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|  | Diagram  Description automatically generated | **FORM: External IRB Supplement***For use when Fred Hutch is engaged in research being reviewed by an External IRB* |

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| **Date:** |       |
| **FHIRB #:** |       |
| **RG # (required):** |       | **Protocol #:** |       |
| **Fred Hutch Investigator (or UW investigator if no FH faculty is involved):***Note: FH Investigator must be a faculty member. If not, contact IRO@fredhutch.org.* |       |
| **Study Title:**  |       |

Instructions

* **If Fred Hutch is** [**engaged**](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html) **in the research, use this form to request authorization from the Fred Hutch IRO to rely on an external IRB (any IRB other than the Fred Hutch IRB).** This is an administrative process for Fred Hutch to fulfill its regulatory requirements as an institution. The process allows the IRO to confirm (a) all Fred Hutch institutional requirements have been met and (b) funds can be released for your research (if applicable). Please contact IRO@fredhutch.org with any questions.
* This form is used in conjunction with Hutch IRB to request authorization to rely on an external IRB.
* **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.
* Steps involved for Fred Hutch to rely on an External IRB:
1. If you haven’t already, email IRBReliance@fredhutch.org to discuss a reliance agreement.
Exceptions: Skip this step if requesting to rely on University of Washington, Seattle Children’s, Advarra, or WCG IRB, or if you otherwise are certain that a broad agreement is in place with the External IRB.
2. Complete a draft of the IRB application form required by the external IRB (the external IRB application form), but do not submit it to the external IRB yet.
3. Complete the External IRB Supplement (this form)
4. Create a New Study in Hutch IRB. Attach this form, a copy of the external IRB application form, and all other required attachments to Hutch IRB.
5. Once the IRO confirms all Fred Hutch institutional requirements have been met, you will be issued an IRO Endorsement letter through Hutch IRB. Include this IRO Endorsement letter when you submit your final IRB application to the external IRB.

General Information

1. Have you consulted with anyone in the IRO about this research? Who and when?

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1. Who is the Principal Investigator at the external institution (if applicable)?

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1. What type of agreement will be used to document reliance?

[ ]  Study-specific IRB Authorization Agreement

[ ]  IRB Services Agreement (commercial IRB: Advarra or WCG)

[ ]  Cooperative Agreement

1. Which Cancer Consortium Site(s) will be [**engaged in this research**](https://extranet.fredhutch.org/en/u/irb/glossary.html#engaged) and relying on the external IRB (check all that apply)?

|  | **Institution** | **Institution Lead Investigator Name** | **Activities performed by staff/employees of this Institution (check all that apply)** |
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| [x]  | Fred Hutch |       | [ ]  Administer study interventions[ ]  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:       |
| [ ]  | Seattle Children’s  |       | [ ]  Administer study interventions[ ]  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:       |
| [ ]  | University of Washington |       | [ ]  Administer study interventions[ ]  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:       |

1. Will Fred Hutch employees obtain consent? *Note: this should align with your response in question 4*

[ ]  Yes ® The Fred Hutch/Cancer Consortium site-specific consent form(s) must include the following:

* + The consent heading **must** include Fred Hutchinson Cancer Center
	+ The consent **must** include references to Fred Hutch having access to identifiable participant data
	+ If Fred Hutch is also the lead PI, the consent **must** also include the name, affiliation, and phone number of the PI

[ ]  No ® The study consent form **must** include references to Fred Hutch having access to identifiable participant data.

[ ]  N/A ® Consent is waived for this study

1. Electronic consent plans: Are you planning to use eConsent?

[ ]  Yes→ Describe the eConsent platform being used:

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[ ]  No

Regulatory and/or institutional review requirements

1. Embryonic Stem Cell Research: 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):

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[ ]  No

1. 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, documenting that informed consent was obtained at the time of tissue collection:

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[ ]  No

1. HIPAA Privacy Board Review:

9.a. Full or partial waiver or alteration of HIPAA: Does the external IRB review requests for waivers/alterations of HIPAA authorization? (Note that Advarra and WCG do review waivers; NCI CIRB and NMDP IRBs do not review waivers.)

[ ]  Yes

[ ]  No → Complete the Fred Hutch [*HRP-257 - FORM - HIPAA Supplement*](https://extranet.fredhutch.org/en/f/irb/hipaa-supp-waiver-authorization.html) and attach.

[ ]  I don’t know → Contact the IRB Reliance Coordinator at iro@fredhutch.org.

[ ]  N/A – I am not requesting a waiver.

9.b. How will you obtain authorization to access PHI?

[ ]  Separate HIPAA Authorization Form(s) as indicated below. Please 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. Current version located [here](https://www.washington.edu/research/forms-and-templates/template-hipaa-authorization/).

[ ]  Seattle Children’s HIPAA form.

[ ]  Other HIPAA authorization form (IRO will facilitate review by Office of General Counsel).

[ ]  HIPAA authorization language included in the research consent form (IRO will facilitate review by Office of General Counsel).

[ ]  N/A – I’ve requested a full waiver of HIPAA authorization for all purposes.

[ ]  N/A – HIPAA does not apply.

1. Is the study funded?

[ ]  Yes → Specify the prime awardee institution:

[ ]  No

1. Will this study receive monetary or other support (study drug, equipment, personnel time, etc.) from a for-profit company?

[ ]  Yes → Provide the name(s) of the for-profit company and briefly describe the type of support being provided:

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[ ]  No

Required Ancillary Reviews

*Identify any other regulatory or institutional approvals that are required for this research. (Check as applicable)*

*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.*

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| **ANCILLARY APPROVAL REQUIRED** | **RESEARCH FOR WHICH THIS IS REQUIRED & HOW TO SUBMIT** |
| **REQUIRED BEFORE SUBMISSION TO THE IRO** |
| [ ]  Cancer Consortium OnCore/CTMS Entry[ ]  N/A: Attach an email from CTMS indicating entry in OnCore is not required | Required for 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 IRO ENDORSEMENT IS ISSUED *(Check all that apply)*** |
| [ ]  Cancer Surveillance System (CSS) | Required if the study involves 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> Attach the letter of support from CSS to the Supporting Documents page 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 Modification, please 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.)Attach the IBC approval documentation to the Study-Related Documents page in Hutch IRB. |
| [ ]  Radiation Safety[ ]  PendingAlso indicate which apply:[ ]  Joint HSRAC for UW or FHCC[ ]  Seattle Children’s RSC[ ]  Fred Hutch Radiation Safety[ ]  Other:       | Required if the study will use radioactive materials (e.g., nuclear medicine, radio-immune therapy) or an ionizing radiation-producing machine (e.g., CT, X-ray, Accelerator, DEXA scanner), 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. Attach the approval documentation to the Study-Related Documents page in Hutch IRB. |
| [ ]  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 to the Study-Related Documents page in Hutch IRB. |

Required attachments

*Identify the required attachments to upload into Hutch IRB*

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| **CHECK ALL THAT APPLY** | **DOCUMENT** | **WHERE TO ATTACH IN HUTCH IRB** |
| [ ]  | **Protocol** | Basic Study Information page |
| [ ]  | **Contract** (fully executed contract required if Fred Hutch is a signatory)Note: For industry sponsored contracts with Fred Hutch, the IRO will facilitate review of contract against the consent form by Office of General Counsel. | Study or Local Funding Sources page |
| [ ]  | If Fred Hutch employees will *not* be consenting: The **study’s template consent form** | Study-Related Documents page:– Consent form templates |
| [ ]  | If Fred Hutch employees *will* be consenting: The Fred Hutch/Cancer Consortium **site-specific consent form** | Local Site Documents page:– Consent Forms |
| [ ]  | **Completed external IRB application form.** Ensure it is clear in the application that the external IRB is asked to review on behalf of Fred Hutch. Note: If Fred Hutch is being added as an amendment to an existing IRB file, include both the initial application and the amendment. | Local Site Documents page:– Other attachments |
| [ ]  | **External IRB Supplement** (this form) | Local Site Documents page:– Other attachments |
| [ ]  | **HIPAA Authorization** (if applicable) | Local Site Documents page:– Other attachments |