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|  | Diagram  Description automatically generated | **FORM: IRB Application****(Contact)** |

|  |  |
| --- | --- |
| **Date:** |       |
| **FHIRB #:** |       |
| **RG # (required):** |       | **Protocol #:** |       |
| **Principal Investigator:** |       |
| **Study Title:**  |       |

Have you consulted with anyone in the Fred Hutch Institutional Review Office (IRO), or with the University of Washington Human Subjects Division or the Seattle Children’s IRB, about this research? Who and when?

|  |
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Instructions

* Use this form if you will **interact with subjects**, such as for an interventional study or a study with blood draws, a web based-survey, telephone interview, focus groups, etc.
	+ Use [*HRP-251 - FORM - IRB Application (No Contact)*](https://extranet.fredhutch.org/en/f/irb/irb-application.html) instead if you will have no interaction of any kind with your subjects (for example a study involving data/specimens only, where there is no contact).
* This form is used in conjunction with Hutch IRB to submit a new study to the Fred Hutchinson Cancer Center IRB.
* **This form is only for studies that will be reviewed by the Fred Hutch IRB**. Before completing this form, check the [IRO website](https://extranet.fredhutch.org/en/u/irb/selecting-the-right-irb.html) to confirm this is the appropriate IRB.
* **Answer all questions**, except when directed to skip one. If a question is not applicable to the research or if you believe you have already answered a question elsewhere in the application, state “N/A” (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 clarification requests.
* Use non-technical language as much as possible.
* **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.

Table of Contents

[**1.** **Research Design and Resources**](#_Toc124978389)

[**2. Risk/Benefit Assessment**](#_Toc124978390)

[**3. Selection and Recruitment**](#_Toc124978391)

[**4.** **Consenting and Compensating Research Participants**](#_Toc124978392)

[**5. Documenting Consent**](#_Toc124978393)

[**6. Data and Safety Monitoring**](#_Toc124978394)

[**7.** **Privacy and Confidentiality**](#_Toc124978395)

[**8.** **Other Regulatory and/or Institutional Review Requirements**](#_Toc124978396)

[**9. Required Ancillary Reviews**](#_Toc124978397)

[**10. Required Supplements**](#_Toc124978398)

1. Research Design and Resources

*The IRB requests the following information to confirm that risks to participants are minimized by using procedures which are consistent with sound research design, and which do not unnecessarily expose participants to risk.*

* 1. Would you like this research to be considered for one of the following?

*Note: UW investigators should submit all minimal risk or Exempt research to UW’s Human Subjects Division, unless single IRB requirements apply or as otherwise agreed to by both institutions.*

[ ]  Minimal risk research qualifying for Expedited Review ® Attach [*HRP-276 - FORM - Expedited Review*](https://extranet.fredhutch.org/en/f/irb/expedited-review-checklist-for-minimal-risk-activities.html)in Hutch IRB along with this application

[ ]  Research Exempt from requirements for IRB review under Exemption categories 1 to 6 ® Attach [*HRP-275 - FORM - Exempt*](https://extranet.fredhutch.org/en/f/irb/exempt-checklist.html) in Hutch IRB along with this application.**Complete only Sections 1, 7, and 8 of this application**.

*Note: For research under Exempt category 4, stop and use* [*HRP-251 - FORM - IRB Application (No Contact)*](https://extranet.fredhutch.org/en/f/irb/irb-application.html) *instead.*

1.2 Research Plan: Attach yourresearch protocol documentto the submission. (A copy of a grant does not suffice.)

*Note: The protocol must address the following elements: Study summary, background/significance and rationale, objectives, endpoints, study procedures, study timelines, subject population and inclusion/exclusion criteria, statistical methods, rationale for number of subjects, risks and benefits, recruitment methods, the proposed consent process, data management and confidentiality, use of data and specimens, and provisions to monitor data and protect privacy.*

1.3 Projected enrollment: What are the estimated number and ages?

* Studies only enrolling within the Cancer Consortium: Complete only the local enrollment row.
* Studies enrolling outside the Cancer Consortium: Both local and study-wide enrollment numbers must be provided.
* For studies without direct participant contact: Enrollment should reflect number of data subjects (distinct individuals from whom you will have information or biospecimens). Indicate “Not Applicable” or N/A for any columns that do not apply or are unknown.

|  |  |  |
| --- | --- | --- |
|  | **NUMBER OF PARTICIPANTS** | **AGE RANGE OF PARTICIPANTS** |
| **First Year** | **Entire Study** |
| **Locally** |       |       |       |
| **Study-wide** |       |       |       |

1.4 Have all members of the research team received training on Human Subject Protections and/or Good Clinical Practice (GCP) as required per [*IRB Policy 2.20 Training*](https://extranet.fredhutch.org/en/u/irb/policies-and-procedures/_jcr_content/leftParsys/download_36/file.res/IRB-Training-Policy.pdf)(038)?

*Note: If any new members join the research team, the Principal Investigator is responsible for ensuring everyone receives and maintains required training.*

[ ]  Yes

[ ]  No, explain:

|  |
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1.5 Does this research activity use a “community-based participatory research” approach?

[ ]  Yes ® Respond to the following questions:

 Describe how community members and organizational representatives will be involved in the research process:

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Describe any process to communicate the progress, interim results, or final results back to the community during or after the research:

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[ ]  No

1.6 Does this research obtain or access information and/or biospecimens from a source other than what is provided to you directly by the enrolled participant? (e.g., medical records, other studies, a repository, etc.)

 [ ]  Yes ® Provide the following information and complete Questions 1.6.a – 1.6.b.

Provide name, address, institution/company, and a brief description of what information and/or biospecimens will be provided from each source.

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Address** | **Institution/Company** | **Description** |
|       |       |       |       |
|       |       |       |       |
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For public or medical record sources, or from sources on the [IRB Pre-Reviewed Sources of De-identified Human Specimens and/or Data](https://extranet.fredhutch.org/en/u/irb/submissionstotheirb/research-not-involving-human-subjects/_jcr_content/leftParsys/download_f2c7/file.res/Pre-Reviewed-Sources-De-identified-Human-Specimens.pdf): You do not need to attach any other documentation about these sources.

For all other sources: **You must attach supporting documentation** (e.g., a gatekeeper letter, material or data transfer agreement, contract, etc.) from the provider of the information and/or biospecimens. The documentation should acknowledge your use of the information and/or biospecimens for this specific project and should confirm consent was appropriately obtained or waived for future research use.

Important Notes:

1. Receiving information and/or biospecimens from outside your home institution may require a material transfer or data use agreement (MTA/DUA). Fred Hutch researchers, review <https://centernet.fredhutch.org/cn/u/business-dev/form-questionnaire.html> or contact Business Development at MTA@fredhutch.org for more information. UW researchers, contact the Agreements Group at mta-group@uw.edu.
2. Use of Seattle Children’s data by Fred Hutch employees: For interventional clinical trials, no DUA is required; however, for an observational study, a limited data use addendum is required. Contact Business Development at MTA@fredhutch.org or Office of General Counsel at generalcounsel@fredhutch.org.
3. If this project involves the use of information and/or biospecimens that are covered by a Certificate of Confidentiality (CoC), you should be aware the CoC protections extend to the information and/or biospecimens permanently. When you receive such biospecimens or data, you are obligated to uphold the disclosure restrictions. For example, data from an NIH repository such as dbGaP or biospecimens and/or data collected or generated by another research project covered by a Certificate of Confidentiality.
4. Per UW Medicine policy, the UW Medicine eCare/MyChart system may not be used for research recruitment purposes. Additionally, researchers may not use UW Medicine’s Epic Care Everywhere data for research purposes unless the clinical data is necessary for patient/participant safety activities. This means Care Everywhere data cannot be used for recruitment, data abstraction, or any research activities other than those necessary for patient/participant safety.

[ ]  No® Continue to [Section 2.0](#Risk_Benefit_Assessment).

1.6.a. Are there any restrictions on the research uses for the information and/or biospecimens (e.g., they may not be transferred from your institution to another researcher, or no genetic testing is allowed on the samples)?

[ ]  Yes ® Explain:

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|       |

[ ]  No

1.6.b. Will the study’s biospecimens include human fetal tissue?

[ ]  Yes ® Provide information about where the tissue is obtained and attach an attestation (from the provider or third-party supplier) that informed consent was obtained at the time of tissue collection.

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[ ]  No

☞ **If requesting an Exempt determination, only complete Sections 7 and 8 in the rest of this application. You do not need to complete Sections 2 - 6.**

1. Risk/Benefit Assessment

*The IRB is responsible for determining that risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result.*

*Ensure the protocol includes a thorough description of the risks and benefits of this research.*

2.1 What procedures in this research are already being performed for diagnostic or treatment purposes?

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2.2 Is it possible that this study will discover a previously unknown condition such as a disease, suicidal intentions, or genetic predisposition in a participant as a result of the procedures?

[ ]  Yes ® Describe how you will manage this situation.

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[ ]  No

2.3 Will this study involve the collection or analysis of biospecimens directly from participants for research purposes?

[ ]  Yes ® Respond to Questions 2.3.a. – 2.3.e.

[ ]  No ® Go to Question 2.4.

2.3.a. Will the results be useful for predicting the occurrence or prognosis of a disease in the participant?

[ ]  Yes ® Describe:

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|       |

[ ]  No

2.3.b. Will the results potentially be used for predicting disease risk/susceptibility in family members?

[ ]  Yes ® Describe:

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|       |

[ ]  No

2.3.c. Will the results reveal information about paternity?

[ ]  Yes ® Describe:

|  |
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|       |

[ ]  No

2.3.d. Which research test results will be provided to research participants?

[ ]  All ® Respond to Questions 2.3.d.i and 2.3.d.ii.

[ ]  Some ® Describe which results and explain why only some of the results will be provided to the research participants. Then respond to Questions 2.3.d.i and 2.3.d.ii.

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*[ ]* None ® Explain why this study will not provide test results to the research participants. Then go to 2.3.e.

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2.3.d.i. Will the research tests returned to the participant be performed in a Clinical Laboratory Improvement Amendments (CLIA) certified lab?

[ ]  Yes

[ ]  No ® Explain why not:

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2.3.d.ii. Also explain how research results will be provided to the participant or his or her healthcare provider. Describe any counseling that will be offered, if applicable.

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2.3.e. Do you plan to collect research blood draws after consent but before confirmation that the participant meets the eligibility criteria?

[ ]  Yes ® Respond to Question 2.3.e.i.

[ ]  No

2.3.e.i. Blood drawn before eligibility confirmation should be limited to the lesser of 50 mL or 3 mL per kg of body weight. Will you exceed this limit?

[ ]  Yes ® Provide justification:

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[ ]  No

2.4 [Third-party subjects](https://extranet.fredhutch.org/en/u/irb/glossary.html#thirdpartysubjects). Will the research collect information about individuals *other than* the study participants? Common examples include collecting medical history information or contact information about family members, caregivers, or donors.

[ ]  Yes **→** These individuals may be considered human subjects in the study, for example if private identifiable information is collected about them for research purposes. Respond to Question 2.4.a. – 2.4.c.

[ ]  No **→** Go to Question 2.5.

2.4.a. Identify the potential third-party subjects:

[ ]  Donors. There may be additional requirements for this study. Refer to the NMDP Algorithm Analysis at the following link for additional instructions. <https://network.bethematchclinical.org/research/institutional-review-board/donors-as-research-subjects/>

[ ]  Family members

[ ]  Caregivers

[ ]  Other:

2.4.a.i List all the personal identifiers that will be collected on third parties.

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2.4.a.ii How will this information be used?

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2.4.a.iii. Will the study seek consent from the third-party subjects?

[ ]  Yes ® Attach the consent form you will use for this purpose.

[ ]  No ® Complete [*HRP-256 - FORM - Consent Supplement*](https://extranet.fredhutch.org/en/f/irb/waiver-consent.html) and indicate you are seeking a partial waiver of consent for the third-party subjects.

2.4.b. If family members: Will family history information, such as disease status of family members, be shared among other family members?

[ ]  Yes ® Respond to 2.4.c.

[ ]  No

[ ]  N/A – Not collecting information about family members. Skip to Question 2.5.

2.4.c. Does the consent form describe how family history information will be shared among other family members?

[ ]  Yes

[ ]  No ® Explain:

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2.5. If the results of this research could raise a potential for stigma being attached to a particular demographic group, what measures will the study take to address this potential for group harms?

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1. Selection and Recruitment

*The IRB is responsible for determining that the research does not exploit vulnerable populations or exclude participants on the basis of race, gender, ethnicity, or socioeconomic status.*

3.1 Will the study identify potential participants through nonpublic sources (e.g., Cancer Surveillance System, other research projects, patients’ medical records, surgery logs, etc.)?

Note: Per UW Medicine policy, the UW Medicine eCare/MyChart system may not be used for research recruitment purposes. Additionally, researchers may not use UW Medicine’s Epic Care Everywhere data for research purposes unless the clinical data is necessary for patient/participant safety activities. This means Care Everywhere data cannot be used for recruitment, data abstraction, or any research activities other than those necessary for patient/participant safety.

[ ]  Yes ® List the nonpublic sources (name of each):

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[ ]  No

3.2 How will this study recruit participants? Check all that apply, and attach any written documents or scripts:

[ ]  In-person contact

[ ]  Contact or approach letters

[ ]  Telephone calls

[ ]  Radio or TV (include a written script before production and brief layout of images)

[ ]  Print advertisements (brochures, flyers, posters, newspaper, etc.)

[ ]  Internet, including social media

[ ]  Other, describe:

|  |
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3.3 Who will approach or recruit potential participants?

[ ]  Principal Investigator

[ ]  Study staff

[ ]  Other, describe:

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3.4 When and where will participants be recruited? (e.g., after a doctor’s visit)

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3.5 What steps will be taken to avoid coercion or undue influence in the recruitment of research participants?

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3.6 Will the research potentially involve participants from any of the following special populations? This includes research procedures, enrollment, and accessing identifiable information or identifiable biospecimens (e.g., name, social security number, age) about any of these populations. **Check all that apply.**

3.6.a. [ ]  Pregnant women. Specify how pregnant women will be involved. Select all that apply.

3.6.a.i. [ ]  Pregnant women will be enrolled in the research study.

3.6.a.ii. [ ]  Pregnant women, either participants or pregnant partners, will be involved for the purposes of following the outcome of a pregnancy. (If following pregnant *partners*, you must also answer yes to Question 4.4.)

3.6.b. [ ]  Fetuses *in utero*

3.6.c. [ ]  Nonviable neonates or neonates of uncertain viability

3.6.d. [ ]  Females of childbearing potential

3.6.e. [ ]  Prisoners (including juvenile detainees) ® Complete [*HRP-265 - FORM - Prisoner Certification Checklist for Investigator*](https://extranet.fredhutch.org/en/f/irb/investigator-prisoner-certification-checklist.html).

3.6.f. [ ]  Children ® Complete[*HRP-264 - FORM - Children Supplement*](https://extranet.fredhutch.org/en/f/irb/children-supplement.html).

3.6.g. [ ]  Adults with impaired decision-making capacity requiring a legally authorized representative (LAR) — *complete Question 4.3 regarding LAR consent.*

3.6.h. [ ]  Limited or non-readers (e.g., illiterate, sight impaired, etc.). Note a witness must be present for the consent discussion and a witness line included in the consent form.

3.6.i. [ ]  Employees

3.6.j. [ ]  Others (e.g., educationally or economically disadvantaged, etc.)

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3.6.k. **If you checked any of the boxes a. – j. above**, describe the additional safeguards taken to protect the rights and welfare of the special population. If applicable, reference the page number(s) in the protocol that describe the additional safeguards.

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3.7 Is it possible that this study may involve non-English speaking participants?

[ ] Yes ® Describe how the study team will communicate with the participant during the course of the research (e.g., interpretation service, study staff who speak the native language, etc.).

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[ ]  No

3.8 Ethnicity, Race and Gender of Anticipated Local Enrollment Table

*Note: The Fred Hutch IRB expects all studies to collect demographic data such as Ethnicity, Race and Gender. You will be expected to submit actual accrual, broken down by demographic categories, at the time of annual Continuing Review (if applicable).*

*For assistance in planning for diverse recruitment, review this page:* [*https://www.fredhutch.org/en/research/institutes-networks-ircs/ocoe/ocoe-research.html*](https://www.fredhutch.org/en/research/institutes-networks-ircs/ocoe/ocoe-research.html)

**Table 3.8**

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| **ANTICIPATED/PLANNED LOCAL ENROLLMENT:**Number of Participants (must provide exact numbers, not a range) |
| **Ethnic Categories** | **Sex/Gender** |
|  | Females | Males | Total |
| Hispanic or Latino |       |       |       |
| Not Hispanic or Latino |       |       |       |
| **Ethnic Categories: Total of All Participants\*** |       |       |  |
|  |
| **Racial Categories** |  |
| American Indian/Alaska Native |       |       |       |
| Asian |       |       |       |
| Native Hawaiian or Other Pacific Islander |       |       |       |
| Black or African American |       |       |       |
| White |       |       |       |
| More Than One Race |       |       |       |
| **Racial Categories: Total of All Participants\*** |       |       |  |

**\*** “Ethnic Categories: Total of All Participants” must be equal to the “Racial Categories:
Total of All Participants.”

Comments:

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3.8.a. Provide the basis for the above ethnic and racial local enrollment targets.

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3.8.b. What is your plan for collecting demographic data, including race and ethnicity, from enrolled participants?

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3.8.c. If the disease being studied disproportionately affects certain populations, **or** if examining health disparities is relevant to this research, describe your plan for recruiting racial and ethnic minorities.

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3.8.d. If the anticipated Ethnic/Racial/Gender data is not available, explain:

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1. Consenting and Compensating Research Participants

*The IRB is responsible for determining that informed consent will be sought from each prospective participant or the participant’s legally authorized representative in accordance with, and to the extent required by regulations. The IRB is also responsible for ensuring compensation is not unduly influential.*

4.1 Describe the consenting process in detail including when participants will be consented (e.g., during intake visit, consultation visit, etc.), in what setting will the consenting process be conducted (e.g., private waiting room, participant’s home, by telephone, etc.), and any waiting period between discussing the research with the prospective participant and obtaining consent. If conducting consent remotely, describe in detail how informed consent will be documented. Refer to [*IRB Policy 2.11 Informed Consent*](https://extranet.fredhutch.org/en/u/irb/policies-and-procedures/_jcr_content/leftParsys/download_11/file.res/017IRBpolicy2_11InformedConsent.pdf) (017) for more information.

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4.2 Who will obtain consent from participants?

[ ]  PI

[ ]  Attending/Physicians

[ ]  Advanced Practice Providers (e.g., Physician assistant, Nurse practitioner)

[ ]  Licensed Registered Nurse (RN)

[ ]  Other ® List role and credentials (e.g., sub-investigators who are all MDs with current U.S. licensure):

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4.2.a. Are you requesting an exception from the guidelines in Appendix A of [*IRB Policy 2.11 Informed Consent*](https://extranet.fredhutch.org/en/u/irb/policies-and-procedures/_jcr_content/leftParsys/download_11/file.res/017IRBpolicy2_11InformedConsent.pdf) (017) for who can consent based on the type of research?

[ ]  Yes ® List the individuals below and attach each individual’s CV/resume along with an explanation of their training and experience related to obtaining consent:

|  |
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[ ]  No

4.3 Will the study enroll adults with impaired decision-making capacity? (Persons whose decision-making capacity is restricted, wholly or in part, due to illness, mental disability, or other circumstances.)

Note: If you answer “Yes” to this question, you must also check “individuals with impaired decision-making capacity” in Question 3.6.g.

[ ]  Yes ® Describe the process you will use to assess and document the individual’s lack of capacity to provide informed consent (e.g., post-consent interview, standardized cognitive tests, court guardianship documentation, etc.):

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[ ]  No ® Go to Question 4.4.

4.3.a. How will you obtain and document verbal assent, or obtain written assent, from the adult research participant with impaired decision-making capacity?

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4.4 If you plan to follow the partner of a research participant who becomes pregnant during the study: Is there a consent form available to allow for the pregnancy outcome to be followed?

[ ]  Yes ® Attach the consent form.

[ ]  No ® If necessary, we will submit [*HRP-252 - FORM - Modification Supplement*](https://extranet.fredhutch.org/en/f/irb/research-modification.html) to add the consent form.

[ ]  N/A

4.5 Is any deception (withholding of complete information) required for the validity of this study?

[ ]  Yes ® Complete [*HRP-256 - FORM - Consent Supplement*](https://extranet.fredhutch.org/en/f/irb/waiver-consent.html). Explain below why the deception is necessary and attach a copy of the debriefing procedure to be used at the conclusion of the study to inform the participant of the deception.

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[ ]  No

4.6 Will participants have travel or other specific expenses reimbursed upon submission of a receipt/invoice? For example, local hotel reimbursed based on actual expenses.

[ ]  Yes ® Respond to Question 4.6.a and include details in the Informed Consent document.

[ ]  No ® Go to Question 4.7.

4.6.a. Describe the maximum amount of reimbursement and the reimbursement process.

|  |
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4.7 Will participants be paid or otherwise be compensated? For example, a predetermined amount of compensation for time and effort required to participate in the study.

[ ]  Yes ® Respond to Questions 4.7.a and 4.7.b and include details in the Informed Consent document.

[ ]  No ® Go to [Section 5](#Documenting_Consent).

4.7.a. What is the amount and type of compensation (e.g., cash, check, gift card)?

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| --- |
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4.7.b. When will this be paid, and will it be prorated if a participant leaves the study early?

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1. Documenting Consent

*The IRB is responsible for determining that informed consent will be appropriately documented in accordance with, and to the extent required by regulations.*

5.1 How will consent be documented? Review [*IRB Policy 2.11 Informed Consent*](https://extranet.fredhutch.org/en/u/irb/policies-and-procedures/_jcr_content/leftParsys/download_11/file.res/017IRBpolicy2_11InformedConsent.pdf) (017) to understand the expectations around documentation of consent. Check all that apply:

5.1.a. [ ]  Written consent document with ink signature of participant ® Attach consent form(s) in Hutch IRB.

5.1.a.i. [ ]  If a phone or video consent conference is planned, also attach a specific written remote consenting plan and/or a consent script in Hutch IRB.

Note: Remote consenting must be documented in the research chart (and if a medical trial, in the patient medical record per policies of the institution where consent is taking place).

5.1.b. [ ]  Electronic consenting (e-consent) with the Florence e-consent tool ® Attach consent form(s) in Hutch IRB.

5.1.c. [ ]  Consent documentation methods allowed for minimal risk studies only:

 *NOTE: if selecting 5.1.c.i – 5.1.c.iii, you must also attach* [*HRP-256 - FORM - Consent Supplement*](https://extranet.fredhutch.org/en/f/irb/waiver-consent.html) *to request a waiver of documentation of consent (waiver of the signature requirement).*

5.1.c.i. [ ]  Electronic consenting (e-consent) with a tool other than Florence (e.g., website, REDCap, DocuSign, etc.) ® Attach consent form(s) in Hutch IRB. Also attach your specific written plan for e-consent and a report from the Information Security Officer.

5.1.c.ii. [ ]  Written consent form with no signature ® Attach consent form(s) in Hutch IRB.

5.1.c.iii. [ ]  Oral consent ® Attach consent script in Hutch IRB.

5.2 How will participants who do not speak/read English document consent? Refer to [*IRB Policy 2.13 Use of Interpreter Services and Translated Documents*](https://extranet.fredhutch.org/en/u/irb/policies-and-procedures/_jcr_content/leftParsys/download_38/file.res/Interpreter-Services-Translated-Documents.pdf) (039) for more information about the requirements. If enrolling non-English speakers, you must also check yes to Question 3.7.

5.2.a. [ ]  Short form translated generic consent in participant’s native language with qualified interpreter providing interpretation of the English consent document(s).

NOTE: To use the short form process, a witness must be present for the consent discussion. An in-person interpreter is permitted to serve as the witness.

5.2.b. [ ]  Translated consent document(s):

Translated document(s) in the non-English language and a certification of translation showing credentials of the translator will be required. Are you submitting these now?

[ ]  Yes ® Note: If the IRB requires changes to the English consent(s), the translated forms will also need to be updated and resubmitted for IRB review. 

[ ]  No, the translated documents and certification of translation will be submitted with a Modification after the IRB approves the English versions of the site-specific consent(s).

5.2.c. [ ]  This research will not allow non-English speaking/reading participants to enroll. Provide rationale for the exclusion of non-English speaking/reading participants. Refer to [*IRB Policy 2.13 Use of Interpreter Services and Translated Documents*](https://extranet.fredhutch.org/en/u/irb/policies-and-procedures/_jcr_content/leftParsys/download_38/file.res/Interpreter-Services-Translated-Documents.pdf) (039) for the types of justifications the IRB may allow.

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1. Data and Safety Monitoring

*The IRB is responsible for determining, when appropriate, that the research plan makes adequate provisions for monitoring the data collected to ensure the safety of participants.*

6.1 Is there a data and safety monitoring plan for this study?

[ ]  Yes ® Ensure the protocol describes the data and safety monitoring plan. At a minimum, describe the plan for monitoring, reporting, and analyzing unanticipated problems, serious adverse events (SAEs), and other adverse events (AEs). Respond to Question 6.1.a.

[ ]  N/A ® This study is observational (does not aim to change outcomes or behaviors). Go to [Section 7](#Privacy_and_Confidentiality).

6.1.a. Does the data safety monitoring plan call for an independent Data Safety Monitoring Board (DSMB), or similar committee for this study?

[ ]  Yes ® Attach the DSMB charter, or if unavailable, explain:

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[ ]  No ® Go to Question 6.2.

6.2 Will there be any external monitoring conducted for this study?

[ ]  Yes ® Describe who will conduct the monitoring (e.g., sponsor, Cancer Consortium Clinical Research Support) and how frequently:

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[ ]  No ® Explain:

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1. Privacy and Confidentiality

*The IRB is responsible for determining that there are provisions for protecting the privacy of research participants and maintaining the confidentiality of information and biospecimens.*

The protocol must contain provisions for protecting participants’ privacy and maintaining the confidentiality of data and biospecimens. Ensure the protocol describes:

* **Privacy protections.** Describe the steps that will be taken, if any, to address possible privacy concerns of subjects and potential subjects.
* **Confidentiality protections.** Describe the methods to safeguard research data and biospecimens: for example, how data/biospecimens will be stored, who has access, who grants access, the timing, and methods for de-identifying and/or destroying identifiable information/biospecimens, and how you will ensure study reports and publications do not directly or indirectly identify participants or small groups of participants.

7.1 Have you applied, or do you plan to apply, for a Certificate of Confidentiality with the NIH or other federal funding agency?

[ ]  Yes ® Attach either a copy of the issued Certificate of Confidentiality or the application you have sent or will send to NIH or other funding agency.

[ ]  No ® If you are collecting information about illegal, sensitive, or socially or politically unacceptable activities (such as information that would be of interest to law enforcement), describe the privacy protections in place for this research:

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[ ]  N/A ® We were automatically issued a Certificate of Confidentiality because we have NIH, CDC, or FDA funding.

 *Note: FDA here refers only to funding by FDA, not research regulated by FDA. Research subject to FDA oversight but not funded by FDA does not automatically receive a Certificate of Confidentiality.*

[ ]  N/A ® We are not collecting information about illegal, sensitive, or socially or politically unacceptable activities (such as information that would be of interest to law enforcement).

*Note: Certificates of Confidentiality generally require researchers to refuse to disclose, in response to legal demands, the name of a participant or any information, document, or biospecimen that contains identifiable, sensitive information about the participant and that was compiled for the purposes of the research. Certificates are issued by NIH and other HHS agencies to researchers to help protect the privacy of human research participants enrolled in research studies. When consent is obtained, the consent should inform subjects that a Certificate is in place and describe the protections and limitations. For more information visit:* [*https://humansubjects.nih.gov/coc/index*](https://humansubjects.nih.gov/coc/index)

1. Other Regulatory and/or Institutional Review Requirements

*The following criteria, where applicable, must also be addressed.*

8.1 Other IRB Reviews

8.1.a. Is this study being transferred from another IRB?

[ ]  Yes ® Attach [*HRP-260 - FORM - Transfer Supplement*](https://extranet.fredhutch.org/en/f/irb/transfer-of-irb-oversight.html)*.*

[ ]  No

8.1.b. Has this study received disapproval from another IRB for this research prior to submission to the Fred Hutch IRB?

[ ]  Yes ® Describe:

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[ ]  No

8.2 Health Insurance Portability and Accountability Act (HIPAA):

8.2.a. Will this study involve access to, or use of, any participant’s protected health information that is not stripped of all [18 identifiers](https://extranet.fredhutch.org/en/u/irb/glossary.html#hipaa_identifiers) defined under HIPAA (45 CFR 164.514(A)(2)) from a [covered entity](https://extranet.fredhutch.org/en/u/irb/glossary.html#covered_entity) or [business associate](https://extranet.fredhutch.org/en/u/irb/glossary.html#business_associate) of a covered entity?

[ ]  Yes

[ ]  No ® HIPAA does not apply; go to Question 8.3.

8.2.b. Will this study be accessing *only* a [limited data set](https://extranet.fredhutch.org/en/u/irb/glossary.html#limiteddataset) of PHI (where 16 of the 18 individual identifiers have been removed)?

[ ]  Yes ® A data use agreement may be required. For Fred Hutch, contact the Office of the General Counsel at generalcounsel@fredhutch.org. Skip to Question 8.3.

[ ]  No, we will be accessing or using more than a limited data set.

8.2.c. Are you requesting a full waiver of HIPAA authorization (for all aspects of the research)?

[ ]  Yes ® Attach [*HRP-257 - FORM - HIPAA Supplement*](https://extranet.fredhutch.org/en/f/irb/hipaa-supp-waiver-authorization.html) to request a full waiver of HIPAA. Go to Question 8.3.

[ ]  No

8.2.d. Will you access or use PHI for the purpose of determining eligibility prior to obtaining written authorization?

[ ]  Yes ® Attach a [*HRP-257 - FORM - HIPAA Supplement*](https://extranet.fredhutch.org/en/f/irb/hipaa-supp-waiver-authorization.html) to request a partial waiver of HIPAA.

[ ]  No

8.2.e. How will you obtain written authorization to access PHI?

[ ]  **Separate HIPAA Authorization Form(s) as indicated below.** Attach a copy of the form(s) checked.

[ ]  Fred Hutch Protocol-Specific HIPAA Authorization for the Use of Patient Information in Research.

[ ]  Fred Hutch Clinical Research Division Transplant Program General HIPAA Research Authorization Form.

[ ]  UW HIPAA form – required for UW Consortium investigators.

[ ]  Seattle Children’s HIPAA form.

[ ]  Other HIPAA authorization form.

[ ]  **HIPAA authorization language included in the research consent form**.

8.2.f. If you may enroll non-English speakers (see Questions 3.7 and 5.2 above), how will participants who do not speak English provide HIPAA authorization? Check all that apply.

8.2.f.i. [ ]  Participants will sign a translated HIPAA authorization form (either stand-alone or combined within the consent) in their language ® Are you submitting this now?

[ ]  Yes® Attach along with certificate of translation.

[ ]  No, the translated documents and certification of translation will be submitted with a Modification later, but prior to use in the study.

NOTE: The IRO does not arrange for, nor pay for, written translation of HIPAAs. This is the responsibility of the study team, or may be provided by the institution (e.g., UW).

8.2.f.ii. [ ]  A qualified interpreter will provide interpretation of an English HIPAA authorization (either stand-alone or combined within the consent) ®  Attach [*HRP-257 - FORM - HIPAA Supplement*](https://extranet.fredhutch.org/en/f/irb/hipaa-supp-waiver-authorization.html) to request an Alteration of HIPAA (to waive the signature) for this specific population.

NOTE: For a verbally obtained HIPAA authorization, the non-English speaking participant does not sign the English HIPAA form. Instead, the researcher documents the verbal HIPAA authorization in the research chart (and if a medical trial, in the patient medical record per policies of the institution where consent is taking place).

8.3 Does the study involve the transfer of materials (e.g., biospecimens or information) to an outside entity other than the sponsor?

[ ]  Yes ® Respond to Questions 8.3.a. – 8.3.b.

[ ]  No ® Go to Question 8.4.

8.3.a. Describe the materials/data to be transferred:

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8.3.b. List the outside entity and what activities they will perform:

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*Note: Transfer of biospecimens or information outside your home institution generally requires a Material or Data Transfer Agreement (MTA/DUA). Fred Hutch researchers, review* [*https://centernet.fredhutch.org/cn/u/business-dev/form-questionnaire.html*](https://centernet.fredhutch.org/cn/u/business-dev/form-questionnaire.html) *or contact the Fred Hutch Technology Transfer Department at* *MTA@fredhutch.org* *for more information. UW researchers, contact the Agreements Group at* *mta-group@uw.edu**.*

8.4 International Conference on Harmonization (ICH) Good Clinical Practice (GCP):

8.4.a. Does the sponsor of this study require compliance with ICH-GCP E6 guidelines? <https://www.fda.gov/downloads/Drugs/Guidances/UCM464506.pdf>

[ ]  Yes ® The PI and research team have completed or will complete training as required by the sponsor.

[ ]  No

8.5 Clinical Trials Registration:

Is this an applicable clinical trial that requires registration and reporting at [www.clinicaltrials.gov](http://www.clinicaltrials.gov)?

[ ]  Yes

[ ]  No

*Note: NIH-funded clinical trials, and certain FDA-regulated clinical trials described here* [*https://clinicaltrials.gov/ct2/manage-recs/fdaaa*](https://clinicaltrials.gov/ct2/manage-recs/fdaaa)*, must register. Contact* *ctgov@fredhutch.org* *for questions about and help with registering.*

1. Required Ancillary Reviews

*Identify any other regulatory or institutional approvals that are required for this research.*

*Note: Additional ancillary reviews may be required before the study can open to accrual. Refer to* [*HRP-309 - WORKSHEET - Ancillary Review Matrix*](https://extranet.fredhutch.org/en/f/irb/ancillary-review-matrix.html) *for additional information.*

*Attach the ancillary approval documentation to the “Other attachments” question on either the “Study-Related Documents” or the “Local Site Documents” page within the study SmartForm in Hutch IRB.*

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| **ANCILLARY APPROVAL REQUIRED** | **RESEARCH FOR WHICH THIS IS REQUIRED & HOW TO SUBMIT** |
| **REQUIRED BEFORE SUBMISSION TO THE IRB** |
| [ ]  Cancer Consortium OnCore/CTMS Entry[ ]  N/A: Attach an email from CTMS indicating entry in OnCore is not required | All new IRB applications involving human subjects (including Exempt submissions). Submit a [REDCap Intake form](https://redcap.iths.org/surveys/?s=99JC9LXMAK) to initiate the creation of a new protocol record in OnCore. Contact the CTMS Program Office at CTMS@fredhutch.org with questions. Record RG number issued by OnCore on page 1 of this document. |
| [ ]  Cancer Consortium Scientific Review Committee (SRC) | Cancer-related Interventional Trials. * “Cancer-related” is defined [here](https://extranet.fredhutch.org/en/u/irb/glossary.html#cancer-related).
* The Cancer Consortium defines an “interventional trial” as research in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.
* Submission to SRC occurs through OnCore/CTMS. Contact PRMS@fredhutch.org with questions. Information can also be found at <https://www.cancerconsortium.org/research-support/clinical-research-support/study-start-up.html#reviews>.

In Hutch IRB, attach SRC approval documentation to the submission under “Other attachments.” |
| [ ]  University of Washington engagement | For investigators whose primary appointments are at UW, **OR** if UW as an institution will be engaged in the research: Documentation of UW Zipline authorization to rely on the Fred Hutch IRB must be included. For more info: <https://www.washington.edu/research/hsd/is-the-uw-irb-the-right-irb/how-to-ask-for-a-non-uw-irb/>In Hutch IRB, attach the Zipline authorization to the submission under “Other attachments.” |
| [ ]  Seattle Children’s engagement | For research where Seattle Children’s (SCH) is engaged, an “Acknowledgement of Reliance on an External IRB” letter from SCH must be included as part of your submission to the Fred Hutch IRB.For instructions on how to obtain this letter, please review Section A of the [SCH-FH Guidance for Relying](https://extranet.fredhutch.org/en/u/irb/submissionstotheirb/_jcr_content/leftParsys/download_copy/file.res/SCH-FH%2520Guidance%2520for%2520Relying%252005.01.22.pdf).In Hutch IRB, attach the SCH letter to the submission under “Other attachments.” |
| **REQUIRED BEFORE IRB APPROVALS CAN BE ISSUED** |
| [ ]  Cancer Surveillance System (CSS)[ ]  Pending | Studies involving confidential identifying information from the CSS database as a data source. Review the “Accessing CSS Data for Research” section on this page for more information: <https://www.fredhutch.org/en/research/divisions/public-health-sciences-division/research/epidemiology/cancer-surveillance-system.html> In Hutch IRB, attach the CSS letter of support to the submission under “Other attachments.”  |
| [ ]  Governance, Risk, and Compliance (GRC) (formerly ISO)[ ]  Pending | Studies involving the collection of potentially sensitive and private information directly from study participants through the use of a website, email, or similar internet-based collection tool (e.g., REDCap).Studies requesting the use of e-consent (exception: use of Florence e-consent does not require GRC review). Contact Governance, Risk, and Compliance (GRC) at grc@fredhutch.org to obtain a security risk assessment and attach it under “Other attachments” in Hutch IRB. |
| [ ]  Institutional Biosafety Committee (IBC)[ ]  PendingAlso indicate which apply:[ ]  UW IBC[ ]  Fred Hutch clinical IBC (for human gene trials)[ ]  Other:       | Required if a study product involves the deliberate transfer/administration of recombinant DNA, DNA/RNA derived from recombinant DNA, synthetic DNA/RNA, or biological materials such as infectious agents into study participants. To confirm whether IBC review is required for this research, contact the Fred Hutch Environmental Health & Safety at 206.667.4866 or ehs@fredhutch.org, or contact the IBC for the institution involved. (Each institution administering a relevant study product needs its own IBC review.)In Hutch IRB, attach the IBC approval documentation to the submission under “Other attachments.” |
| [ ]  Radiation Safety[ ]  PendingAlso indicate which apply:[ ]  Joint HSRAC for UW or FHCC[ ]  Seattle Children’s RSC[ ]  Fred Hutch Radiation Safety[ ]  Other:       | If the use of radioactive materials (e.g., nuclear medicine, radio-immune therapy) or an ionizing radiation-producing machine (e.g., CT, X-ray, Accelerator, DEXA scanner) is to be used as part of the study, resulting in a study participant or a healthy volunteer receiving a radiation dose they would not otherwise receive as part of their standard clinical care. In Hutch IRB, attach the approval documentation to the submission under “Other attachments.” |
| [ ]  Total Body Irradiation[ ]  Pending | Required if the study is adding a new use of Total Body Irradiation procedures (even if considered standard of care). This is a review by the University of Washington Radiation Oncology department. Contact radoncrc@uw.edu with questions.Attach documentation of protocol approval under “Other attachments” in Hutch IRB. |

1. Required Supplements

*Identify relevant Supplement forms that should also be completed. If none apply, select “None of Above.”**In Hutch IRB, attach Supplements to the submission under “Other attachments” (except as indicated below).*

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| **CHECK ALL THAT APPLY** | **ELEMENTS OF RESEARCH** | **SUPPLEMENT NAME AND LINK** |
| [ ]  | **Children** This includes research procedures, enrollment, and accessing identifiable information or identifiable biospecimens about minors. | [*HRP-264 - FORM - Children Supplement*](https://extranet.fredhutch.org/en/f/irb/children-supplement.html) |
| [ ]  | **Department of Defense (DoD)**The research involves funding, facilities, data, or personnel from the DoD or one of its component entities (e.g., Dept. of Army, DARPA)  | [*HRP-263 - FORM - Department of Defense Supplement*](https://extranet.fredhutch.org/en/f/irb/dod-supplement.html) |
| [ ]  | **Drug, biologics, food, or dietary supplement**Procedures involve the evaluation of any drug, biologic, botanical, food, or dietary supplement. *Note: In Hutch IRB, attach the Drug Supplement to the Drugs SmartForm page, under “Attach files.”*  | [*HRP-259 - FORM - Drug Supplement*](https://extranet.fredhutch.org/en/f/irb/drug-supplement.html) |
| [ ]  | **Genomic data sharing**Genomic data are being collected and are planned to be deposited into a public database (such as the NIH dbGaP database) for sharing with other researchers, and Fred Hutch is being asked to provide the NIH-required [Institutional Certification](https://sharing.nih.gov/genomic-data-sharing-policy/institutional-certifications/completing-an-institutional-certification-form) or to ensure that the consent forms allow such sharing. | [*HRP-268 - FORM - Genomic Data Sharing Supplement*](https://extranet.fredhutch.org/en/f/irb/genomic-data-sharing-supplement.html) |
| [ ]  | **International research**The PI on this application is overseeing any research activities to be conducted outside the United States | [*HRP-266 - FORM - International Research Performance Site Assessment Supplement*](https://extranet.fredhutch.org/en/f/irb/intl-research-performance-site-assessment.html) |
| [ ]  | **Medical devices**Studies that:* Evaluate a device, including a software function (this may include medical mobile applications), or
* Use an unapproved *in vitro* diagnostic test; or
* Use an unapproved *in vitro* diagnostic test for decision-making (e.g., eligibility determination or treatment assignment) or data analysis (e.g., response assessment)
* Use a humanitarian use device (HUD)

*Note: In Hutch IRB, attach the Device Supplement to the Devices SmartForm page, under “Attach files.”* | [*HRP-258 - FORM - Device Supplement*](https://extranet.fredhutch.org/en/f/irb/device-supplement.html) |
| [ ]  | **Multi-site or collaborative study, or serving as the coordinating center**Only required for multi-site studies where the Fred Hutch IRB is being asked to review on behalf of one or more non-Cancer Consortium institutions, or Fred Hutch is serving as the coordinating center. *Note: For each site outside Fred Hutch and the Cancer Consortium relying on Fred Hutch IRB, you will need to submit a separate Participating Site submission after this main application is approved.* | [*HRP-254 - FORM - Multi-Center Supplement*](https://extranet.fredhutch.org/en/f/irb/multi-center-supplement.html) |
| [ ]  | **Prisoners**This includes research procedures, enrollment, and accessing identifiable information or identifiable biospecimens about prisoners. | [*HRP-265 - FORM - Prisoner Certification Checklist for Investigator*](https://extranet.fredhutch.org/en/f/irb/investigator-prisoner-certification-checklist.html) |
| [ ]  | **Repository or Registry**A collection of information and/or biospecimens that are specifically intended to be used, stored, and/or shared for Secondary Research purposes. | [*HRP-267 - FORM - Repository or Registry Supplement*](https://extranet.fredhutch.org/en/f/irb/repository-registry-databank-supp.html) |
| [ ]  | **Transfer of IRB oversight**This study is being transferred from another IRB. | [*HRP-260 - FORM - Transfer Supplement*](https://extranet.fredhutch.org/en/f/irb/transfer-of-irb-oversight.html) |
| [ ]  | **Waiver or Alteration of Consent** If requesting to waive some or all elements of consent.If requesting to waive the consent signature (including for e-consent) | [*HRP-256 - FORM - Consent Supplement*](https://extranet.fredhutch.org/en/f/irb/waiver-consent.html) |
| [ ]  | **Waiver or Alteration of HIPAA**If requesting to waive HIPAA for screening purposes or for the entire study.If requesting to waive the HIPAA signature (including for e-consent or for non-English speakers) | [*HRP-257 - FORM - HIPAA Supplement*](https://extranet.fredhutch.org/en/f/irb/hipaa-supp-waiver-authorization.html) |
| [ ]  | **NONE OF ABOVE** |  |