|  |  |  |
| --- | --- | --- |
|  | Diagram  Description automatically generated | **FORM - IRB Application****(No 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?

|  |
| --- |
|       |

Instructions

* **Use this form ONLY if the research consists solely of obtaining and using data or specimens from some source other than the participants** (for example, it is a medical records review project or a study on leftover biospecimens).
	+ Use [*HRP-262 - FORM - Not Human Research Determination*](https://extranet.fredhutch.org/f/irb/human-subjects-research.html) instead if you are requesting an NHR determination.
	+ Use [*HRP-250 - FORM - IRB Application (Contact)*](https://extranet.fredhutch.org/f/irb/irb-application.html)instead if you will **interact with subjects**, such as to consent participants to collection of biospecimens, or if this project involves overseeing sites that interact directly with participants.
* 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 [Selecting the Right IRB](https://extranet.fredhutch.org/u/irb/selecting-the-right-irb.html) webpage 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 “back and forth” for clarification.
* 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](#_Toc125036408)

[2. Risk/Benefit Assessment](#_Toc125036409)

[3. Selection of Human Subjects (Biospecimens and Information)](#_Toc125036410)

[4. Consent](#_Toc125036411)

[5. Documenting Consent](#_Toc125036412)

[6. Data and Safety Monitoring](#_Toc125036413)

[7. Privacy and Confidentiality](#_Toc125036414)

[8. Other Regulatory and/or Institutional Review Requirements](#_Toc125036416)

[9. Required Ancillary Reviews](#_Toc125036417)

[10. Required Supplements](#_Toc125036418)

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/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/f/irb/exempt-checklist.html)in Hutch IRB along with this application*.* **Complete only Sections 1, 7, and 8 of this application.**

1.2 Research Plan: Attach yourresearch protocol documentto the submission in Hutch IRB. (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, the type of biospecimens (e.g., whole blood, tumor tissue, etc.) and/or participant information records (including the specific data elements) that are included, use of data and specimens, study timelines, subject population and inclusion/exclusion criteria, statistical methods, rationale for number of subjects, risks and benefits, subject selection methods, data management and confidentiality, and provisions to monitor data and protect privacy.*

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

 *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:

|  |
| --- |
|       |

1.4 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:

|  |
| --- |
|       |

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

|  |
| --- |
|       |

[ ]  No

1.5 What are the study’s sources of biospecimens and/or participant information (e.g., medical records, other studies, a repository, etc.)? 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** |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |

For public or medical record sources, or from sources on [*HRP-151 - IRB Pre-Reviewed Sources of De-identified Human Specimens and/or Data*](https://extranet.fredhutch.org/u/irb/submissions-to-the-irb/research-not-involving-human-subjects.html#prereviewed): You do not need to attach any other documentation about these sources.

For all other sources: **You must submit 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 the Business Development [Agreement Form Questionnaire](https://centernet.fredhutch.org/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 legal@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.

1.5.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:

|  |
| --- |
|       |

[ ]  No

1.5.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.

|  |
| --- |
|       |

[ ]  No

1.5.c. Does this study involve the use or destruction of embryonic stem cells?

[ ]  Yes → Provide information about where the stem cells are obtained (e.g., NIH-approved cell line). For UW investigators, also provide the location and approval date of the [Embryonic Stem Cell Research Oversight](https://www.washington.edu/research/embryonic-stem-cell-research-oversight-escro/) (ESCRO) Committee review and submit a copy of the ESCRO approval letter. 

|  |
| --- |
|       |

[ ]  No

1.6 De-identification: Are **both** the following criteria met in relation to the human biospecimens and information?

* The human biospecimens and information are de-identified prior to receipt by the research team, and the identities of subjects cannot be readily ascertained or otherwise associated with the data
* The provider of the human biospecimens and information either does not have the identifiers or is prohibited by contract or agreement from providing the identifiers.

[ ]  Yes → This project may qualify for a determination of “Not Human Research” (NHR). Complete the Not Human Research Determination form to confirm. If in completing the NHR determination form, you determine the project will **not** qualify for an NHS determination, mark “No” and continue with this form.

[ ]  No

1.7 Is this activity a “[secondary use](https://extranet.fredhutch.org/u/irb/glossary.html#secondary_research)” of biospecimens and/or information (i.e., the biospecimens and/or information were or will be collected for a different purpose [e.g. clinical care, repository research project, etc.])?

[ ]  Yes → Continue to Question 1.7.a

[ ]  No → Go to [Section 2.0](#Section2).

1.7.a Will this research involve accessing, without consent, any Washington state agency records[[1]](#footnote-2) (other than University of Washington records) containing individually identifiable information?

*Note: Washington state law protects certain state records from disclosure without consent and mandates safeguards including a confidentiality agreement signed by the researchers who will have access to individually identifiable information. To obtain the confidentiality agreement, you must contact the appropriate records custodian.*

[ ]  Yes → Complete and submit [*HRP-276 - FORM - Expedited Review*](https://extranet.fredhutch.org/f/irb/expedited-review-checklist-for-minimal-risk-activities.html) with this form. Go to [Section 2](#Section2).

[ ]  No → This project likely qualifies for a determination of “Exemption” from IRB review under category 4. Complete the [*HRP-275 - FORM - Exempt*](https://extranet.fredhutch.org/f/irb/exempt-checklist.html) and continue to Question 1.7.b.

1.7.b Based on your assessment using the [*HRP-275 - FORM - Exempt*](https://extranet.fredhutch.org/f/irb/exempt-checklist.html), does this project qualify for an “Exemption”?

[ ]  Yes → Submit your completed [*HRP-275 - FORM - Exempt*](https://extranet.fredhutch.org/f/irb/exempt-checklist.html)

* **Proceed to** [**Section 7.0**](#Section8) **(skip sections 2 through 6).**

[ ]  No → If in completing [*HRP-275 - FORM - Exempt*](https://extranet.fredhutch.org/f/irb/exempt-checklist.html) you determine the research project will not qualify for exempt category 4:

* **Attach** [***HRP-276 - FORM - Expedited Review***](https://extranet.fredhutch.org/f/irb/expedited-review-checklist-for-minimal-risk-activities.html) **and complete the rest of this application.**
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 Is it possible that this study will discover a previously unknown condition such as a disease or genetic predisposition, as a result of evaluating biospecimens and/or information?

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

|  |
| --- |
|       |

[ ]  No

2.2 Will this study involve the return of any research results to a participant who originally provided the biospecimens or information?

[ ]  Yes → Explain (including how results will be communicated back to participants):

|  |
| --- |
|       |

[ ]  No

2.3 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?

|  |
| --- |
|       |

1. Selection of Human Subjects (Biospecimens and Information)

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

3.1 What is the estimated number of data subjects (distinct individuals from whom you will have information or biospecimens) involved in this research project?

* Studies only enrolling within the Cancer Consortium: Complete only the **local** row.
* Studies enrolling outside the Cancer Consortium: **Both** local and study-wide numbers must be provided.

|  |  |
| --- | --- |
|  | **NUMBER OF BIOSPECIMENS or RECORDS** |
| **First Year** | **Entire Study** |
| **Locally** |       |       |
| **Study-wide** |       |       |

3.2 Will you have sufficient information about participants to determine whether specimens and/or information relating to the following special populations are included in this research?

[ ]  No

[ ]  Yes → **Check all that apply.**

3.2.a. [ ]  Pregnant women

3.2.b. [ ]  Fetuses *in utero*

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

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

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

3.2.f. [ ]  Employees

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

|  |
| --- |
|       |

3.2.h. **If you checked any of the boxes a. – g. above**: Are there any additional risks for these special populations beyond loss of confidentiality?

[ ]  Yes → Describe the additional safeguards taken to protect the rights and welfare of the special population. Reference the page number(s) in the protocol that describe the additional safeguards.

|  |
| --- |
|       |

[ ]  No

3.3 Ethnicity, Race and Gender Accrual

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). Will your research include these demographic data points?

[ ]  Yes

[ ]  No, the Ethnic/Racial/Gender data is not available to us (e.g., the original data source does not include demographic information). Explain:

|  |
| --- |
|       |

1. Consent

*The IRB is responsible for determining that “No contact” activity meets the criteria for a waiver of consent.*

4.1 Did the foundational consent originally signed by the participant when their biospecimens or information were collected cover the future research use of their biospecimens or information consistent with the purpose of this project? (If no foundational consent exists, select the third option below.)

[ ]  Yes → Attach a copy of the foundational consent form(s) originally used to collect the biospecimens or information; or attach a copy of the gatekeeper letter from the provider of the biospecimens or information confirming that informed consent was obtained when the biospecimens or information was collected. Also complete [*HRP-256 - FORM - Consent Supplement*](https://extranet.fredhutch.org/f/irb/waiver-consent.html) to request a full waiver of consent specifically for this research use of biospecimens or information*.* Go to [Section 6.0](#Section6).

[ ]  No → Provide a detailed explanation why use of the biospecimens or information for this research is acceptable given the foundational consent forms did not contemplate this future use (e.g., the proposed technology did not exist at the time of consent). Also complete [*HRP-256 - FORM - Consent Supplement*](https://extranet.fredhutch.org/f/irb/waiver-consent.html) to request a full waiver of consent*.*

|  |
| --- |
|       |

[ ]  No → No foundational consent form exists, because the biospecimens or information were originally collected under a waiver of consent *or* as part of clinical care. Describe below. Also complete a [*HRP-256 - FORM - Consent Supplement*](https://extranet.fredhutch.org/f/irb/waiver-consent.html) to request a full waiver of consent*.*

|  |
| --- |
|       |

1. Documenting Consent

This section is not applicable since there will be no participant contact in this research project. If you have participant contact planned, use [*HRP-250 - FORM - IRB Application (Contact)*](https://extranet.fredhutch.org/f/irb/irb-application.html)instead, or consult with **IRO@fredhutch.org** before proceeding. If the IRB determines that consent of participants is necessary to cover this research use of biospecimens and/or information, you will be directed to complete [*HRP-250 - FORM - IRB Application (Contact)*](https://extranet.fredhutch.org/f/irb/irb-application.html) instead.

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 → Briefly describe the plan:

|  |
| --- |
|       |

[ ]  No → There are no participant safety implications for this research.

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.
* **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](https://extranet.fredhutch.org/u/irb/special-topics/coc.html) 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. (The response from the federal agency will be a contingency of the IRB approval.)

[ ]  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:

|  |
| --- |
|       |

[ ]  N/A → We were automatically issued a Certificate of Confidentiality because we have NIH, CDC, HRSA, BARDA, 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://extranet.fredhutch.org/u/irb/special-topics/coc.html*](https://extranet.fredhutch.org/u/irb/special-topics/coc.html) *and https://grants.nih.gov/policy/humansubjects/coc.htm*

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 → Submit [*HRP-260 - FORM - Transfer Supplement*](https://extranet.fredhutch.org/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:

|  |
| --- |
|       |

[ ]  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/u/irb/glossary.html#hipaa_identifiers) defined under HIPAA (45 CFR 164.514(A)(2)) from a [covered entity](https://extranet.fredhutch.org/u/irb/glossary.html#covered_entity) or [business associate](https://extranet.fredhutch.org/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/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. For Fred Hutch, contact the Office of the General Counsel at legal@fredhutch.org.

[ ]  No, we will be accessing or using more than a limited data set. Attach [*HRP-257 - FORM - HIPAA Supplement*](https://extranet.fredhutch.org/f/irb/hipaa-supp-waiver-authorization.html) to request a full HIPAA waiver.

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 Section 9.

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

|  |
| --- |
|        |

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

|  |
| --- |
|       |

 *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/u/business-dev/form-questionnaire.html*](https://centernet.fredhutch.org/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 Does your research involve any of the following components: [Artificial Intelligence, Machine Learning, Generative AI, or Large Language Model](https://centernet.fredhutch.org/u/data-science-lab/data-governance/ai/understanding-artificial-intelligence.html)?

[ ]  Yes ® IRO staff will route for AI Governance triage. If AI Governance Workgroup review is required, you will be contacted.

[ ]  No

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/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.*

|  |  |
| --- | --- |
| **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. |
| **REQUIRED BEFORE IRB APPROV ALS 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 the [Cancer Surveillance System (CSS)](https://www.fredhutch.org/en/research/divisions/public-health-sciences-division/research/epidemiology/cancer-surveillance-system.html) webpage for more information: In Hutch IRB, attach the CSS letter of support to the submission under “Other attachments” in Hutch IRB.  |
| [ ]  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/u/irb/submissions-to-the-irb.html#guidance).In Hutch IRB, attach the SCH letter to the submission under “Other attachments.” |

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.*

|  |  |  |
| --- | --- | --- |
| **CHECK ALL THAT APPLY** | **ELEMENTS OF RESEARCH** | **SUPPLEMENT NAME AND LINK** |
| [ ]  | **Children**If this research will contain sufficient information to determine that you have biospecimens and/or information from children. | [*HRP-264 - FORM - Children Supplement*](https://extranet.fredhutch.org/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/f/irb/dod-supplement.html) |
| [ ]  | **Drug, biologics, food, or dietary supplement**If you or the sponsor is intending to use results from the study to support FDA approval of a new indication for a drug, biologic, or food supplement or to support any other significant change in the labeling or advertising*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/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/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/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/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/f/irb/multi-center-supplement.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/f/irb/repository-registry-databank-supp.html) |
| [ ]  | **Prisoners**If this research will contain sufficient information to determine that you have biospecimens and/or information from prisoners. | [*HRP-265 - FORM - Prisoner Certification Checklist for Investigator*](https://extranet.fredhutch.org/f/irb/investigator-prisoner-certification-checklist.html) |
| [ ]  | **Transfer of IRB oversight**This study is being transferred from another IRB. | [*HRP-260 - FORM - Transfer Supplement*](https://extranet.fredhutch.org/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/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 non-English speakers) | [*HRP-257 - FORM - HIPAA Supplement*](https://extranet.fredhutch.org/f/irb/hipaa-supp-waiver-authorization.html) |
| [ ]  | **NONE OF ABOVE** |  |

1. RCW Chapter 42.48: Washington "state agency" records means records from: (a) The department of social and health services; (b) the department of corrections; (c) the department of health; or (d) the department of children, youth, and families. [↑](#footnote-ref-2)