| U W  and H S D logo | **APPLICATION IRB Protocol, No Contact with Subjects** |
| --- | --- |
|  |
|  |

The Human Subjects Division (HSD) strives to ensure that people with disabilities have access to all services and content. **If you experience any accessibility-related issues with this form or any aspect of the application process, email** **hsdinfo@uw.edu** **for assistance.**

INSTRUCTIONS

* **This form is only for studies that will be reviewed by the UW IRB**. Before completing this form, check [HSD’s website](https://www.washington.edu/research/hsd/is-the-uw-irb-the-right-irb/) to confirm that this should not be reviewed by an external (non-UW) IRB.
* **If you are requesting a determination** about whether the planned activity is human subjects research or qualifies for exempt status, you may skip all questions except those marked with **[DETERMINATION]** For example **1.1. [DETERMINATION]** must be answered.
* **Answer all questions**. If a question is not applicable to the research or if you believe you have already answered a question elsewhere in the application, state “NA” (and if applicable, refer to the question where you provided the information). If you do not answer a question, the IRB does not know whether the question was overlooked or whether it is not applicable. This may result in unnecessary “back and forth” for clarification. Use non-technical language as much as possible.
* For collaborative or multi-site research, describe only the UW activities unless you are requesting that the UW IRB provide the review and oversight for non-UW collaborators or co-investigators as well.
* You may reference other documents (such as a grant application) if they provide the requested information in non-technical language. Be sure to provide the document name, page(s), and specific sections, and upload it to ***Zipline***. Also, describe any changes that may have occurred since the document was written (for example, changes that you’ve made during or after the grant review process). In some cases, you may need to provide additional details in the answer space as well as referencing a document.
* **NOTE: Do not convert this Word document to PDF.** The ability to use “tracked changes” is required in order to modify your study and respond to screening requests.

VERIFY THAT YOU ARE USING THE CORRECT FORM

**Will you interact with subjects in any way as part of this research?** Interaction includes communication of any kind whether it be in person or over email, the internet, or social media. If subjects fill out an online survey, even if you never directly interact with them, that is also considered to be an interaction.

[ ]  **No interaction →** You are using the correct form, please proceed.

[ ]  **Yes interaction → STOP.** You are using the wrong form. Fill out the full IRB Protocol [APPLICATION IRB Protocol](https://www.washington.edu/research/forms-and-templates/zipline-application-irb-protocol/) instead.

INDEX

**1.** [Overview](#OVERVIEW)

**2.** [Participants](#PARTICIPANTS)

**3.** [Non-UW Research Settings](#NONUWRESEARCHSETTINGS)

**4.** [Recruiting and Selecting](#RECRUTINGANDSELECTING)

**5.** [Procedures](#PROCEDURES)

**6.** [Children (Minors) and Parental Permission](#CHILDRENANDPARENTALPERMISSION)

**7.** [Privacy and Confidentiality](#PRIVACYANDCONFIDENTIALITY)

**8.** [Risk / Benefit Assessment](#RISKBENEFITASSESSMENT)

**9.** [Resources](#RESOURCES)

**10.** [Other Approvals, Permissions and Regulatory Issues](#OTHERAPPROVALSPERMISSIONSANDREGULATORYIS)

1 OVERVIEW

**Title:**

|  |
| --- |
| Click or tap here to enter text. |

**1.1. [DETERMINATION]**  **Home institution.** Identify the institution through which the lead researcher listed on the IRB application will conduct the research. Provide any helpful explanatory information.

*In general, the home institution is the institution (1) that provides the researcher’s paycheck and that considers them to be a paid employee, or (2) at which the researcher is a matriculated student. Scholars, faculty, fellows, and students who are visiting the UW and who are the lead researcher: identify your home institution and describe the purpose and duration of your UW visit, as well as the UW department/center with which you are affiliated while at the UW.*

*Note that many UW clinical faculty members are paid employees of non-UW institutions.*

*The UW IRB provides IRB review and oversight for only those researchers who meet the criteria described in the* [*Engagement Guidance*](https://www.washington.edu/research/hsd/guidance/engagement/#agent)*.*

|  |
| --- |
| Click or tap here to enter text. |

**1.2. [DETERMINATION]**  **Consultation history**. Has there been any consultation with someone at UW HSD, the Fred Hutch IRO or the Seattle Children’s IRB about this study?

*It is not necessary to obtain advance consultation. However, if advance consultation was obtained, answering this question will help ensure that the IRB is aware of and considers the advice and guidance provided in that consultation.*

[ ]  **No**

[ ]  **Yes →** Briefly describe the consultation: approximate date, with whom, and method (e.g., by email, phone call, in-person meeting).

|  |
| --- |
| Click or tap here to enter text. |

**1.3. [DETERMINATION]** **Similar and/or related studies**. Are there any related IRB applications that provide context for the proposed activities?

*Examples of studies for which there is likely to be a related IRB application: Using samples or data collected by another study; recruiting subjects from a registry established by a colleague’s research activity; conducting Phase 2 of a multi-part project, or conducting a continuation of another study; serving as the data coordinating center for a multi-site study that includes a UW site.*

*Providing this information (if relevant) may significantly improve the efficiency and consistency of the IRB’s review.*

[ ]  **No**

[ ]  **Yes →** Briefly describe the other studies or applications and how they relate to the proposed activities. If the other applications were reviewed by the UW IRB, please also provide: the UW IRB number, the study title, and the lead researcher’s name.

|  |
| --- |
| Click or tap here to enter text. |

**1.4. [DETERMINATION]**  **Externally-imposed urgency or time deadlines**. Are there any externally-imposed deadlines or urgency that affect the proposed activity?

*HSD recognizes that everyone would like their IRB applications to be reviewed as quickly as possible. To ensure fairness, it is HSD policy to review applications in the order in which they are received. However, HSD will assign a higher priority to research with externally-imposed urgency that is beyond the control of the researcher. Researchers are encouraged to communicate as soon as possible with their HSD staff contact person when there is an urgent situation (in other words, before submitting the IRB application). Examples: a researcher plans to test an experimental vaccine that has just been developed for a newly emerging epidemic; a researcher has an unexpected opportunity to collect data from students when the end of the school year is only four weeks away.*

*HSD may ask for documentation of the externally-imposed urgency. A higher priority should not be requested to compensate for a researcher’s failure to prepare an IRB application in a timely manner. Note that IRB review requires a certain minimum amount of time; without sufficient time, the IRB may not be able to review and approve an application by a deadline.*

[ ]  **No**

[ ]  **Yes** **→** Briefly describe the urgency or deadline as well as the reason for it.

|  |
| --- |
| Click or tap here to enter text. |

**1.5. [DETERMINATION]**  **Objectives**. Using lay language, describe the purpose, specific aims, or objectives that will be met by this specific project. If hypotheses are being tested, describe them. You will be asked to describe the specific procedures in a later section.

|  |
| --- |
| Click or tap here to enter text. |

**1.6. [DETERMINATION]**  **Study design**. Provide a one-sentence description of the general study design and/or type of methodology.

*Your answer will help HSD in assigning applications to reviewers and in managing workload. Examples: a longitudinal observational study; a double-blind, placebo-controlled randomized study; ethnographic interviews; web scraping from a convenience sample of blogs; medical record review; coordinating center for a multi-site study.*

|  |
| --- |
| Click or tap here to enter text. |

**1.7. [DETERMINATION]**  **Intent**. Check all the descriptors that apply to your study. You must check at least one box.

*This question is essential for ensuring that your application is correctly reviewed. Please read each option carefully.*

| **Check all that apply** | **Descriptor** |
| --- | --- |
|[ ]  Class project or other activity whose purpose is to provide an educational experience for the researcher (for example, to learn about the process or methods of doing research). |
|[ ]  Part of an institution, organization, or program’s own internal operational monitoring. |
|[ ]  Improve the quality of service provided by a specific institution, organization, or program. |
|[ ]  Designed to expand the knowledge based of a scientific discipline or other scholarly field of study, and produce results that:* Are expected to applicable to a larger population beyond the site of data collection or the specific subjects studied, or
* Are intended to be used to develop, test, or support theories, principles, and statements of relationships, or to inform policy beyond the study.
 |
|[ ]  Focus directly on the specific individuals about whom the information or biospecimens are collected through oral history, journalism, biography, or historical scholarship activities, to provide an accurate and evidence-based portrayal of the individuals. |
|[ ]  A quality improvement or program improvement activity conducted to improve the implementation (delivery or quality) of an accepted practice, or to collect data about the implementation of the practice for clinical, practical, or administrative purposes. This does not include the evaluation of the efficacy of different accepted practices, or a comparison of their efficacy. |
|[ ]  Public health surveillance activities conducted, requested, or authorized by a public health authority for the sole purpose of identifying or investigating potential public health signals or timely awareness and priority setting during a situation that threatens public health. |
|[ ]  Preliminary, exploratory or research development activities (such as pilot and feasibility studies, or reliability/validation testing of a questionnaire). |
|[ ]  Other. Explain: |

|  |
| --- |
| Click or tap here to enter text. |

**1.8. Supplements**. Check all boxes that apply, to identify relevant SUPPLEMENTS that should be completed and uploaded to ***Zipline***.

*This section is here instead of at the end of the form to reduce the risk of duplicating information in this IRB Protocol form that you will need to provide in these Supplements.*

| **Check all that apply** | **Type of Research** | **Supplement Name and Link** |
| --- | --- | --- |
|[ ]  **Artificial Intelligence Systems** (School of Medicine only)Research involving the use of [Artificial Intelligence](https://depts.washington.edu/comply/docs/308_G1.pdf) when:(1) it is led by School of Medicine PIs; and, (2) It involves either the targeted enrollment of UW Medicine patients, OR use of [UW Medicine Data](https://depts.washington.edu/comply/docs/308_G1.pdf). | [SUPPLEMENT Artificial Intelligence](https://www.washington.edu/research/forms-and-templates/supplement-ai/) |
|[ ]  **Department of Defense**The research involves Department of Defense funding, facilities, data, or personnel. | [SUPPLEMENT Department of Defense](https://www.washington.edu/research/forms-and-templates/supplement-department-of-defense/) |
|[ ]  **Department of Energy**The research involves Department of Energy funding, facilities, data, or personnel. | [SUPPLEMENT Department of Energy](https://www.washington.edu/research/forms-and-templates/supplement-department-of-energy/) |
|[ ]  **Genomic data sharing**Genomic data are being collected and will be deposited in an external database (such as the NIH dbGaP database) for sharing with other researchers, and the UW is being asked to provide the required certification or to ensure that the consent forms can be certified. | [SUPPLEMENT Genomic Data Sharing](https://www.washington.edu/research/forms-and-templates/supplement-genomic-data-sharing/) |
|[ ]  **Medical device**Procedures involve the use of any medical device, even if the device is not the focus of the proposed research, except when the device is FDA-approved and is being used through a clinical facility in the manner for which it is approved. | [SUPPLEMENT Devices](https://www.washington.edu/research/forms-and-templates/supplement-devices/) |
|[ ]  **Multi-site or collaborative study**The UW IRB is being asked to review on behalf of one or more non-UW institutions in a multi-site or collaborative study. | [SUPPLEMENT Multi-site or Collaborative Research](https://www.washington.edu/research/forms-and-templates/supplement-multi-site-or-collaborative-research/) |
|[ ]  **Non-UW Individual Investigators**The UW IRB is being asked to review on behalf of one or more non-UW individuals who are not affiliated with another organization for the purpose of the research. | [SUPPLEMENT Non-UW Individual Investigators](https://www.washington.edu/research/forms-and-templates/supplement-non-uw-individual-investigators/) |
|[ ]  None of the above. |  |

2. PARTICIPANTS

**2.1. [DETERMINATION]**  **Participants**. Describe the general characteristics of the subject populations or groups, including age range, gender, health status, and any other relevant characteristics.

|  |
| --- |
| Click or tap here to enter text. |

**2.2. [DETERMINATION]**  **Inclusion and exclusion criteria.**

**2.2.a. Inclusion criteria**. Describe the specific criteria that will be used to decide who will be included in the research from among interested or potential subjects. Define any technical terms in lay language.

|  |
| --- |
| Click or tap here to enter text. |

**2.2.b. Exclusion criteria**. Describe the specific criteria that will be used to decide which of the subjects who meet the inclusion criteria listed above will be excluded from the research. Define any technical terms in lay language.

|  |
| --- |
| Click or tap here to enter text. |

**2.3. [DETERMINATION]**  **Prisoners**. IRB approval is required in order to include prisoners in research, even when prisoners are not an intended target population.

**2.3.a.** Will the proposed research obtain data about individuals that are known to be prisoners?

*For records reviews: if the records do not indicate prisoner status and prisoners are not a target population, select “No”. See the* [***GUIDANCE Prisoners***](https://www.washington.edu/research/hsd/guidance/prisoners/) *for the definition of “prisoner”, which is not necessarily tied to the type of facility in which a person is residing.*

[ ]  **No**

[ ]  **Yes →** Describe the type of prisoners, and their locations.

|  |
| --- |
| Click or tap here to enter text. |

**2.4. [DETERMINATION]**  **Protected populations.** IRB approval is required for the use of the subject populations listed here. Check the boxes for any of these populations that will be purposefully included. (In other words, being a part of the populations is an inclusion criterion for the study.)

*The WORKSHEETS describe the criteria for approval but do not need to be completed and should not be submitted.*

| **Check all that apply** | **Population** | **Worksheet Name and Link** |
| --- | --- | --- |
|[ ]  Fetuses in utero | [WORKSHEET Pregnant Women](https://www.washington.edu/research/forms-and-templates/worksheet-pregnant-women/) |
|[ ]  Neonates of uncertain viability | [WORKSHEET Neonates](https://www.washington.edu/research/forms-and-templates/worksheet-neonates/) |
|[ ]  Non-viable neonates | [WORKSHEET Neonates](https://www.washington.edu/research/forms-and-templates/worksheet-neonates/) |
|[ ]  Pregnant women | [WORKSHEET Pregnant Women](https://www.washington.edu/research/forms-and-templates/worksheet-pregnant-women/) |

**2.4.a.** If you check any of the boxes above, use this space to provide any information that may be relevant for the IRB to consider.

|  |
| --- |
| Click or tap here to enter text. |

**2.5. [DETERMINATION]**  **Native Americans or non-U.S. Indigenous populations**. Will data or specimens about or from Native American or non-U.S. Indigenous populations be actively recruited through a tribe, tribe-focused organization, or similar community-based organization?

*Indigenous people are defined in international or national legislation as having a set of specific rights based on their historical ties to a particular territory and their cultural or historical distinctiveness from other populations that are often politically dominant.*

*Examples: a reservation school or health clinic; recruiting during a tribal community gathering.*

[ ]  **No**

[ ]  **Yes →** Name the tribe, tribal-focused organization, or similar community-based organization. The UW IRB expects that tribal/Indigenous approval will be obtained before beginning the research. This may or may not involve approval from a tribal IRB. The study team and any collaborators/investigators are also responsible for identifying any tribal laws that may affect the research.

|  |
| --- |
| Click or tap here to enter text. |

**2.6. [DETERMINATION]**  **Third party subjects.** Will the research collect private identifiable information about individuals *other than* the study subjects? Common examples include: collecting medical history information or contact information about family members, friends, co-workers.

*“Identifiable” means any direct or indirect identifier that, alone or in combination, would allow you or another member of the research team to* ***readily identify*** *the person. For example, suppose that the research is about immigration history. If subjects are asked questions about their grandparents but are not asked for names or other information that would allow easy identification of the grandparents, then private identifiable information is not being collected about the grandparents and the grandparents are not subjects.*

[ ]  **No**

[ ]  **Yes →** These individuals are considered human subjects in the study. Describe them and what data will be collected about them.

|  |
| --- |
| Click or tap here to enter text. |

**2.7. Number of subjects**. Is it possible to predict or describe the maximum number of subjects (or subject units) you plan to enroll to meet study objectives?

***Subject units*** *mean units within a group. For most research studies, a group will consist of individuals. However, the unit of interest in some research is not the individual. Examples:*

* *Dyads such as caregiver-and-Alzheimer’s patient, or parent and child*
* *Families*
* *Other units, such as student-parent-teacher*

***Subject group*** *means categories of subjects that are meaningful for the specific study. Some research has only one subject group – for example, all UW students taking Introductory Psychology. Some common ways in which subjects are grouped include:*

* *By intervention – for example, an intervention group and a control group.*
* *By subject population or setting – for example, urban versus rural families*
* *By age – for example, children who are 6, 10, or 14 years old.*

*The IRB reviews the number of subjects in the context of risks and benefits. Unless otherwise specified, if the IRB determines that the research involves no more than minimal risk: there are no restrictions on the total number of subjects that may be enrolled. If the research involves more than minimal risk: The number of enrolled subjects must be limited to the number described in this application. You will be asked about subject enrollment, as well as subject withdrawals and completions, when completing your status report. Please request the maximum number of subjects you expect to enroll. If it is necessary later to increase the number of subjects, submit a Modification. Exceeding the IRB-approved number (*[*over-enrollment*](https://www.washington.edu/research/glossary/over-enrollment/)*) will be considered non-compliance.*

[ ]  **No →** Provide the rationale in the box below. Also, provide any other available information about the scope/size of the research. You do not need to complete the table.

*Example: It may not be possible to predict the number of subjects who will complete an online survey advertised through Craigslist, but you can state that the survey will be posted for two weeks and the number who respond is the number who will be in the study.*

|  |
| --- |
| Click or tap here to enter text. |

[ ]  **Yes →** For each subject group, use the table below to provide the estimate of the maximum desired number of individuals (or other subject unit, such as families) who will enroll in the research.

| **Group name/description** | **Maximum desired number or individuals (or other subject unit) who will enroll in the research*****Provide numbers for the site(s) reviewed by the UW IRB and for the study-wide total number; example: 20/100*** |
| --- | --- |
| Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. |

3. NON-UW RESEARCH SETTINGS

*Complete this section only if UW investigators and people named in the* [*SUPPLEMENT Non-UW Individual Investigators*](https://www.washington.edu/research/forms-and-templates/supplement-non-uw-individual-investigators) *will conduct research procedures outside of UW and Harborview*

**3.1. [DETERMINATION]**  **Reason for locations**. Describe the reason(s) for choosing the locations for the research.

*This is especially important when the research will occur in locations or with populations that may be vulnerable to exploitation. One of the three ethical principles the IRB must consider is Justice: ensuring that reasonable, non-exploitative, and well-considered procedures are administered fairly, with a fair distribution of costs and potential benefits.*

|  |
| --- |
| Click or tap here to enter text. |

**3.2. [DETERMINATION]**  **Local context**. Culturally appropriate procedures and an understanding of local context are an important part of protecting subjects. Describe any site-specific cultural issues, customs, beliefs, or values that may affect the research, how it is conducted, or how consent is obtained or documented.

*Examples: It would be culturally inappropriate in some international settings to obtain residual clinical specimens for research without consent.*

*This federal site maintains an international list of human research standards and requirements:* [*http://www.hhs.gov/ohrp/international/index.html*](http://www.hhs.gov/ohrp/international/index.html)

|  |
| --- |
| Click or tap here to enter text. |

**3.3. [DETERMINATION]**  **Location-specific laws.** Describe any local laws that may affect the research. The most common examples are laws about:

* **Specimens** – for example, some countries will not allow biospecimens to be taken out of the country.
* **Use of healthcare records** – many states have laws that are similar to the federal HIPAA law but that have additional requirements.

|  |
| --- |
| Click or tap here to enter text. |

**3.4. [DETERMINATION]**  **Location specific administrative or ethical requirements**. Describe local administrative or ethical requirements that affect the research.

*Example: A school district may require you to obtain permission from the head district office as well as school principals before releasing student records.*

|  |
| --- |
| Click or tap here to enter text. |

**3.5. [DETERMINATION]**  **If the PI is a student: Does the research involve traveling outside of the U.S.?**

[ ]  **No**

[ ]  **Yes →** Confirm by checking the box that (1) you will register with the [UW Office of Global Affairs](http://www.washington.edu/globalaffairs/) before traveling; (2) you will notify your advisor when the registration is complete; and (3) you will request a UW Travel Waiver is the research involves travel to the [list of countries](http://www.washington.edu/globalaffairs/global-travelers/warnings-waivers/#myanchor) requiring a UW Travel Waiver.

[ ]  **Confirmed**

4. RECRUITING AND SELECTING

**4.1. [DETERMINATION]** Describe how subjects will be identified and selected. Include information about: how, when, where, and in what setting. List all sources of information.

|  |
| --- |
| Click or tap here to enter text. |

5. PROCEDURES

**5.1. [DETERMINATION]**  **Study procedures**. Using lay language, provide a complete description of the study procedures, including the sequence, use of records, time required, and setting/location. If it is available: Upload a study flow sheet or table to ***Zipline***.

|  |
| --- |
| Click or tap here to enter text. |

**5.2. [DETERMINATION]**  **Data variables**. Describe the specific data that will be obtained (including a description of the most sensitive items). Alternatively, a list of the data variables may be uploaded to ***Zipline***.

|  |
| --- |
| Click or tap here to enter text. |

**5.3. [DETERMINATION]**  **Data sources**. For all types of data that will be accessed or collected for this research: Identify whether the data are being obtained from the subjects (or subjects’ specimens) or whether they are being obtained from some other source (and identify the source). List all sources.

|  |
| --- |
| Click or tap here to enter text. |

**5.4. [DETERMINATION]**  **Consent.** Will subjects have provided their consent for the proposed use of the data and specimens that will be obtained?

*For example: suppose specimens will be obtained from a repository created and managed by another investigator (not part of this study team). Will the repository have obtained consent from the subjects when the specimens were placed in the repository, for future sharing of the specimens? NOTE: If identifiable information or identifiable biospecimen are obtained without consent, any waiver granted by the IRB does not override a subject’s refusal to provide broad consent (for example, through the Northwest Biotrust).*

[ ]  **No →**

[ ]  **Yes →** Describe the nature of the consent and uses of data/specimens to which the subjects consented.

|  |
| --- |
| Click or tap here to enter text. |

**5.5. [DETERMINATION]**  **Identifiability of data and specimens.** Answer these questions carefully and completely. This will allow HSD to accurately determine the type of review that is required and the relevant compliance requirements. Review the following definitions before answering the questions:

***Access*** *means to view or perceive data, but not to possess or record it. See, in contrast, the definition of “obtain”.*

***Identifiable*** *means that the identity of an individual is or may be readily (1) ascertained by the researcher or any other member of the study team from specific data variables or from a combination of data variables, or (2) associated with the information.*

***Direct identifiers*** *are direct links between a subject and data/specimens. Examples include (but are not limited to): name, date of birth, medical record number, email or IP address, pathology or surgery accession number, student number, or a collection of data that is (when taken together) identifiable.*

***Indirect identifiers*** *are information that links between direct identifiers and data/specimens. Examples: a subject code or pseudonym.*

***Key*** *refers to a single place where direct identifiers and indirect identifiers are linked together so that, for example, coded data can be identified as relating to a specific person. Example: a master list that contains the data code and the identifiers linked to the codes.*

***Obtain*** *means to possess or record in any fashion (writing, electronic document, video, email, voice recording, etc.) for research purposes and to retain for any length of time. This is different from* ***accessing****, which means to view or perceive data.*

**5.5.a.** Will you or any members of your team have **access** to any direct or indirect identifiers?

[ ]  **Yes →** Describe which identifiers and for which data/specimens.

|  |
| --- |
| Click or tap here to enter text. |

[ ]  **No →** Select the reason(s) why you (and all members of your team) will not have access to direct or indirect identifiers.

[ ]  There will be no identifiers

[ ]  Identifiers or the key have been (or will have been) destroyed before access.

[ ]  There is an agreement with the holder of the identifiers (or key) that prohibits the release of the identifiers (or key) to study team members under any circumstances.

*This agreement should be available upon request from the IRB. Examples: a Data Use Agreement, Repository Gatekeeping form, or documented email.*

[ ]  There are written policies and procedures for the repository/database/data management center that prohibit the release of the identifiers (or identifying link). This includes situations involving an Honest Broker.

[ ]  There are other legal requirements prohibiting the release of the identifiers or key. Describe them below.

|  |
| --- |
| Click or tap here to enter text. |

**5.5.b**. Will you or any study team members **obtain** any direct or indirect identifiers?

[ ]  **Yes →** Describe which identifiers and for which data/specimens.

|  |
| --- |
| Click or tap here to enter text. |

**5.5.b.1.** Explain why you cannot carry out this research without using the information or biospecimens in an identifiable format. **You must answer this question**, because of a new requirement in the revised human subjects regulations.

|  |
| --- |
| Click or tap here to enter text. |

[ ]  **No →** Select the reason(s) why you (and all members of your team) will not obtain direct or indirect identifiers.

[ ]  There will be no identifiers.

[ ]  Identifiers or the key have been (or will have been) destroyed before access.

[ ]  There will be an agreement with the holder of the identifiers (or key) that prohibits the release of the identifiers (or key under any circumstances.

*This agreement should be available upon request from the IRB. Examples: a Data Use Agreement, Repository Gatekeeping form, or documented email.*

[ ]  There are written policies and procedures for the repository/database/data management center that prohibit the release of the identifiers (or identifying link). This includes situations involving an Honest Broker.

[ ]  There are other legal requirements prohibiting the release of the identifiers or key. Describe them below.

|  |
| --- |
| Click or tap here to enter text. |

**5.5.c.** If any identifiers will be obtained, indicate how the identifiers will be stored (and for which data). NOT: Do not describe the data security plan here, that information is requested in [question **7.5.**](#QSevenDotFive)

[ ]  Identifiers will be stored with the data. Describe the data to which this applies:

|  |
| --- |
| Click or tap here to enter text. |

[ ]  Identifiers and study data will be stored separately but a link will be maintained between the identifiers and the study data (for example, through the use of a code). Describe the data to which this applies:

|  |
| --- |
| Click or tap here to enter text. |

[ ]  Identifiers and study data will be stored separately, with no link between the identifiers and the study data. Describe the data to which this applies:

|  |
| --- |
| Click or tap here to enter text. |

**5.5.d. Research collaboration**. Will individuals who **provide coded information or specimens** for the research also collaborate on other activities for this research? If yes, identify the activities and provide the name of the collaborator’s institution/organization.

*Examples include but are not limited to: (1) study, interpretation, or analysis of the data that results from the coded information or specimens; and (2) authorship on presentations or manuscripts related to this work*.

|  |
| --- |
| Click or tap here to enter text. |

**5.6. [DETERMINATION]**  **Protected Health Information (PHI).** Will any member of the study team access, obtain, use, or disclose participants’ identifiable PHI for any reason (for example, to identify or screen potential subjects, to obtain study data or specimens, for study follow-up)?

*PHI is individually identifiable healthcare record information or clinical specimens from an organization considered a “covered entity” by federal HIPAA regulations, in any form or media, whether electronic, paper, or oral.* ***You must answer yes to this question if the research involves identifiable health care records (e.g., medical, dental, pharmacy, nursing, billing, etc.), identifiable healthcare information from a clinical department repository, or observations or recordings of clinical interactions.***

*For information about what constitutes the UW Covered Entity, see UW Medicine Compliance* [*Patient Information Privacy Policy 101*](https://depts.washington.edu/comply/docs/comp_101.pdf) *and* [*diagram of the healthcare components*](http://depts.washington.edu/comply/docs/101_G1.pdf)*.*

*For information about the circumstances in which UW Medicine PHI may be released for research purposes, review* [*Comp. 306 Release of Clinical Data for Research Purposes*](https://uwnetid.sharepoint.com/sites/uw_medicine_honest_broker/SitePages/Clinical-Data-For-Research-Purposes-Policy.aspx) *and* [*Comp. 307 Honest Broker Policy for UW Medicine Clinical Data*](https://uwnetid.sharepoint.com/sites/uw_medicine_honest_broker/SitePages/Honest-Broker-Policy.aspx)*. Additional information can also be found on the* [*UW Medicine Honest Broker Program website*](https://uwnetid.sharepoint.com/sites/uw_medicine_honest_broker/SitePages/Clinical-Data-For-Research-Purposes-Policy.aspx)*.*

[ ]  **No →** Skip the rest of this question; go to [question **5.7.**](#QFiveDotSeven)

[ ]  **Yes →** Answer all of the questions below (**5.6.a.** through **5.6.e.**)

**5.6.a.** Describe the PHI and the reason for using it. *Be specific. For example, will any “free text” fields (such as physician notes) be accessed, obtained or used?*

|  |
| --- |
| Click or tap here to enter text. |

**5.6.b**. Is any of the PHI located in Washington State?

[ ]  **No**

[ ]  **Yes**

**5.6.c**. Describe the pathway of how the PHI will be accessed or obtained, starting with the source/location and then describing the system/path/mechanism by which it will be identified, accessed, and copied for the research. *Be specific. For example: directly view records; search through a department’s clinical database; submit a request to Leaf.*

|  |
| --- |
| Click or tap here to enter text. |

**5.6.d.** Provide the following assurances by checking the boxes.

[ ]  The minimum necessary amount of PHI to accomplish the purposes described in this application will be accessed, obtained and/or used.

[ ]  The PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted.

[ ]  The HIPAA “accounting for disclosures” requirement will be fulfilled, if applicable. See [UW Medicine Compliance Policy #104](https://depts.washington.edu/comply/docs/comp_104.pdf). THIS IS ONLY FOR UW RECORDS.

[ ]  There will be reasonable safeguards to protect against identifying, directly or indirectly, any patient in any report of the research.

**5.7. [DETERMINATION]**  **Genomic data sharing**. Will the research obtain or generate genomic data?

[ ]  **No**

[ ]  **Yes** **→** Answer the question below.

**5.7.a.** Will genomic data from this research be sent to a national database (for example, NIH’s dbGaP database)?

[ ]  **No**

[ ]  **Yes** **→** Complete the [SUPPLEMENT Genomic Data Sharing](https://www.washington.edu/research/forms-and-templates/supplement-genomic-data-sharing/) and upload it to ***Zipline***.

**5.8. Whole genome sequencing**. For research involving biospecimens: Will the research include whole genome sequencing?

*Whole genome sequencing is sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen.*

[ ]  **No**

[ ]  **Yes**

**5.9.** **[DETERMINATION]**  **Possible secondary use or sharing of information, specimens, or subject contact information.** Please consider the broadest possible future plans.

*Many federal grants and contracts now require data or specimen sharing as a condition of funding, and many journals require data sharing as a condition of publication. “Sharing” may include (for example): analyzing data using machine learning models; informal arrangements to share banked data/specimens with other investigators; establishing a repository that will formally share with other researchers through written agreements; or sending data/specimens to a third-party repository/archive/entity such as the Social Science Open Access Repository (SSOAR), or the UCLA Ethnomusicology Archive.*

**5.9.a.** Is this research funded by an NIH funding application submitted on or after January 25, 2023.

[ ]  **No →** Continue to **5.9.b**.

[ ]  **Yes** **→**  [NIH Data Management and Sharing Policy](https://sharing.nih.gov/data-management-and-sharing-policy/about-data-management-and-sharing-policy/research-covered-under-the-data-management-sharing-policy%22%20%5Cl%20%22after) applies to this research*.* If the policy applies and data will not be shared, provide the justification in the text box below and complete the remaining questions in this section, as applicable.

|  |
| --- |
| Click or tap here to enter text. |

**5.9.b.** Describe **what will be stored for future use**, including whether any direct or indirect (e.g., subject codes) identifiers will be stored.

|  |
| --- |
| Click or tap here to enter text. |

**5.9.c.**  Describe **what will be shared with other researchers, or with a repository/database/registry/machine learning platform**, including whether direct identifiers will be shared and (for specimens) what data will be released with the specimens.

|  |
| --- |
| Click or tap here to enter text. |

**5.9.d.** Who will oversee and/or manage the sharing?

|  |
| --- |
| Click or tap here to enter text. |

**5.9.e.**  Describe **the possible future uses**, including limitations or restrictions (if any) on future uses or users. As stated at the beginning of this question, consider the broadest possible uses.

*Examples of limitations:*

* *If consent was obtained for primary collection of the data being used for this project and that consent prohibits or limits the scope of sharing and use (e.g., consent states that data will be used only for cardiovascular research)*
* *Privacy or safety or research participants would be compromised (e.g., there is risk of reidentification and/or harm)*
* *Explicit federal, state, or local, or Tribal law, regulation, or policy prohibits disclosure*
* *Restrictions imposed by existing or anticipated agreements (e.g., with third party funders, partners, with repositories, medical centers providing health information under a data use agreement)*

|  |
| --- |
| Click or tap here to enter text. |

**5.9.f**. **Consent.** Did subjects provide consent for future research use when the information/specimens were initially collected?

[ ]  **No**

[ ]  **Yes** **→** Upload a copy of the consent form to *Zipline*.

**5.9.g.** **Agreements for sharing or release.** Confirm by checking the box that the sharing or release will comply with UW (and, if applicable, UW Medicine) policies that require a formal agreement with the recipient for release of data or specimens to individuals or entities other than federal databases.

*Data Use Agreements or Gatekeeping forms are used for data; Material Transfer Agreements are used for specimens (or specimens plus data). Do not attach any template agreement forms; the IRB neither reviews nor approves them.*

[ ]  **Confirmed**

**5.10.** **Future contact with subjects**. Is there a plan to retain any contact information for subjects so that they can be contacted in the future?

[ ]  **No**

[ ]  **Yes →** Describe the purpose of the future contact, and whether use of the contact information will be limited to the study team; if not, describe who else could be provided with the contact information. Describe the criteria for approving requests for the information.

*Examples: inform subjects about other studies; ask subjects for additional information or medical record access that is not currently part of the study proposed in this application; obtain another sample.*

|  |
| --- |
| Click or tap here to enter text. |

6. CHILDREN (MINORS) AND PARENTAL PERMISSION

**6.1. [DETERMINATION]**  **Involvement of minors**. Does the research include minors (children)?

**Minor or child** means someone who has not yet attained the legal age for consent for the research procedures, as described in the applicable laws of the jurisdiction in which the research will be conducted. This may or may not be the same as the definition used by funding agencies such as the National Institutes of Health.

* In Washington State the generic age of consent is 18, meaning that anyone under the age of 18 is considered a child.
* There are some procedures for which the age of consent is much lower in Washington State.
* The generic age of consent may be different in other states, and in other countries.

[ ]  **No →** Go to Section 7.

[ ]  **Yes →** Provide the age range of the minor subjects for this study and the legal age for consent in the study population(s). If there is more than one answer, explain.

|  |
| --- |
| Click or tap here to enter text. |

[ ]  **Don’t know →** This means is it not possible to know the age of the subjects. For example, this may be true for some research involving social media, the Internet, or a dataset that is obtained from another researcher or from a government agency. Go to [Section 7.](#PRIVACYANDCONFIDENTIALITY)

**6.2. Parental permission.** Parental permission means actively obtaining the permission of the parents. This is not the same as “passive” or “opt out” permission where it is assumed that parents are allowing their children to participate because they have been provided with information about the research and have not objected or returned a form indicating they don’t want their children to participate.

**6.2.a.** Will parental permission be obtained for:

[ ]  All of the research procedures **→** Go to [question **6.2.b.**](#QSixDotTwoDotB)

[ ]  None of the research procedures **→** Use the table below to provide justification and skip question **6.2.b.**

[ ]  Some of the research procedures **→** Use the table below to identify the procedures for which parental permission will not be obtained.

*Be sure to consider all research procedures and plans, including screening, future contact, and sharing/banking of data and specimens for future work.*

| **Children Group1** | **Describe the procedures or data/specimen collection (if any) for which there will be NO parental permission2** | **Reason why parental permission will not be obtained** | **Will parents be informed about the research?3** |
| --- | --- | --- | --- |
|  |  |  | **YES** | **NO** |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |[ ] [ ]
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |[ ] [ ]
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |[ ] [ ]
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |[ ] [ ]
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |[ ] [ ]

*Table footnotes*

1. *If the answer is the same for all children groups or all procedures: collapse the answer across the groups and/or procedures.*
2. *If identifiable information or biospecimens will be obtained without parent permission, any waiver granted by the IRB does not override parents’ refusal to provide broad consent (for example, through the Northwest Biotrust).*
3. *Will parents be informed about the research beforehand even though active permission is not being obtained?*

**6.2.b.** Indicate the plan for obtaining parental permission. One or both boxes must be checked.

[ ]  Both parents, unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

[ ]  One parent, even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.

*This is all that is required for minimal risk research.*

If both are checked explain:

|  |
| --- |
| Click or tap here to enter text. |

**6.3. Children who are wards**. Will you know whether the data or specimens you obtain are from a child who is a ward of the State or any other agency, institution, or entity?

[ ]  **No**

[ ]  **Yes** **→** An advocate may need to be appointed for each child who is a ward. The advocate must be in addition to any other individual acting on behalf of the child as guardian or in loco parentis. The same individual can serve as advocate for all children who are wards.

Describe who will be the advocate(s). The description must address the following points:

* Background and experience
* Willingness to act in the best interests of the child for the duration of the research
* Independence of the research, research team, and any guardian organization

|  |
| --- |
| Click or tap here to enter text. |

7. PRIVACY AND CONFIDENTIALITY

**7.1. [DETERMINATION]**  **Identification of individuals in publications and presentations.** Will potentially identifiable information about subjects be used in publications and presentations, or is it possible that individual identities could be inferred from what is planned to be published or presented?

[ ]  **No**

[ ]  **Yes →** Will subject consent be obtained for this use?

[ ]  **Yes**

[ ]  **No →** Describe the steps that will be taken to protect subjects (or small groups of subjects) from being identifiable.

|  |
| --- |
| Click or tap here to enter text. |

**7.2. [DETERMINATION]**  **Records retention requirements.** Check the box below to indicate assurance that any identifiers (or links between identifiers and data/specimens) and data that are part of the research records will not be destroyed until after the end of the applicable records retention requirements (e.g., Washington State; funding agency or sponsor; Food and Drug Administration). If it is important to say something about destruction of identifiers (or links to identifiers) in the consent form, state that identifying information will be destroyed at the end of the study or after the records retention period required by state and/or federal law.

*See the “Research Data” and “Personal Identifiers” sections of the following website for UW Records management for the Washington State research records retention schedules that apply in general to the UW (not involving UW Medicine data):* [***http://f2.washington.edu/fm/recmgt/gs/research?title=R***](http://f2.washington.edu/fm/recmgt/gs/research?title=R)***;*** [***https://finance.uw.edu/recmgt/gs/research?title=P***](https://finance.uw.edu/recmgt/gs/research?title=P).

*See the “Research Records and Data” information in Section 8 of this document for the retention schedules for UW Medicine Records:* [***https://www.uwmedicine.org/recordsmanagementuwm-records-retention-schedule.pdf***](https://www.uwmedicine.org/recordsmanagementuwm-records-retention-schedule.pdf)

[ ]  **Confirm**

**7.3. [DETERMINATION]**  **Certificates of Confidentiality.** Will a federal Certificate of Confidentiality be obtained for the research data? *NOTE: Answer “No” if the study is funded by NIH or the CDC, because most NIH-funded and CDC-funded studies automatically have a Certificate.*

[ ]  **No**

[ ]  **Yes**

**7.4. [DETERMINATION]**  **Data security protections**. Identify the data risk level and the security protections that will be provided for all sites where data will be collected, transmitted, or stored. In some cases, a study may include data that qualifies for more than one risk level. All data in the same system should be maintained at the highest risk level of any type of data. For example, if some of the data are level 1 (L1) and some are level 3 (L3), then the whole system should be protected at level 3 (L3).

**7.4.a.** Choose the level(s) of protections you will apply to the data. Refer to the [WEBPAGE Data Security Requirements Guidance](https://www.washington.edu/research/hsd/guidance/data-security/) to answer this question.

[ ]  **Level 1**

**Note:** Level 1 applies to a very limited set of studies. Most human subjects research data will require Level 2 or higher. If you believe your study qualifies for Level 1 based on information on our [WEBPAGE Data Security Requirements Guidance](https://www.washington.edu/research/hsd/guidance/data-security/), provide justification in the text box below.

[ ]  **Level 2**

[ ]  **Level 3**

[ ]  **Level 4**

If you checked more than one box above, use the text box to describe which level will apply to which data and in which system and/or site(s) it will be stored.

|  |
| --- |
| Click or tap here to enter text. |

**7.4.b.** HSD allows researchers to request exceptions to data security requirements, **if the exception is necessary and does not significantly increase risk to participants**. If there are data security requirements within the selected risk level(s) listed in 7.4.a which will not be followed, list those here. Specify the data and the system or site(s) where this exception will apply. Provide a rationale for the exception and explain what (if any) alternative measures will be taken to protect the data.

**Example -** If you intend to store subject identifiers with study screening data (not permitted under requirement U9 for Risk Levels 3-4), then indicate this in the box below (e.g., “We will not adhere to requirement U9 for screening data because we are capturing this in REDCap via subject surveys which maintains the data together. The REDCap system has other sufficient security measures that we feel mitigates the risk of maintaining the information together”).

|  |
| --- |
| Click or tap here to enter text. |

8. RISK / BENEFIT ASSESSMENT

**8.1. [DETERMINATION]**  **Anticipated risks.** Describe the reasonably foreseeable risks of harm, discomforts, and hazards to the subjects and others of the research procedures. For each harm, discomfort, or hazard:

* Describe the magnitude, probability, duration, and/or reversibility of the harm, discomfort, or hazard, AND
* Describe how the risks will be reduced or managed. Do not describe data security protections here, these are already described in [question **7.4**.](#QSevenDotFive)
* *Consider possible physical, psychological, social, legal, and economic harms, including possible negative effects on financial standing, employability, insurability, educational advancement or reputation. For example, a breach of confidentiality might have these effects.*
* *Examples of “others”: embryo, fetus, or nursing child; family members; a specific group.*
* *Do not include the risks of non-research procedures that are already being performed.*
* *Examples of mitigation strategies: inclusion/exclusion criteria; applying appropriate data security measures to prevent unauthorized access to individually identifiable data; coding data*
* *As with all questions on this application, you may refer to uploaded documents*

|  |
| --- |
| Click or tap here to enter text. |

**8.2. [DETERMINATION]**  **Unforeseeable risks**. Are there any research procedures that may have risks that are currently unforeseeable?

[ ]  **No**

[ ]  **Yes** **→** Identify the procedures.

|  |
| --- |
| Click or tap here to enter text. |

**8.3. [DETERMINATION]**  **Return of individual research results.**

*Review the* [**GUIDANCE Return of Individual Results**](https://www.washington.edu/research/hsd/guidance/results/) *for information about results that should and should not be returned, validity of results, the Clinical Laboratory Improvement Amendment (CLIA), consent requirements, and communicating results.*

**8.3.a.** Is it anticipated that the research will produce any individual research results that are clinically actionable?

*“Clinically actionable” means that there are established therapeutic or preventive interventions or other available actions that have the potential to change the clinical course of the disease/condition or lead to an improved health outcome.*

*An “individual research result” is any information collected, generated, or discovered in the course of a research study that is linked to the identity of a research participant.*

[ ]  **No**

[ ]  **Yes** **→** Describe the clinically actionable results that will be produced.

|  |
| --- |
|  |

**8.3.b.** Will you return any individual research results to subjects, either by direct contact or by adding study results to subjects’ medical records?

[ ]  **No**

[ ]  **Yes** **→** Explain which results will be returned to subjects and provide the rationale for doing so.

|  |
| --- |
| Click or tap here to enter text. |

**8.4. Commercial products or patents**. Is it possible that a commercial product or patent could result from this study?

[ ]  **No**

[ ]  **Yes →** Describe whether subjects might receive any remuneration/compensation and, if yes, how the amount will be determined.

|  |
| --- |
| Click or tap here to enter text. |

9. RESOURCES

**9.1. [DETERMINATION]**  **Faculty Advisor**. **If the PI is a student or resident,** provide the following information about the faculty advisor.

* Advisor’s name
* Your relationship with your advisor (for example: graduate advisor; course instructor)
* Your plans for communication/consultation with your advisor about progress, problems, and changes.

|  |
| --- |
| Click or tap here to enter text. |

**9.2. UW Principal Investigator Qualifications**. Upload a current or recent Curriculum Vitae (CV), Biosketch (as provided to federal funding agencies), or similar document to the Local Site Documents page in ***Zipline***. The purpose of this is to address the PI’s qualifications to conduct the proposed research (education, experience, training, certifications, etc.).

*For help with creating a CV, see* [*http://adai.uw.edu/grants/nsf\_biosketch\_template.pdf*](http://adai.uw.edu/grants/nsf_biosketch_template.pdf) *and* [*https://intranet.medicine.uw.edu/academic-hr/curriculum-vitae-cv*](https://intranet.medicine.uw.edu/academic-hr/curriculum-vitae-cv)

[ ]  **The CV will be uploaded.**

**9.3. UW Study team qualifications**. Describe the qualifications and/or training for each UW study team member to fulfill their role on the study and perform study procedures. (You may be asked about non-UW study team members during the review; they should not be described here.) You may list these individuals by name, however if you list an individual by name, you will need to modify this application if that individual is replaced. Alternatively, you can describe study roles and the qualifications and training the PI or study leadership will require for any individual who might fill that role. The IRB will use this information to assess whether risks to subjects are minimized because study activities are being conducted by properly qualified and trained individuals.

**Describe: The role (or name of person), the study activities they will perform, and the qualifications or training that are relevant to performing those study activities.**

|  |
| --- |
| **Examples**: **Research Study Coordinator:** Obtain consent, administer surveys, blood draw. Will have previous experience coordinating clinical research and be a certified phlebotomist in WA.**Undergraduate Research Assistant:** Obtain consent, perform all study procedures. Will have had coursework in research methods, complete an orientation to human subjects protections given by the department, and will receive training from the PI or the graduate student project lead on obtaining consent and debriefing subjects.**Acupuncturist:** Perform acupuncture procedures and administer surveys. Must be licensed with WA State DoH and complete training in administering research surveys given by the project director, an experienced survey researcher.**Co-Investigator:** Supervise MRI and CT scan procedures and data interpretation, obtain consent. MD, specialty in interventional radiology and body imaging. 5-years clinical research experience. |

|  |
| --- |
| Click or tap here to enter text. |

10. OTHER APPROVALS, PERMISSIONS, AND REGULATORY ISSUES

**10.1. [DETERMINATION]** **Approvals and permissions**. Identify any other approvals or permissions that will be obtained. For example: from a school, external site/organization, funding agency, employee union, UW Medicine clinical unit.

*Do not attach the approvals and permissions unless requested by the IRB.*

|  |
| --- |
| Click or tap here to enter text. |

**10.2. [DETERMINATION]** **Financial Conflict of Interest**. Does any UW member of the team have ownership or other Significant Financial Interest (SFI) with this research as defined by [UW policy GIM 10?](https://www.washington.edu/research/policies/gim-10/)

[ ]  **No**

[ ]  **Yes** **→** Has the Office of Research made a determination regarding this SFI as it pertains to the proposed research?

[ ]  **No** **→** Contact the Office of Research (206.616.0804, research@uw.edu) for guidance on how to obtain the determination.

[ ]  **Yes** **→** Upload the Conflict Management Plan for every UW team member who has a FCOI with respect to the research, to ***Zipline***. If it is not yet available, use the text box to describe whether the Significant Financial Interest has been disclosed already to the UW Office of Research and include the FIDS Disclosure ID if available.

|  |
| --- |
| Click or tap here to enter text. |