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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:     |  | | --- | | **IRB Registration #(s):** | | **Federalwide Assurance (FWA) #:** | |

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| **Institution B -** Name of Institution Relying on the Designated IRB:  ***Fred Hutchinson Cancer Center (Fred Hutch)***   |  | | --- | | **Federalwide Assurance (FWA) #: FWA00001920** | |

The Officials signing below agree that Fred Hutch may rely on Institution A’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 Fred Hutch’s FWA.

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

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

The review performed by Institution A’s IRB will meet the human subjects protection requirements of Fred Hutch’s OHRP-approved FWA. The IRB at Institution A will follow written procedures for reporting its findings and actions to appropriate officials at Fred Hutch. Relevant minutes of IRB meetings will be made available to Fred Hutch upon request. Fred Hutch 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, Institution A agrees to provide continued IRB oversight of ongoing research for the reasonable time necessary to appropriately transfer oversight of the protocol(s) to the Fred Hutch’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 considered incorporated herein by reference.

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

**Attachment to IRB Authorization Agreement:**

Division of Responsibilities between Fred Hutch and Institution A

When Fred Hutch relies on Institution A’s IRB as the IRB of Record

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

**The responsibilities of Institution A’s 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;
* Conduct continuing review of the research and review study amendments;
* Review any researcher or research staff financial conflict of interest management plans submitted by Fred Hutch to 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 Fred Hutch of any reported allegations of non-compliance relating to Fred Hutch. Institution A will work with Fred Hutch to 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 Fred Hutch when warranted;
* Either directly, or through the appropriate coordinating center at Institution A, inform the Principal Investigator at Fred Hutch in writing of Institution A’s 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 coordinating center at Institution A, notify the Principal Investigator at Fred Hutch 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 Institution A, the Principal Investigator at Fred Hutch, and appropriate officials at Fred Hutch of any determinations by Institution A’s IRB 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. Institution A’s IRB will submit required reports to the applicable federal department (e.g., OHRP, FDA) and/or funding agency head(s). Institution A will provide Fred Hutch 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;
* 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 Fred Hutch the roster of Institution A’s IRB membership and Institution A’s IRB Standard Operating Procedures (SOPs);
* Ensure that IRB members at Institution A receive orientation and continuing education on topics relevant to human subjects protection;
* Ensure that Institution A’s IRB has adequate meeting space and sufficient staff to support the IRB’s review and recordkeeping duties;
* Notify Fred Hutch immediately if there is ever a suspension or restriction of the IRB at Institution A’s authorization to review a study; and
* Notify Fred Hutch of any changes in Institution A’s IRB SOPs that might affect Fred Hutch reliance on Institution A’s IRB reviews or performance of the research at Fred Hutch.

**The responsibilities of Fred Hutch (Institution B) are to:**

* When needed, provide a local context reviewer who has knowledge of the local Fred Hutch 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 Institution A’s IRB that these documents comply with applicable federal, state or local laws, institutional requirements, or IRB policies of Fred Hutch;
* Notify Institution A of any changes in local policies or laws that might affect Institution A’s IRB review of Fred Hutch research activities;
* Conduct other ancillary reviews required by the protocol or Fred Hutch institutional requirements (e.g., scientific review, biosafety, radiation safety, etc.);
* Ensure the safe and appropriate performance of the research at Fred Hutch. This includes, but is not limited to, conducting the research as approved by Institution A’s IRB, monitoring protocol compliance (after becoming aware of protocol deviations, unanticipated problems or noncompliance through Institution A’s 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 Institution A 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 Institution A, except where necessary to eliminate apparent immediate hazards to the participants;
* Provide the names and addresses to Institution A of local contact persons who have the authority to correspond on behalf of Fred Hutch (e.g. the IRB Director);
* Maintain records of Institution A’s IRB approved research as per institution policies;
* Maintain an OHRP-approved Assurance for human subjects research;
* Promptly notify Institution A if Fred Hutch becomes aware of events that may change the ability of Fred Hutch 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 in accordance with Fred Hutch policies and procedures. Provide conflict of interest management plans to Institution A; and
* Notify Institution A if officials at Fred Hutch have disapproved the research, even if it has been approved by the IRB of Institution A.

**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.

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. Fred Hutch will notify Institution A’s IRB before enrolling prisoners in research overseen by Institution A’s IRB. For research that is approved to include prisoners in accordance with Subpart C, Institution A will prepare any Prisoner Certification Letters to OHRP with a copy to Fred Hutch.

Serious Adverse Events and Other Unanticipated Problems  
It is the responsibility of the Fred Hutch Principal Investigator to identify and report Serious Adverse Events and Other Unanticipated Problems in accordance with Institution A’s IRB policy. Institution A accepts the responsibility to ensure reporting to the appropriate regulatory agencies (i.e., OHRP and/or FDA) if the IRB at Institution A determines the event constitutes and Unanticipated Problem Involving Risk to Subjects or Others.

Noncompliance:

It is the responsibility of the Fred Hutch Principal Investigator to identify and report Noncompliance in accordance with Institution A’s IRB policy. Institution A accepts the responsibility to ensure reporting to the appropriate regulatory agencies (i.e., OHRP and/or FDA) if the IRB at Institution A determines the event constitutes Serious or Continuing Noncompliance.