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|  | Diagram  Description automatically generated | **FORM - Participating Site Supplement** |

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| **Date:** |       |
| **FHIRB #:** |       |
| **RG #:** |       | **Protocol #:** |       |
| **Study Title:**  |       |
| **Site Name:** |       |
| **Site Address:** | Street:       | City:       | State:      Postal Code:       |
| **Site Principal Investigator:** | First Name:       | Middle Initial:       | Last Name:       |
| Credentials:       | Phone:       | Email:       |

Instructions

* This form should be used to obtain approval for a participating site outside the Fred Hutch/UW Cancer Consortium that relies on the Fred Hutchinson Cancer Center IRB. IRB approval cannot be granted for the site until the lead file has been IRB approved.
* This form is used in conjunction with Hutch IRB to submit the site to the Fred Hutch IRB. The site completes this form, and the Cancer Consortium study team submits it in Hutch IRB with all required attachments.
* **Answer all questions**, except when directed to skip some. 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 “back and forth” for clarification.

Table of Contents

1. General Site Information

2. Investigator and Research Staff Qualifications

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4. Consenting and Compensating Research Participants

5. Documenting Consent

6. Other Regulatory and/or Administrative Review Requirements

7. Required Supplements

8. Other Required Attachments

1. General Site Information
	1. Is your site part of the [Fred Hutch/UW/Seattle Children’s Cancer Consortium](https://www.cancerconsortium.org/en.html)?

[ ]  Yes, but the lead PI does **not** have oversight of the site PI or the conduct of the research at this site. Explain.

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[ ]  Yes, and the lead PI has oversight of the site PI and the conduct of the research at this site → **Stop.** You do not need to complete this form. If your Cancer Consortium site is not identified on the lead file (main application), submit a Modification in Hutch IRB to add this research location.

[ ]  No

* 1. Has an IRB [reliance agreement](https://extranet.fredhutch.org/en/u/irb/glossary.html#reliance) been finalized between your site and Fred Hutch?

[ ]  Yes → Go to Question 1.3.

[ ]  No → **Stop.** **Your site application cannot be reviewed until an IRB reliance agreement is in place.** To establish a reliance agreement, please contact irbreliance@fredhutch.org.

* 1. Complete the table below for the location listed on page 1, **and** for any other locations at which you or members of your research team will be personally conducting research activities for this protocol, or at which you as site PI will be directly overseeing research activities.If there are more than two locations, unlock the form and add more rows to the table.

*Note: If any of these locations is under a separate FWA#, please contact* *irbreliance@fredhutch.org* *to discuss how to proceed.*

|  |  |  |
| --- | --- | --- |
| **Location (Name and Address):** | **Research Activities** to be conducted at each site location (check all that apply): | Briefly describe the **adequacy and capacity** of each site location to conduct the research activities (e.g., emergency room facilities, any specialized equipment, etc.): |
| Main Site Location (cited on pg. 1) | [ ]  Administer study interventions[ ]  Conduct entire protocol[ ]  Conduct informed consent conferences[ ]  Direct recipient of federal award[ ]  Obtain consent and/or assent[ ]  Obtain, use, or analyze identifiable data and/or specimens[ ]  Other participant contact[ ]  Perform research procedures[ ]  Other responsibilities or roles:       |       |
|       | [ ]  Administer study interventions[ ]  Conduct entire protocol[ ]  Conduct informed consent conferences[ ]  Direct recipient of federal award[ ]  Obtain consent and/or assent[ ]  Obtain, use, or analyze identifiable data and/or specimens[ ]  Other participant contact[ ]  Perform research procedures[ ]  Other responsibilities or roles:       |       |

2. Investigator and Research Staff Qualifications

2.1 Have all members of the research team received training on Human Subject Protections and/or Good Clinical Practice as required per *[HRP-062 – POLICY - Training](https://extranet.fredhutch.org/u/irb/policies-and-procedures.html%22%20%5Cl%20%22training)*?

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

[ ]  Yes

[ ]  No, please explain:

|  |
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2.2 Have there been any regulatory or disciplinary actions against the site investigator (e.g., investigator debarment, disqualification, revoked medical licenses, regulatory warning letters, etc.)?

[ ]  Yes → Describe the issue and the corrective actions taken at the site:

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[ ]  No

1. Selection and Recruitment

[ ]  If no participants will be recruited at this site, check this box and skip to Question 3.6.

3.1 What are the approximate number and ages of participants planned to be enrolled at the site?

|  |  |
| --- | --- |
| **Number of Participants** | **Age range of participants(as specified per study)** |
| **First Year** | **Entire Study** | **First Year** | **Entire Study** |
|       |       |       |       |

* 1. How will this site recruit participants? Check all that apply, and submit any ***site-specific*** written documents or scripts with this IRB application:

[ ]  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, please describe:

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* 1. Who will approach or recruit potential participants?

[ ]  Site investigator

[ ]  Study staff

[ ]  Other, please describe:

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

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

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* 1. Will the research site 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 at this site.

**Enrollment of special populations must be approved at the study level. Contact the Fred Hutch study team to confirm the populations you are planning to enroll have been approved.**

NOTE: If this study at this site involves no contact with participants, only check the boxes for the special populations about whom you will have sufficient information to determine the population is included in the research.

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 at this site.

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)

3.6.f. [ ]  Children

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 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 Ethnicity, Race and Gender of Anticipated Local Enrollment Table

Note: All NIH-funded studies that meet the [NIH definition for clinical research](https://grants.nih.gov/grants/glossary.htm#ClinicalResearch) must address plans for the inclusion of women and minorities. See <https://grants.nih.gov/policy/inclusion/women-and-minorities.htm>. All other studies should also collect this information to the extent possible based on the study design.

**Table 3.7**

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

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

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3.7.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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3.7.d. If the anticipated Ethnic/Racial/Gender data is not available, explain:

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1. Consenting and Compensating Research Participants

*Consider the site-specific conditions below. The study-wide information is described in the main application.*

4.1 Is this site requesting a waiver of consent for any part of the research?

[ ]  A waiver of consent that covers this site was approved under the main application. Contact the Fred Hutch study team to confirm.

[ ]  Yes → Partial waiver (for only certain aspects of the research at this site or for specific cohorts): Submit [*HRP-256 - FORM - Consent Supplement*](https://extranet.fredhutch.org/en/f/irb/waiver-consent.html) and go to Question 4.2.

*Note: Under the 2018 Common Rule, a waiver is not required for screening, recruitment, and determining eligibility when those activities only involve gathering information. See* [*HRP-256 - FORM - Consent Supplement*](https://extranet.fredhutch.org/en/f/irb/waiver-consent.html)*, Section D, for more information.*

[ ]  Yes → Full waiver (for all aspects of the research at this site): Submit [*HRP-256 - FORM - Consent Supplement*](https://extranet.fredhutch.org/en/f/irb/waiver-consent.html)and go to Section 5.

[ ]  No

* 1. Fred Hutch strongly recommends adhering to the consenting plan approved in the main application, including the category of individuals allowed to obtain consent from participants. Will this site follow the consenting plan that was approved under the main application?

[ ]  Yes → The consenting plan at this site matches what was approved under the main application. Contact the Fred Hutch study team to confirm. Skip to question 4.3.

[ ]  No → We will have a site-specific consenting plan. Please respond to 4.2.a-c.

4.2.a. 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 [*HRP-090 - POLICY - Informed Consent*](https://extranet.fredhutch.org/u/irb/policies-and-procedures.html#informed) for more information.

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4.2.b. Who will obtain consent from participants?

[ ]  Site investigator

[ ]  Attending/Physicians

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

[ ]  Licensed Registered Nurse (RN)

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

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4.2.c. Are you requesting an exception from the guidelines in Appendix A of [*HRP-090 - POLICY - Informed Consent*](https://extranet.fredhutch.org/u/irb/policies-and-procedures.html#informed) for who can consent based on the type of research?

[ ]  Yes → Complete [*HRP-286 - FORM - Consent Process Exception Request*](https://extranet.fredhutch.org/f/irb/consent-process-exception-request.html) and include it with the submission.

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[ ]  No

* 1. Will the site enroll adult individuals with impaired decision-making capacity? (Persons whose decision-making capacity is restricted, wholly or in part, due to illness, mental disability, or other circumstances.) **This population must be approved at the study level.**

*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? Explain:

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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. You must track site-specific changes into the model version of the consent form approved in the main application and submit both tracked and clean copies of the site consent form.

[ ]  No → If necessary, we will submit a Modification form to add the site-specific pregnancy consent form.

[ ]  N/A

4.5 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 → The reimbursement plan at this site matches what was approved under the main application. Contact the Fred Hutch study team to confirm.

[ ]  Yes → We will have a site-specific reimbursement plan. Respond to 4.5.a. and include details in the Informed Consent document.

[ ]  No → Go to Question 4.6.

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

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4.6 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 → The compensation plan at this site matches what was approved under the main application. Contact the Fred Hutch study team to confirm.

[ ]  Yes → Respond to 4.6.a – b and include details in the Informed Consent document.

[ ]  No → Go to Section 5.

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

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4.6.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

*Consider the site-specific conditions below. The study-wide information is described in the main application.*

* 1. How will consent be documented at this participating site? Check all that apply:

5.1.a. [ ]  Written consent document with ink signature of participant and all other necessary individuals (person conducting consent discussion, witness if applicable, etc.). **You must track site-specific changes into the model version of the consent/assent form(s) approved in the main application, and submit both tracked and clean copies of the site consent/assent form(s).**

5.1.a.i. [ ]  If phone or video consent is planned, review [*HRP-090 - POLICY - Informed Consent*](https://extranet.fredhutch.org/u/irb/policies-and-procedures.html#informed) to understand the expectations for still receiving a signed form back and include a specific plan or phone script with this application.

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. [ ]  Oral consent or written information sheet with no signature. Complete [*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), and submit it along with the consent script or written materials used to consent the participant. If a waiver of documentation of consent that covers this site was approved under the main application, submit a copy as an FYI.

5.1.c. [ ]  Electronic consenting (e-consent) (e.g., REDCap form). Review [*HRP-090 - POLICY - Informed Consent*](https://extranet.fredhutch.org/u/irb/policies-and-procedures.html#informed)) to understand the requirements for e-consent. Select one of the following:

5.1.c.i [ ]  Minimal risk study: Complete [*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), and include a specific plan with this application. Also attach your institution’s e-consent policy or a report from your institution showing the e-consent method has been determined to meet confidentiality requirements.

5.1.c.ii. [ ]  Greater than minimal risk study: E-consent may only be allowed if your institution has confirmed the electronic platform allows for a legally effective signature compliant with any state or local laws.

For FDA-regulated research, the institution must have also implemented the necessary technological and procedural controls to ensure FDA Part 11 Compliance. Attach documentation confirming these requirements have been met (e.g., letter from your IRB office, institutional policy, etc.).

5.1.c.iii. [ ]  Other. Describe:

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5.1.d. [ ]  N/A, this site is not consenting participants.

1. Enrollment of Non-English Speaking Participants

*The IRB is responsible for ensuring researchers do not inappropriately exclude speakers of other languages and that they consent, document, and support their equal participation to the extent possible.*

6.1 Will the site enroll non-English speaking participants? This should be understood to include individuals who either do not speak English or those with another language preference who are unable to understand English at a level of proficiency that would allow them to participate in meaningful informed consent.

NOTE: If the primary language spoken at your site is not English, consult with IRO@fredhutch.org for how to respond to these questions. Generally you will swap out the term “non-English speaking participants” to instead consider participants who do not speak the primary language spoken at your site.

[ ] Yes ® Describe how the site team will communicate with non-English speaking participants during the course of the research at this site (e.g., interpretation service, study staff who speak the native language).

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[ ]  No ® This research/site proposes to exclude non-English speaking participants. Complete one:

[ ] Rationale for the exclusion was provided at the study-level in the main file. Contact the Fred Hutch study team to confirm.

[ ] This site is proposing to exclude non-English speaking participants. Provide clear and specific rationale for the proposed exclusion. Refer to [*HRP-129 - POLICY - Use of Interpreter Services and Translated Documents*](https://extranet.fredhutch.org/en/u/irb/policies-and-procedures.html#language) for the types of justifications the IRB may allow. Respond below and then skip to Section 7.

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6.2 For non-English speakers, how will consent be provided and documented at this site? Refer to [*HRP-129 - POLICY - Use of Interpreter Services and Translated Documents*](https://extranet.fredhutch.org/u/irb/policies-and-procedures.html#language) for more information about the requirements.

Note: If you are requesting a waiver of consent or a waiver of documentation of consent (waiver of the signature) as described in the prior section, those would apply to non-English speakers as well.

Select **one** option below:

6.2.a Targeted enrollment of non-English speakers: Consent form(s) must be translated up front and available for the consent discussion. Select one:

6.2.a.i [ ]  Translated consent forms and a translation certificate are included in this submission. 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.

6.2.a.ii [ ]  Translated documents will be submitted via Modification after the IRB approves the English versions of the site consent form(s).

6.2.a.iii [ ]  N/A ® A consent waiver requested in Question 5.1, or approved in the main file, applies to this population at this site.

6.2.b Unexpected enrollment of non-English speakers: A [short form consent process](https://extranet.fredhutch.org/u/irb/informed-consent/non-english-speaking-participants.html#process) is allowed under federal regulations.

In the short form consent process, if a potential participant who is non-English speaking is encountered, a translated generic “short form” consent in the participant’s language is used, with a qualified interpreter present to provide interpretation of the study-specific full consent form. 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.

6.2.b.i. If checking this option, indicate which short form consents will be used:

[ ]  Fred Hutch’s short form versions that are already IRB approved. See <https://extranet.fredhutch.org/en/f/irb/short-form-consent.html> (no need to attach to the submission).

[ ]  Site-specific short forms that already have IRB approval by my local institution (no need to attach to the submission).

[ ]  Site-specific short forms that do not yet have IRB approval. Please attach English-language version and translated version(s) along with certificate of translation.

6.2.b.ii. After use of the short form consent process, will the consent form be translated into the participant’s language?

6.2.b.ii.a [ ]  Yes, short form consent process WILL be followed by translation of the full English consent form as required per policy. If the participant enrolls on study, you may begin study procedures immediately. Following consent with the short form, you must translate the English consent form and submit it to the IRB within 30 days and then provide it to the participant within 2 weeks of IRB approval (e.g., viaMyChart, email, mail, or at the next clinic visit). No reconsent signature is required.

6.2.b.ii.b [ ]  No, short form consent process will NOT be followed by translation of the full English consent form. Allowable exceptions to full translation are rare. Provide rationale below, after referring to [*HRP-129 - POLICY - Use of Interpreter Services and Translated Documents*](https://extranet.fredhutch.org/en/u/irb/policies-and-procedures.html#language):

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6.2.b.ii.c [ ]  N/A ® A consent waiver requested in question 5.1.c, or approved in the main file, applies to this population.

6.3 Will other participant-facing site material be translated? For example, recruitment material, surveys and questionnaires, diaries, mobile apps, etc.

6.3.a Targeted enrollment of non-English speakers: Participant-facing materials should be translated before use. Select one option below:

6.3.a.i [ ]  Translated documents and a translation certificate are included in this submission. Note: If the IRB requires changes to the English documents, the translated documents will also need to be updated and resubmitted for IRB review.

6.3.a.ii [ ]  Translated documents will be submitted via Modification after the IRB approves the English versions.

6.3.a.iii [ ]  Other, describe below:

|  |
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6.3.b Unexpected enrollment of non-English speakers: Generally, participant-facing materials should be translated before use. Reasonable exceptions may be granted by the IRB, for example if there are plans to verbally administer a survey using an interpreter for non-English speakers. Refer to [*HRP-129 - POLICY - Use of Interpreter Services and Translated Documents*](https://extranet.fredhutch.org/en/u/irb/policies-and-procedures.html#language) for other examples. Describe your plans and any exceptions requested below.

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7. Other Regulatory and/or Administrative Review Requirements

7.1 Other IRB Reviews

7.1.a. Is this site for this research being transferred from another IRB?

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

[ ]  No

7.1.b. Has this site been disapproved by another IRB for this research prior to submission to the Fred Hutch IRB?

[ ]  Yes → Explain:

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[ ]  No

7.2 Health Insurance Portability and Accountability Act (HIPAA):

7.2.a Will this site have access to, or use of, any participants’ health information that is not stripped of the [18 identifiers](https://extranet.fredhutch.org/en/u/irb/glossary.html#hipaa_identifiers) defined under HIPAA ([45 CFR 164.514(A)(2)](https://www.gpo.gov/fdsys/pkg/CFR-2002-title45-vol1/pdf/CFR-2002-title45-vol1-sec164-514.pdf)) from a [covered entity](https://extranet.fredhutch.org/en/u/irb/glossary.html#covered_entity)?

[ ]  Yes

[ ]  No → HIPAA does not apply. Skip to Question 7.3.

7.2.b. Will this site 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 might be required. Consult with your site’s legal counsel. Skip to Question 7.3.

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

7.2.c. Are you requesting a full waiver of HIPAA authorization (for all aspects of the research at this site)?

[ ]  A full waiver of HIPAA that covers this site was granted under the main application.

[ ]  Yes → Submit [*HRP-257 - FORM - HIPAA Supplement*](https://extranet.fredhutch.org/en/f/irb/hipaa-supp-waiver-authorization.html) to request a full waiver of HIPAA. Skip to Question 7.3.

[ ]  No

7.2.d. Will this site access or use PHI for the purpose of determining eligibility prior to obtaining written authorization, or will you be waiving HIPAA for some other part of the study?

[ ]  A partial waiver of HIPAA that covers this site was granted under the main application.

[ ]  Yes → Complete and submit [*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

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

[ ]  **Separate HIPAA Authorization Form(s) as indicated below:** Submit 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 (e.g., site-specific HIPAA form).

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

7.2.f. If you may enroll non-English speakers (see section 6 above), how will participants who do not speak English provide HIPAA authorization? Check all that apply.

7.2.f.i. [ ]  Participants will sign a site-specific 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.

[ ]  N/A → We are using the HIPAA authorization used by the lead site approved under the main application.

7.2.f.ii. [ ]  A qualified interpreter will provide interpretation of the site-specific English HIPAA authorization (either stand-alone or combined within the consent). Select one:

[ ]  An Alteration of HIPAA (to waive the signature) that covers this activity at this site was granted under the main application.

[ ]  Submit [*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).

7.3 Does the site PI or any study team member have a financial conflict of interest that is the subject of a conflict management plan?

[ ]  Yes → Provide the name(s) of those with a Conflict of Interest and their role(s) in the study. Fred Hutch IRB staff will contact the site PI, PI Proxy (if applicable), and Primary Contact to obtain a copy of the conflict management plan.

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[ ]  No

7.4 Have all of your institution’s ancillary reviews occurred and has the site otherwise received approval to proceed with IRB review (e.g., radiation safety committee, scientific review committee, etc.)?

[ ]  Yes → List ancillary reviews and approval dates:

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[ ]  No → Explain:

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1. Required Supplements

*Check all boxes that apply, to identify relevant Supplement forms that should be completed for this site and uploaded to Hutch IRB by the coordinating center staff. If none apply, check “None of Above.”*

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| **CHECK ALL THAT APPLY** | **ELEMENTS OF RESEARCH** | **SUPPLEMENT NAME AND LINK** |
| [ ]  | **If this site is serving as the coordinating center** | [*HRP-254 - FORM - Multi-Center Supplement*](https://extranet.fredhutch.org/en/f/irb/multi-center-supplement.html) |
| [ ]  | **International research**The site PI 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) |
| [ ]  | **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) |
| [ ]  | **Site-Specific Department of Defense (DoD) funding or support**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) |
| [ ]  | **Site-Specific 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) |
| [ ]  | **Site-Specific 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 non-English speakers) | [*HRP-257 - FORM - HIPAA Supplement*](https://extranet.fredhutch.org/en/f/irb/hipaa-supp-waiver-authorization.html) |
| [ ]  | **Transfer of IRB oversight**This site is being transferred from another IRB. | [*HRP-260 - FORM - Transfer Supplement*](https://extranet.fredhutch.org/en/f/irb/transfer-of-irb-oversight.html) |
| [ ]  | **NONE OF ABOVE** |  |

9. Other Required Attachments

**[ ]** Site investigator’s current *Curriculum Vitae* or resume

[ ]  For sites conducting clinical procedures, a copy of the site investigator’s current medical license

[ ]  Site investigator’s Documentation of Human Subjects Protection training completed in the last 3 years

[ ]  If the site is conducting a clinical trial (defined in [*HRP-062 - POLICY - Training*](https://extranet.fredhutch.org/u/irb/policies-and-procedures.html#training), documentation of Good Clinical Practice training completed in the last 3 years

[ ]  [*HRP-270 - FORM - Local Context Review*](https://extranet.fredhutch.org/en/f/irb/local-context-review-form.html). Note: This form is to be completed by site’s IRB office or regulatory office

10. SITE PI ACKNOWLEDGMENT AND SIGNATURE

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| **Study Title:**  |       |

As the site Principal Investigator (PI) or designated proxy for this study, I provide assurances for the following:

A. All of the information provided in this submission is complete and correct;

B. This submission accurately indicates whether the site PI or any study team members have a conflict management plan; and

C. The site PI will conduct this research in accordance with requirements in the *HRP-103 - Investigator Manual*.

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| Name of Site Investigator or Designee\* |  | Signature of Investigator or Designee\* |  | Date |

[ ]  \*I am signing this form as a designee. By checking this box, I affirm the site PI is aware of this submission and has given me permission to submit on their behalf. I will save documentation of the site PI’s permission to submit this form.