
* Unanticipated problems, adverse events, and new information that may affect the risk– benefit assessment for this research will be reported to the WSU IRB Office (509-335-7646; irb@wsu.edu) and to my Department Chair/Director/Dean.
* I am familiar with the latest edition of the WSU IRB Policies and Procedures Manual , and I will adhere to the policies and procedures explained therein.
* Student and co-investigators on this project have received adequate training and are knowledgeable about the regulations and policies governing this research.
* No change will be made to the human subjects protocol or consent form(s) until approved by the WSU IRB.
* I will ensure adequate supervision of all research project personnel and to meet with the investigator(s), if different from myself, on a regular basis to monitor study progress.

[ ]  **I certify that the proposed research has not yet been done, is not currently underway, and will not begin until IRB approval has been obtained.**

**PI name:** [REQUIRED FIELD]

**Date:** [REQUIRED FIELD]

**PI Signature\*: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

*If submitting from the PI’s WSU email, signature is not needed.*

**Name (if not submitted by PI):** [REQUIRED FIELD]

**Date:** [REQUIRED FIELD]

**Signature\*: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

*If submitting from the PI’s WSU email, signature is not needed.*