|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Date:** |       | **IR File #:** |       | **RG #:** |       |
| **Fred Hutch Principal Investigator:** |       | **Email:** |       | **Phone:** |       |
| **Fred Hutch Contact Person:** |       | **Email:** |       | **Phone:** |       |
| **Study Title:** |       |
| Have you consulted with anyone in the IRO about this research? Who and when? |       |

|  |  |  |
| --- | --- | --- |
|  | Diagram  Description automatically generated | **Reliance Agreement Intake Form** |

*A reliance agreement is only necessary when a site is* [*engaged*](https://extranet.fredhutch.org/en/u/irb/selecting-the-right-irb/is-fred-hutch-engaged-.html) *in human subjects research per OHRP guidance. Please review the* [*OHRP guidance*](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html) *to determine if a reliance agreement with Fred Hutch will be required. If you are unsure whether Fred Hutch or a relying site is engaged, please visit IRO website* [*here*](https://extranet.fredhutch.org/en/u/irb/selecting-the-right-irb/is-fred-hutch-engaged-.html) *or contact* *irbreliance@fredhutch.org**.*

*If Fred Hutch has been requested to serve as the IRB for sites outside the Cancer Consortium, please complete Sections 1-3. If Fred Hutch has been asked to rely on an external IRB, please complete Sections 1-2 and Section 4.*

*Submit this completed form and all attachments to* *irbreliance@fredhutch.org**.*

**Section 1. Study Information**

* 1. Lead Principal Investigator (PI) Information (only if different from Fred Hutch PI listed above)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| PI Name: |       | Email: |       | Phone: |       |
| Home Institution (Primary Affiliation): |       |

* 1. Lead Study Coordinator (only if different from Fred Hutch Contact Person listed above):

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| PI Name: |       | Email: |       | Phone: |       |

* 1. Brief description of research study (or attach protocol with this form):

|  |
| --- |
|       |

* 1. Anticipated Study Start Date:

|  |
| --- |
|       |

**Section 2. IRB Information**

2.1 Requested IRB:

[ ] Fred Hutch IRB – Complete Sections 2 and 3

[ ] Non-Fred Hutch IRB – Complete Sections 2 and 4

2.2 Reason for requesting this specific IRB:

[ ] Lead PI Home Institution IRB

[ ] Requested IRBExpertise

[ ] Fred Hutch is prime awardee on federal funding

[ ] Location of research activities

[ ] Proposed IRB has already reviewed this study or another similar/related study

[ ]  Other - Describe →

2.3. Is single IRB (sIRB) required for this research?*Please see* [*How to Determine When a Single IRB (sIRB) is Required*](https://extranet.fredhutch.org/en/u/irb/selecting-the-right-irb/how-to-determine-when-sirb-required.html) *for guidance on when sIRB is required.*

[ ]  Yes, due to [2018 NIH Policy on the Use of a Single IRB for Multi-Site Research](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html)

[ ]  Yes, due to [2018 Common Rule](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html)

[ ]  No, sIRB requirements do not apply to this research

[ ]  Not sure – Please contact IRBreliance@fredhutch.org for support

2.4. Has the protocol/lead file already been approved by the IRB?

[ ]  Approved

[ ]  Submitted to IRB

[ ]  Not yet submitted to IRB (Estimated submission date:      )

**Section 3. Participating Sites Relying on Fred Hutch IRB**

*If Fred Hutch will be the IRB for participating sites, please complete the information below. If Fred Hutch will be relying on an External IRB, skip to Section 4.*

3.1 List the Non-Fred Hutch institution(s)/sites that wish to rely on the Fred Hutch IRB and indicate the ways that the institution(s) will be involved in the research. To add additional sites, unprotect form and copy/paste additional site grids here as necessary. Alternatively, you can use an Excel document to list multiple sites and attach for Section 3. For assistance, contact IRBreliance@fredhutch.org.

*If a single research site will engage more than one* [*Federalwide Assurance (FWA)*](https://ohrp.cit.nih.gov/search/fwasearch.aspx?styp=bsc)*, please list each engaged Institution separately.*

|  |  |
| --- | --- |
| Full name of participating site: |       |
| Federalwide Assurance number of participating site if applicable:(If no FWA, enter N/A) | FWA Number →       |
| Name, credentials, and contact information of the local Investigator responsible for the research conducted at this participating site:  | Local PI Name →      Credentials (e.g., MD, PhD) →      Contact Info (e-mail) →       |
| Name, title, and e-mail of the local IRB/Institutional Contact Person for IRB matters at this participating site:  | IRB Reliance Contact Name:     Contact Info (e-mail) →       |
| How will reliance be documented? | [ ]  SMART IRB Online Reliance Request [ ]  SMART IRB Letter of Authorization (LOA) [ ]  Protocol Specific IRB Authorization Agreement [ ]  Individual Investigator Agreement[ ]  Unknown/To Be Determined |
| What research activities will take place at this site? | [ ]  Direct recipient of federal award[ ]  Obtain consent and/or assent[ ]  Perform research procedures[ ]  Administer study interventions[ ]  Obtain, use, or analyze identifiable data and/or specimens[ ]  Other participant contact[ ]  Other responsibilities or roles: Describe →       |

**Section 4. External IRB Information**

*If Fred Hutch will be relying on an external IRB, please complete the information below.*

4.1 Are any other sites of the Cancer Consortium engaged in this research?

Note: A separate agreement may be needed with each engaged Cancer Consortium site.

[ ]  Seattle Children’s – contact SCH IRB at irb@seattlechildrens.org.

[ ]  UW – contact HSD Reliance Team (link/email) at hsdrely@uw.edu.

|  |  |
| --- | --- |
| Full name of the external IRB: |       |
| Federal Wide Assurance number of External IRB: | FWA Number →       |
| Name, title, and e-mail of the local Contact Person for IRB reliance matters at the External IRB:  | External IRB Reliance Contact Name:     Contact Info (e-mail) →       |
| Is External IRB AAHRPP accredited? | [ ]  Yes [ ]  No / Unsure  |
| How will reliance be documented? | [ ]  SMART IRB Online Reliance Request [ ]  SMART IRB Letter of Authorization (LOA) [ ]  Protocol Specific IRB Authorization Agreement [ ]  Individual Investigator Agreement[ ]  Unknown/To Be Determined |
| Outline which research activities will take place at Fred Hutch. | [ ]  Direct recipient of federal award[ ]  Obtain consent and/or assent[ ]  Perform research procedures[ ]  Administer study interventions[ ]  Obtain, use, or analyze identifiable data and/or specimens[ ]  Other participant contact[ ]  Other responsibilities or roles: Describe →       |
| Does the external IRB review site-specific funding? | [ ]  Yes [ ]  No / Unsure |
| Will the external IRB serve as the HIPAA privacy board? | [ ]  Yes [ ]  No / Unsure |