Human Research Protection Program (HRPP) - Office of Research Assurances
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NON-EXEMPT REVIEW CHECKLIST

HRPP USE ONLY	
IRB Application Number:	
Study Title:	
PI Name:	
Review Category:	☐ **Expedited** ☐ **Full Board**
Review Type:	☐ **New** ☐ **Amendment** ☐ **Renewal** ☐ **Adverse Event** ☐ **Other, please specify:**
Review Due Date:	
1st Reviewer:	
2nd Reviewer:	

IRB APPROVAL CRITERIA 45 CFR 46.111

IRB approval of research must meet the following criteria found in 45 CFR 46.111

1. **Risks to subjects are minimized** (through study design and procedures, and if possible, using procedures already being performed on the subjects for diagnostic and treatment purposes);
    - *Most likely to be explained in Section 2, Section 8*
2. **Risks to subjects are reasonable in relation to anticipated benefits**, if any, to subjects. Risks and benefits considered by the IRB should only be those that result from the research (as distinguished from the risks and benefits of therapies participants would receive even if not participating in the research);
    - *Most likely to be explained in Section 8, Section 12*
3. **Selection of subjects is equitable**, taking into account the purposes of the research and the setting which the research will be conducted;
    - *Most likely to be explained in Section 2, Section 5*
4. **Informed consent will be sought from each prospective participant** or their legally authorized representative;
    - *Most likely to be explained in Section 6, Section 7, Recruitment Materials, Consent documents*
5. **When appropriate, there is a provision for monitoring the data** collected to ensure the safety of subjects (e.g. a data safety monitoring board, a biostatistician on the study team);
    - *Most likely to be explained in Section 2, Section 8*
6. There are **adequate provisions to protect the privacy of subjects and to maintain the confidentiality of the data**;
    - *Most likely to be explained in Section 4, Consent documents*
7. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, **additional safeguards have been included in the study to protect the rights and welfare of these subjects**;

Most likely to be explained in Section 2, Section 5, Section 6, Section 7, Section 8

STUDY DESIGN 45 CFR 46.111.a(1)

Consider the following questions:

- Is the purpose clearly stated?
- Is the study design appropriate to the purpose?
- Will the research contribute to generalizable knowledge?
- Is it worth exposing subjects to stated risk?

Reviewer notes (Optional, write "N/A" if none):

CONFIDENTIALITY/PRIVACY 45 CFR 46.111.a(6)/45 CFR 46.111.a(7)

Consider the following questions:

- Will personally identifiable research data be protected to the extent possible from access or use?
- Are any special privacy & confidentiality issues properly addressed (e.g., use of genetic information)?

Reviewer notes (Optional, write "N/A" if none):

SUBJECT SELECTION/RECRUITMENT 45 CFR 46.111.a(3)

Consider the following questions:

- Who is enrolled?
- Are these subjects appropriate for the protocol?
- Is subject selection equitable?
- Is rationale for inclusion/exclusion criteria addressed?

Reviewer notes (Optional, write "N/A" if none):

VULNERABLE SUBJECTS 45 CFR 46.111.a(3)/45 CFR 46.111.b

Additional safeguards are required for subjects likely to be vulnerable to coercion or undue influence.

Consider the following questions:

- Are appropriate protections in place for vulnerable subjects (e.g., fetuses, children, prisoners, students [both for children and those in university], individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons)?
- What Safeguards or protections are included?
    - Permission/assent procedures
    - Ad litem/legally authorized representative consent
    - Cultural sensitivity considerations
    - Alternate methods of consent (including visuals, videos, etc.) or instruments like the University of California, San Diego Brief Assessment of Capacity to Consent (UBACC)
    - Sufficient evidence of the teacher/professor separating the research role from their role as an instructor.

Reviewer notes (Optional, write "N/A" if none)::

INFORMED CONSENT, 45 CFR 46.111.a(4-5)/45 CFR 46.116			
Informed consent is obtained from research subjects or their legally authorized representative(s).			
YES	**NO**	**N/A**	**Answer the following REQUIRED questions. If not applicable, please check "N/A":**
HEADING			
☐	☐	☐	Study title and name(s) of researcher(s) are at the beginning of the consent form. This includes the PI's and local contact person's (if a remote site location) phone number and email.
☐	☐	☐	Financial Conflicts of Interest or External Funding are disclosed if applicable.
KEY INFORMATION			
☐	☐	☐	For consent forms over 2000 words, a summary of key information is presented at the beginning of the consent document; 45 CFR 46.116(a)(5)(i).
☐	☐	☐	The approximate number of subjects involved in the study (more than minimal risk research only); 45 CFR 46.116(c)(6).
WHAT YOU SHOULD KNOW			
☐	☐	☐	A statement that the study involves research; 45 CFR 46.116(b)(1).
☐	☐	☐	A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; 45 CFR 46.116(b)(8).
☐	☐	☐	The following statement is included: This study (IRB #) has been approved for human subject participation by the Washington State University Institutional Review Board.
WHAT IS THE PURPOSE OF THIS STUDY			
☐	☐	☐	An explanation of the purpose(s) of the research; 45 CFR 46.116(b)(1).
☐	☐	☐	Inclusion and exclusion criteria from Section 5 are clearly stated.
WHAT WILL I BE ASKED TO DO IF I AM IN THIS STUDY			
☐	☐	☐	A description of procedures to be followed (Match to Section 2 and 3 of the Application - should include all the types of data collection, not just the subject's involvement) ; 45 CFR 46.116(b)(1).
☐	☐	☐	Identification of any procedures which are experimental; 45 CFR 46.116(b)(1).
☐	☐	☐	Expected duration of the subject's participation (Match to Section 2 of the Application - time required/involved); 45 CFR 46.116(b)(1).
☐	☐	☐	A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; 45 CFR 46.116(c)(8).

☐	☐	☐	A disclosure of appropriate alternative procedures of courses of treatment, if any, that might be advantageous to the participant—**Usually biomedical research**; 45 CFR 46.116(b)(4).
☐	☐	☐	A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject; 45 CFR 46.116(c)(5).
☐	☐	☐	For research involving bio-specimens, whether the research will or might include whole genome sequencing; 45 CFR 46.116(c)(9).
ARE THERE ANY RISKS TO ME IF I AM IN THIS STUDY			
☐	☐	☐	A description of any reasonably foreseeable risks or discomforts to the participant. (Match to Section 8.4 and 8.5 of the Application); 45 CFR 46.116(b)(2).
☐	☐	☐	A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable; 45 CFR 46.116(c)(1).
☐	☐	☐	**For research involving more than minimal risk**, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained; 45 CFR 46.116(b)(6).
☐	☐	☐	That the research consent form and information will be posted on clinicaltrials.gov if applicable; 45 CFR 46.116(h).
ARE THERE ANY BENEFITS TO ME IF I AM IN THIS STUDY			
☐	☐	☐	A description of any benefits to the participant or to others which may reasonably be expected from the research (Match to Section 8.7 of the Application). **Note:** The description must not include compensation as a benefit and should not emphasize compensation or overstate potential benefits; 45 CFR 46.116(b)(3).
WILL MY INFORMATION BE KEPT PRIVATE			
☐	☐	☐	A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained (Match to Section 4.1 of the Application); 45 CFR 46.116(b)(5).
☐	☐	☐	If data is being collected in, or transferred from, the European Union (GDPR) or another country or state that has its own data security or privacy requirements, that those have been met.

☐	☐	☐	If the research involves collection of identifiable private information or identifiable bio-specimens that there is a statement that identifiers might be removed from the identifiable private information or identifiable bio-specimens and that, after such removal, the information or bio-specimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative. **Note:** WSUHRPP does not allow option b9ii without prior institutional approval; 45 CFR 46.116(b)(9)(i).
☐	☐	☐	If an NIH Certificate of Confidentiality is or will be issued, that the appropriate language is included.
☐	☐	☐	If the protocol is FDA sponsored research, language that FDA personnel may review any and all documents related to the research including subject medical records, in either a directed or routine audit of the investigator, the institution or IRB.
ARE THERE ANY COSTS OR PAYMENTS FOR BEING IN THIS STUDY?			
☐	☐	☐	Compensation information is clearly explained, including timing and amounts. **Note:** There should not be an emphasis on maximum compensation in cases where all participants are not likely to receive the maximum. In cases where drawings are held, the approximate probability of "winning" should be indicated.
☐	☐	☐	Any additional costs to the subject that may result from participation in the research; 45 CFR 46.116(c)(3).
☐	☐	☐	If applicable: A statement that the subject's bio-specimens (even if the identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit; 45 CFR 46.116(c)(7).
WHO CAN I TALK TO IF I HAVE QUESTIONS			
☐	☐	☐	An explanation of whom to contact for answers to pertinent questions about the research, subjects' rights, concerns, or complaints, and whom to contact in the event of a research-related injury to the subject; 45 CFR 46.116(a)(2), 45 CFR 46.116(b)(7).
WHAT IF I HAVE A STUDY RELATED INJURY OR WANT TO WITHDRAW			
☐	☐	☐	The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject; 45 CFR 46.116(c)(4).

☐	☐	☐	Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent; 45 CFR 46.116(c)(2).
☐	☐	☐	Contact information in case of a study-related injury, illness, or distress is provided; 45 CFR 46.116(b)(6).
WHAT ARE MY RIGHTS AS A RESEARCH STUDY VOLUNTEER			
☐	☐	☐	A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; 45 CFR.
WHAT DOES MY SIGNATURE ON THIS CONSENT FORM MEAN / STATEMENT OF CONSENT			
☐	☐	☐	Signature block includes participant, researcher(s), witness if appropriate (not required in most cases), and date of signature Note: no signature block required if a waiver of documentation has been granted; 45 CFR 46.116(a)(1).
☐	☐	☐	When appropriate, check box or signature provided to indicate agreement to audio or videotape is included.
☐	☐	☐	Statement that the participant will receive a copy of the consent form.
COMPREHENSION/READABILITY			
☐	☐	☐	Consent document is written at a reading and comprehension level appropriate for the age and/or background of the participant (6th-8th grade for most); 45 CFR 46.116(a)(5)(ii).
☐	☐	☐	Lay language is used so the content (especially explanation of purpose, duration, experimental procedures, alternatives, risks, and benefits) is understandable to the participants; 45 CFR 46.116(a)(3).
☐	☐	☐	Unless PI has provided documentation of institutional approval, consent form does NOT contain elements of Broad Consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens; 45 CFR 46.116(d).
☐	☐	☐	Consent form is free of exculpatory language through which the subject is made to waive, or appear to waive, any of the subject's legal rights; 45 CFR 46.116(a)(6).
PARENT PERMISSION (IF APPLICABLE), 45 CFR 46.408			
☐	☐	☐	Statement that the researcher is asking for parent permission:

			• for their child to take part in research, and • to ask the child if they are willing to take part in the study (assent)
☐	☐	☐	Description of procedures explained in terms of what the **child** will be asked to do.
☐	☐	☐	Statement that the child may choose not to take part even if parent gives permission to participate.
☐	☐	☐	Description of what, if any, study data about their child will be shared with the parent, if applicable.
☐	☐	☐	Purpose, risks, risk minimization, benefits, procedures, and confidentiality protections described in relation to the child as participant.
☐	☐	☐	When relevant, a statement of mandatory reporting requirements is included.
☐	☐	☐	For greater than minimal risk studies, signature lines are provided for both parents.
ASSENT (IF APPLICABLE), 45 CFR 46.408			
☐	☐	☐	An explanation that the parent(s) know the child is being asked to be in the research.
☐	☐	☐	The purpose, procedure, risks, benefits, and data confidentiality explained in developmentally-appropriate lay language
☐	☐	☐	A description of what, if any, information the be shared with shared with their parent(s), if applicable .
☐	☐	☐	An explanation is provided about audio or video taping if recording is required for participation. If this is not required, a check box or signature line to opt out of taping is included.
☐	☐	☐	When relevant, statement of mandatory reporting requirements included.

Reviewer notes (Optional, write "N/A" if none):

INFORMED CONSENT WAIVER/ALTERATION 45 CFR 46.111.a(5)

**Complete only if a waiver or alteration is requested in Section 7*

For broad consent, the IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable information or biospecimens.

Consider the requirements for Waiver/Alteration (45 CFR 46.116[f][3]):

i. The research involves **no more than minimal risk** to the subjects;
ii. The research could not practicably be carried out without the requested waiver or alteration [records research];
iii. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
iv. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
v. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

Consider that to waive the requirement for the PI to obtain a signed informed consent form for some or all subjects the study must meet any of the following (45 CFR 46.117[c][1]):

i. That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;
ii. That the research presents **no more than minimal risk** of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or
iii. If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents **no more than minimal risk** of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

Reviewer notes (Optional, write "N/A" if none)*:*

RISK LEVEL 45 CFR 46.111.a(2)

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45 CFR 46.102[j]). Long-range effects are applying knowledge gained in the research (e.g., the possible effects of the research on public policy" as among those research risks that fall within the purview of the IRB.

YES	NO	N/A	Answer the following REQUIRED questions. If not applicable, please check "N/A":
☐	☐	☐	The research involves minimal risk to subjects.
☐	☐	☐	The research involves a minor increase over minimal risk to subjects (children only).
☐	☐	☐	The research involves more than minimal risk (adults only).

Reviewer notes (Optional, write "N/A" if none):

RISKS MINIMIZED 45 CFR 46.111.a(2)/45 CFR 46.111.a(6)

Consider the following questions:

- Does the research design minimize risks to subjects?
- If applicable, are procedures used already being performed on subjects for diagnostic or treatment purposes?
- Would use of a data & safety monitoring board (DSMB) or other research oversight process enhance subject safety?

Reviewer notes (Optional, write "N/A" if none):

BENEFITS 45 CFR 46.111.a(2)

Definition: A research benefit is considered something of health-related, psychosocial, or other value to an individual research subject, or something that will contribute to the acquisition of generalizable knowledge.

Money or other compensation for participation in research is not considered to be a benefit, but rather compensation for research-related inconveniences.

YES	NO	N/A	Answer the following REQUIRED questions. If not applicable, please check "N/A":
☐	☐	☐	There is no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's status or condition.
☐	☐	☐	There is no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge to further society's understanding.
☐	☐	☐	The research involves the prospect of direct benefit to individual subjects.

Reviewer notes (Optional, write "N/A" if none):

RISK TO BENEFIT RATIO 45 CFR 46.111.a(2)

Consider the following questions:

- Are the potential risks to subjects are reasonable in relation to potential benefits to subjects or society?

Reviewer notes (Optional, write "N/A" if none):

REQUIRED CHANGES

Please number all changes and reference the location (e.g., Section 1.3, "What is the purpose of this study?" If no recommendations are provided, please indicate with "N/A."

Application:

Recruitment Materials:

Informed Consent/Permissions/Assent:

Data Collection Instruments:
Other Required Changes:

Recommendations/Additional Comments * Optional:

REVIEWER DETERMINATION

Disposition Recommendation: Submitted in writing for expedited reviews. Presented as a motion in full board meetings.

Please select one of the following determinations:

☐ Approve as submitted

☐ Defer approval, pending **minor** changes/clarifications

If selected, please indicate to be reviewed by:

- ☐ HRPP/IRB Coordinator
- ☐ IRB Chair
- ☐ Assigned reviewers/expert, **please specify**:
- ☐ Full Board

☐ Defer approval, pending **substantive** changes/clarifications

If selected, please indicate to be reviewed by:

- ☐ IRB Chair
- ☐ Assigned reviewers/expert, **please specify**:
- ☐ Full Board

☐ Expedited studies: Not approvable as submitted

If selected, provide justification:

☐ Full board studies: Not approvable as submitted

If approval is withheld at the full board level the justification will be documented in the meeting minutes.

REVIEWER RECOMMENDED APPROVAL PERIOD	
Please select from the following recommended approval periods:	
☐	Approve for 1 year
☐	Continuing review is necessary **If selected**, please explain: **If CR approval is different from 1 year**, please provide approval period:

REVIEWER CERTIFICATION	
If Expedited, indicate category (1-7):	
Reviewed by :	
Date:	