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|  | Diagram  Description automatically generated | FORM - Individual Investigator Agreement |

Please print clearly and complete all sections. Submit to the Institutional Review Office, Fred Hutch

Email: irbreliance@fredhutch.org

Telephone: 206.667.5900

**Name of Institution with the Federalwide Assurance (FWA):**

Fred Hutchinson Cancer Center (Fred Hutch)

**Applicable FWA #:** FWA00001920

**Individual Investigator’s Name:**

**Name of Institution / Hospital / Clinic:**

**Research Covered by this Agreement:**

**IR Number:** **Protocol Number:**

1. The above-named Individual Investigator has reviewed: 1) *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (or other internationally recognized equivalent; see section B.1. of the Terms of the Federalwide Assurance (FWA) for International (Non-U.S.) Institutions); 2) the U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR part 46 (or other procedural standards; see section B.3. of the Terms of the FWA for International (Non-U.S.) Institutions); 3) the FWA and applicable Terms of the FWA for the institution referenced above; and 4) the relevant institutional policies and procedures for the protection of human subjects.
2. The Investigator understands and hereby accepts the responsibility to comply with the standards and requirements stipulated in the above documents and to protect the rights and welfare of human subjects involved in research conducted under this Agreement.
3. The Investigator will comply with all other applicable federal, international, state, and local laws (including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe), regulations, and policies that may provide additional protection for human subjects participating in research conducted under this agreement.
4. The Investigator will abide by all determinations of the Fred Hutch Institutional Review Board (IRB) designated under the above FWA and will accept the final authority and decisions of the IRB/IEC, including but not limited to directives to terminate participation in designated research activities.
5. The Investigator will complete any educational training required by the Institution and/or the IRB under Fred Hutch Policy [*HRP-062 - POLICY - Training*](https://extranet.fredhutch.org/u/irb/policies-and-procedures.html#training)prior to initiating research covered under this Agreement. This includes training on Human Subject Protection and, when applicable, training in Good Clinical Practice.
6. The Investigator will report promptly to the IRB/IEC any proposed changes in the research conducted under this Agreement. The investigator will not initiate changes in the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.
7. The Investigator understands that some problems must be reported to the IRB promptly. Examples of problems to report promptly include:
8. Unanticipated Problems Involving Risks to Subjects or Others which are unexpected, related or possible related and serious, including biomedical or biobehavioral adverse events
9. Breach of confidentiality
10. Participant complaints
11. Unanticipated adverse device effects
12. Incarceration of a subject in a protocol
13. Any allegation or finding of non-compliance with regulations or IRB approved activities

Please review [*HRP-131 - POLICY - Unanticipated Problems Involving Risks to Subjects or Others*](https://extranet.fredhutch.org/u/irb/policies-and-procedures.html#unanticipatedproblems), and [*HRP-024 - POLICY - Noncompliance*](https://extranet.fredhutch.org/u/irb/policies-and-procedures.html#noncompliance) with the [*Office of the Director’s Human Research Protection Program Policy*](https://fredhutch-fhccresearchcenter.policystat.com/policy/11593719/latest/) on the Fred Hutch IRB website for specific instructions, responsibilities, and timelines of reporting.

* 1. The Investigator, when responsible for enrolling subjects, will obtain, document, and maintain records of informed consent for each such subject or each subject’s legally authorized representative as required under HHS regulations at 45 CFR part 46 (or any other international or national procedural standards selected on the FWA for the institution referenced above) and stipulated by the IRB.
	2. The Investigator acknowledges and agrees to cooperate in the IRB/IECs responsibility for initial and continuing review, record keeping, reporting, and certification for the research referenced above. The Investigator will provide all information requested by the IRB/IEC in a timely fashion.
	3. The Investigator will not enroll subjects in research under this Agreement prior to its review and approval by the IRB.
	4. Emergency medical care may be delivered without IRB review and approval to the extent permitted under applicable federal regulations and state law.
	5. This Agreement does not preclude the Investigator from taking part in research not covered by this Agreement.
	6. The Investigator acknowledges that they are primarily responsible for safeguarding the rights and welfare of each research subject, and that the subject’s rights and welfare must take precedence over the goals and requirements of the research.

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| Investigator Signature |  | Date |

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| Name: |       |  |       |  |       |
|  | (Last) |  | (First) |  | (Middle Initial) |
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| Institutional Official (or Designee) Signature |  | Date |

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| --- | --- | --- | --- | --- |
| Name: | Meghan Scott |  | Institutional Title: | IRO Director |
| Address: | Fred Hutchinson Cancer Center1100 Fairview Avenue North, Mailstop: J2-100Seattle, WA 98109 |
| Phone #: | 206.667.4372 | Fax #: | 206.667.6831 |