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|  | Diagram  Description automatically generated | FORM - IRB Authorization Agreement |

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| **Institution A -** Name of Institution or Organization Providing IRB Review: ***Fred Hutchinson Cancer Center (Fred Hutch)***

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| **IRB Registration #: Com A (00000021), Com B (00000022), Com C (00005619), Com D (00009831)** |
| **Federalwide Assurance (FWA) #: FWA00001920**  |

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| **Institution B -** Name of Institution Relying on the Designated IRB:

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| **Federalwide Assurance (FWA) #:**  |

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The Officials signing below agree that Institution B may rely on the Fred Hutchinson Cancer Center’s IRB for review and continuing oversight of the human subject research described below: (*check one*)

[ ]  This agreement applies to all human subject research covered by Institution B’s FWA.

[ ]  This agreement is limited to the following specific protocol(s):

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| Title of Research Project:  |       |
| Fred Hutch Principal Investigator:      | Institution B’s Principal Investigator:      |

The review performed by Fred Hutch’s IRB will meet the human subjects protection requirements of Institution B’s OHRP-approved FWA. The IRB at Fred Hutch will follow written procedures for reporting its findings and actions to appropriate officials at Institution B. Relevant minutes of IRB meetings will be made available to Institution B upon request. Institution B remains responsible for ensuring compliance with the IRB’s determinations and with the Terms of its OHRP-approved FWA. This agreement will become effective upon the date of the last signature by the Institutional Officials below and will remain in effect until such time that either institution provides 30 days written notice of termination to the other institution. Following termination of this Agreement, Fred Hutch agrees to provide continued IRB oversight of ongoing research for the reasonable time necessary to appropriately transfer oversight of the protocol(s) to the relying institution’s IRB. This document must be kept on file at both institutions, and will be amended if any information herein changes. It will be provided to OHRP upon request. Additional terms and responsibilities are outlined on the attached addendum and shall be deemed incorporated herein by reference.

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| Authorized Official of Fred Hutch: | Authorized Official of Institution B: |
|  |  |
| (signature) (date) | (signature) (date) |
| *Name:* Meghan Scott | *Name:*       |
| *Title:* Director, Institutional Review Office | *Title:*       |
| *Mailing Address:* 1100 Fairview Avenue N | *Mailing Address:*       |
| Mailstop: J2-100Seattle, WA 98109 |       |
| *Phone:* (206) 667-4372 *Fax:* (206) 667-6831 | *Phone:*       *Fax:*       |
| *Email:* mscott@fredhutch.org | *Email:*        |

**Attachment to IRB Authorization Agreement:**

Division of Responsibilities between Fred Hutch and Institution B

 When Fred Hutch IRB is the IRB of Record

The following Division of Responsibilities is based on the premise that the Fred Hutch IRB is providing IRB oversight for human subjects research activity occurring at Institution B, and that Institution B’s primary function is (a) to contribute local context to the Fred Hutch IRB review and (b) conduct oversight of local performance of these studies. As the IRB of record, the Fred Hutch IRB will conduct all reviews in accordance with 45 CFR 46, 21 CFR 50 and 56, 45 CFR 164, and RCW 70.02 as applicable.

**The responsibilities of the Fred Hutch IRB are to:**

* Perform initial review of new studies, discuss any issues with the Principal Investigator, require necessary modifications to the study, and make a final decision of approval or disapproval of the study;
* Perform initial and periodic review of the qualifications of the site investigator and the adequacy of the site to conduct the research;
* Conduct continuing review of the research and review study amendments;
* Review any researcher or research staff financial conflict of interest management plans submitted by Institution B and determine whether the management plan is appropriate to approve the research;
* Conduct review of serious, unexpected, and related adverse events; serious or continuing noncompliance; and other unanticipated problems;
* Promptly notify Institution B of any reported allegations of non-compliance relating to Institution B. Fred Hutch and Institution B will agree upon a plan to determine if the allegation has a basis in fact on a case-by-case basis;
* Audit the conduct of the research being carried out by Institution B when warranted;
* Either directly, or through the appropriate Fred Hutch coordinating center, inform the Principal Investigator at Institution B in writing of Fred Hutch IRB determinations including approvals and disapproval, required modifications, determinations related to unanticipated problems and noncompliance, and any changes in the study approval status;
* Either directly, or through the appropriate Fred Hutch coordinating center, notify the Principal Investigator at Institution B of new materials that have been reviewed for an active study and any changes in the study approval status;
* Promptly notify the Principal Investigator at Fred Hutch, the Principal Investigator at Institution B, and appropriate officials at Institution B of any Fred Hutch IRB determinations that require reporting to institutional officials and/or regulatory agencies under 45 CFR 46.103(b)(5) and 21 CFR 56.108(b) and 56.113. The Fred Hutch IRB, through the Fred Hutch Institutional Review Office, will submit required reports to the applicable federal department (e.g. OHRP, FDA) and/or funding agency head(s). The Fred Hutch Institutional Review Office will provide Institution B an opportunity to review and provide input on any reports prior to transmission to regulatory agencies; however, in no case will such opportunity for review and comment interfere with timely submission of required reports. Although Fred Hutch will consider any comments submitted, the final content of the report is up to the discretion of Fred Hutch;
* Maintain an IRB membership that satisfies the requirements of 45 CFR 46 and 21 CFR 56 and provides special expertise as needed to adequately assess all aspects of each study;
* Make available to Institution B the roster of Fred Hutch IRB membership and the Fred Hutch IRB Standard Operating Procedures (SOPs);
* Ensure that Fred Hutch IRB members receive orientation and continuing education on topics relevant to human subjects protection;
* Ensure that the Fred Hutch IRB has adequate meeting space and sufficient staff to support the Fred Hutch IRB’s review and recordkeeping duties;
* Notify Institution B immediately if there is ever a suspension or restriction of the Fred Hutch IRB’s authorization to review a study; and
* Notify Institution B of any changes in Fred Hutch IRB SOPs that might affect the institution’s reliance on Fred Hutch IRB reviews or performance of the research at the local institution.

**The responsibilities of Institution B are to:**

* Researchers must comply with the Fred Hutch IRB policies. These policies are available at: <https://extranet.fredhutch.org/u/irb/policies-and-procedures.html>
* When needed, provide a local context reviewer who has knowledge of the local research context and is able to review the informed consent form and related documents (e.g. authorizations for testing and release of medical records or donation of human specimens) to verify for the Fred Hutch IRB that these documents comply with applicable federal, state or local laws, institutional requirements, or IRB policies of Institution B;
* Notify Fred Hutch of any changes in local laws, institutional requirements, or IRB policies that might affect the Fred Hutch IRB review of Institution B;
* Conduct other ancillary reviews required by the protocol or by Institution B (e.g., scientific review, biosafety, radiation safety, etc.);
* Ensure the safe and appropriate performance of the research at Institution B. This includes, but is not limited to, conducting the research as approved by the Fred Hutch IRB, monitoring protocol compliance (after becoming aware of protocol deviations, unanticipated problems or noncompliance through the Fred Hutch IRB), managing any major protocol violations, managing any serious adverse events occurring at the institution, ensuring qualifications and training of research staff are commensurate with the research activity and providing a mechanism by which complaints about the research can be made by local study participants or others;
* Promptly notify Fred Hutch of any proposed changes to the research. Changes to the research (including changes in the consent document) may not be implemented without prior IRB review and approval by the Fred Hutch IRB, except where necessary to eliminate apparent immediate hazards to the participants;
* Provide the names and addresses to the Fred Hutch Institutional Review Office of local contact persons who have the authority to correspond on behalf of Institution B (e.g. the local IRB Director);
* Maintain records of Fred Hutch IRB approved research at Institution B as per institution policies;
* Maintain an OHRP-approved Assurance for human subjects research;
* Promptly notify the Fred Hutch Institutional Review Office if Institution B becomes aware of events that may change the ability of the site to conduct the research (e.g., suspension of the institution’s FWA);
* Maintain a human subjects protection program compliant with 45 CFR 46 and 21 CFR 50 and 56;
* Maintain compliance with state, local, or institutional requirements related to the protection of human subjects;
* Review and monitor individual and institutional conflicts of interest per Institution B’s policies and procedures. Provide conflict of interest management plans to the Fred Hutch IRB; and
* Notify Fred Hutch if officials of Institution B have disapproved the research, even if it has been approved by the Fred Hutch IRB.

**Further Delineation by Topic**

Confidentiality Laws and Regulations:
Compliance with confidentiality laws and regulations, including HIPAA and state law requirements, is considered a local institutional issue. The Fred Hutch IRB expects the designated local context reviewer to have knowledge of these requirements for Institution B and to be able to provide comments before or during the Fred Hutch IRB review process. Institution B remains responsible for how compliance with these confidentiality requirements is implemented at the institution.

Prisoners:

The Fred Hutch adheres to 45 CFR 46 Subpart C and needs to re-review a protocol when it becomes aware of an investigator wanting to conduct research on a prisoner. Institution B must notify the Fred Hutch IRB before enrolling prisoners in research overseen by Fred Hutch IRB. For research that is approved to include prisoners in accordance with Subpart C, the Fred Hutch IRB, through the Fred Hutch Institutional Review Office, will prepare the Prisoner Certification Letter to OHRP.

Serious Adverse Events and Other Unanticipated Problems:
It is the responsibility of Institution B’s Principal Investigator to identify and report serious adverse events and other unanticipated problems in accordance with Fred Hutch IRB Policy [*HRP-131 - POLICY - Unanticipated Problems Involving Risks to Subjects or Others*](https://extranet.fredhutch.org/u/irb/policies-and-procedures.html#unanticipatedproblems). For events that must be reported to the Fred Hutch IRB, the Principal Investigator at Institution B will be responsible for providing the appropriate documentation directly to the Fred Hutch IRB, or to the appropriate coordinating center at Fred Hutch which will report the event to the Fred Hutch IRB. The Fred Hutch IRB accepts the responsibility to ensure reporting to the appropriate regulatory agencies (i.e. OHRP and/or FDA) if the Fred Hutch IRB determines the event constitutes an Unanticipated Problem Involving Risk to Subjects or Others.

Noncompliance:

It is the responsibility of Institution B’s Principal Investigator to identify and report noncompliance in accordance with Fred Hutch IRB Policy [*HRP-024 - POLICY - Noncompliance*](https://extranet.fredhutch.org/u/irb/policies-and-procedures.html#noncompliance). For events that must be reported to the Fred Hutch IRB, the Principal Investigator at Institution B will be responsible for providing the appropriate documentation directly to the Fred Hutch IRB, or to the appropriate coordinating center at Fred Hutch which will report the event to the Fred Hutch IRB. The Fred Hutch IRB accepts the responsibility to ensure reporting to the appropriate regulatory agencies (i.e. OHRP and/or FDA) if the Fred Hutch IRB determines the event constitutes Serious or Continuing Noncompliance.