|  |  |
| --- | --- |
|  | WORKSHEET - Ancillary Review Matrix |

This worksheet shows **other regulatory or institutional reviews that may be required** for the research taking place at a Cancer Consortium institution. These are called “ancillary” reviews because they are additional requirements beyond IRB review.

Once an ancillary review is determined to be necessary based on the context of the study, researchers should work directly with the relevant entities to ensure compliance.

The impact of an ancillary review group’s approval on the IRB’s review process varies.

* Typically, final IRB approval is held until the ancillary group concludes their review.
* In some instances, the IRB will not initiate its review without documentation of approval by critical review entities.
* Documentation of approval by an ancillary review group is generally provided to the researcher. **The researcher is responsible for uploading ancillary review documentation in Hutch IRB: On the study SmartForm page, attach the ancillary review documentation either on the “Study-Related Documents” or “Local Site Documents” page.**
* In rare instances, either the ancillary review group or the IRB may request deviations from the typical review path. For example, the IRB may recommend holding a submission until an approval is granted from a key committee **OR** an ancillary review group may recommend IRB review move forward while a required approval is still pending.

The tables below highlight the typical impact an ancillary review has on IRB review. Please contact the IRO@fredhutch.org or relevant ancillary review contacts (listed below) with any questions about the ancillary review process or specific requirements.

NOTE: Participating Sites outside the Cancer Consortium will have their own ancillary review processes, and if any of these are pending it should be noted on the Participating Site Supplement or the Modification Supplement, as applicable.

**COMPLETE PRIOR TO SUBMISSION TO THE IRB: IRB submission not accepted until ancillary review is completed**

If applicable to the study, you must start and complete these ancillary reviews before submitting to the IRB.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Organization | When Required | IRB Submission Types Affected | Contact | How to Request |
| Cancer Consortium CMTS/OnCore Entry | All new IRB applications involving human subjects (including Exempt submissions) | * New IRB Applications
 | CTMS@fredhutch.org | Complete a REDCap intake form [here](https://redcap.link/studyintake).  |
| Cancer Consortium Scientific Review Committee (SRC) | [Cancer-related](https://extranet.fredhutch.org/u/irb/glossary.html#cancer-related) Interventional Protocols  | * New IRB Applications
* Modifications that alter the study design, eligibility, therapy, or risk/benefit ratio
 | CRSSupportedCommittees@fredhutch.org | For new studies, the entry into OnCore via the REDCap form above also starts the SRC process. For modifications, complete the SRC form [here](https://www.cancerconsortium.org/content/dam/consortium/research-support/clinical-research-support/forms/PRMS.0022%20SRC%20Modification%20Form.pdf).  |
| Conflict of Interest | Individual conflicts of interest related to the research as defined by your institution | * New IRB Applications
* Modifications
 | For Fred Hutch: COIAdmin@fredhutch.org | For Fred Hutch investigators, review the [Conflict of Interest Program](https://centernet.fredhutch.org/cn/u/coi.html) webpage. |
| Other institution: UW | If you are a UW investigator relying on the Fred Hutch IRB.If UW as an institution will be [engaged](https://extranet.fredhutch.org/u/irb/selecting-the-right-irb/is-fred-hutch-engaged.html) in the research. | * New IRB Applications
* Modifications, if switching from a Fred Hutch PI to a UW PI.
 | hsdrely@uw.edu | If you are a UW investigator relying on the Fred Hutch IRB, **or** if UW as an institution will be engaged in the research, submit the project in Zipline to obtain a review authorization. Review the UW [How to Ask for a Non-UW IRB](https://www.washington.edu/research/hsd/is-the-uw-irb-the-right-irb/how-to-ask-for-a-non-uw-irb/) webpage.  |
| Other institution: Seattle Children’s | If you are a Seattle Children’s investigator relying on the Fred Hutch IRB.If Seattle Children’s as an institution will be [engaged](https://extranet.fredhutch.org/u/irb/selecting-the-right-irb/is-fred-hutch-engaged.html) in the research.  | * New IRB Applications
* Modifications, if switching from a Fred Hutch PI to a SCH PI, or if adding SCH engagement.
 | irb@seattlechildrens.org | If you are a Children’s investigator relying on the Fred Hutch IRB, **or** if Seattle Children’s as an institution will be engaged in the research, you must submit the project in Click to obtain a review authorization. Review the [Seattle Children’s Hospital and Fred Hutchinson Cancer Center Guidance for Relying](https://extranet.fredhutch.org/u/irb/submissions-to-the-irb.html#guidance) document. |
| Other institution: relying institutions  | If a site outside the Cancer Consortium will be relying on the Fred Hutch IRB | * Participating Site applications
 | irbreliance@fredhutch.org  | See the [Reliance Agreements](https://extranet.fredhutch.org/u/irb/reliance-agreements.html) webpage.  |

**CONCURRENT WITH IRB SUBMISSION: IRB approval is withheld until corresponding documentation is provided to the IRB.**

You may start these ancillary reviews before submitting to the IRB, and this is encouraged because some of these will add time to the process. You can submit to the IRB while these ancillary reviews are pending, but final IRB approval will be contingent on completion of the relevant ancillary review.

| Organization | When Required | Affected IRB Submission Types | Relevant Contact | How to Obtain Review |
| --- | --- | --- | --- | --- |
| Cancer Surveillance System  | Studies involving confidential identifying information from the CSS database as a data source. | * New IRB Applications
* Modifications, if adding CSS
 | Steve Schwartz / Tiffany Janes | Review the “Accessing CSS Data for Research” section on the [Cancer Surveillance System (CSS)](https://www.fredhutch.org/en/research/divisions/public-health-sciences-division/research/epidemiology/cancer-surveillance-system.html) webpage for more information.Attach the letter of support from CSS under “Other Documents” in Hutch IRB. |
| Governance, Risk, and Compliance (GRC) (formerly ISO) | Studies involving the collection of potentially sensitive and private information directly from study participants through the use of a website, email, or similar internet-based collection tool (e.g., REDCap).Studies requesting the use of e-consent on any platform other than Florence.  | * New IRB Applications
* Modifications
 | grc@fredhutch.org | Send all requests to the Governance, Risk, and Compliance (GRC) group (formerly the Information Security Officer) at grc@fredhutch.org to obtain a security risk assessment and attach it under “Other Documents” in Hutch IRB.NOTE: Standard turn-around time for GRC reviews is **two weeks**; during high-volume times, the more lead time GRC receives the better.  |
| Institutional Biosafety Committee (IBC) | 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. | * New IRB Applications
* Modifications
 | ehs@fredhutch.org | To confirm whether IBC review is required, 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 under “Other Documents” in Hutch IRB. |
| Radiation Safety | If the use of radioactive materials (e.g., nuclear medicine, radio-immune therapy) or an ionizing radiation-producing machine (e.g., CT, X-ray, Accelerator, DEXA scanner) is to be used as part of the study, 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. | * New IRB Applications
* Modifications
 | See website | Review the [Radiation Safety Review](https://extranet.fredhutch.org/u/irb/special-topics/radiation-safety-review.html) webpage. Attach the approval documentation under “Other Documents” in Hutch IRB. |
| Total Body Irradiation | Required if the study is adding a new use of Total Body Irradiation procedures (even if considered standard of care).  | * New IRB Applications
* Modifications
 | radoncrc@uw.edu  | This is a review by the University of Washington Radiation Oncology department.Attach documentation of protocol approval under “Other Documents” in Hutch IRB. |
| AI Governance | Required if the study involves any of the following components: [Artificial Intelligence, Machine Learning, Generative AI, or Large Language Model](https://centernet.fredhutch.org/u/data-science-lab/ai/understanding-artificial-intelligence.html) | * New IRB Applications
* Modifications
 | dataprotection@fredhutch.org | IRB Analyst facilitates initial triage. If a complete AI Governance Workgroup review is required, the investigator will be contacted.  |
| Office of General Counsel (OGC) | HIPAA compliance, if not using a Cancer Consortium template | * New IRB Applications
* Modifications, if changes to HIPAA
 |  | IRB Analyst facilitates review |
| Office of General Counsel (OGC) | Concurrence review between executed contract and consent form(s) | * New IRB Applications
* Modifications, if changes to consent impact costs or injury language
 |  | IRB Analyst facilitates review |

**REQUIRED BEFORE STUDY CAN BE OPENED TO ACCRUAL: Required before study can be implemented**

You may start these ancillary reviews at any time. OnCore study implementation sign-off will be held until these ancillary reviews are completed, if applicable.

|  |  |  |  |
| --- | --- | --- | --- |
| Organization | When Required | Relevant Contact | How to Obtain Review |
| Cellular Processing Facility (CPF)  | If the study utilizes a gene or cell therapy product manufactured by the CPF  | TPPTeam@fredhutch.org  | Review the [Therapeutic Products Cell Processing Facility](https://www.fredhutch.org/en/research/shared-resources/core-facilities/therapeutic-products/cell-processing-facility.html) webpage.  |
| Cellular Therapeutics Lab (CTL) | If the study utilizes a gene or cell therapy product manufactured by the CTL | ctlsupervisor@scca.org or 206.606.1200 | Assessed via entry in OnCore |
| Embryo and Embryonic Stem Cell Research Oversight (ESCRO) Committee | If a Cancer Consortium study involves the use or destruction of embryonic stem cells | escro@uw.edu | Review the UW [Human Embryo and Embryonic Stem Cell Research Oversight](https://www.washington.edu/research/embryonic-stem-cell-research-oversight-escro/) webpage. |
| Clinical Research Support Regulatory Review | If submitting to FDA or requiring other drug/device guidance | CRS Regulatory Affairs:RegulatoryAffairs@fredhutch.org | Contact via email. Also review the Cancer Consortium [Regulatory Affairs](https://www.cancerconsortium.org/research-support/clinical-research-support/regulatory-affairs.html) webpage. |

**ADDITIONAL ANCILLARY REVIEWS: These are checked as needed.**

|  |  |  |  |
| --- | --- | --- | --- |
| Organization | When Required | Relevant Contact | How to Obtain Review |
| Clinical trial registries, including clinicaltrials.gov  | Review information on Cancer Consortium to determine if applicable  | CTgov@fredhutch.org for assistance with ClinicalTrials.gov and FDAAA regulationsCTreporting@fredhutch.org for assistance with CTRP and NCI reporting requirements | Review the Cancer Consortium [Clinical Trial Registries](https://www.cancerconsortium.org/research-support/clinical-research-support/resources/clinical-trial-registries.html) webpage. |
| Business Development | Greater than minimal risks studies with a Fred Hutch PI  | BDS@fredhutch.org  | This is a review to confirm whether any institutional conflicts of interest might exist or whether Fred Hutch licensing might be applicable. IRO staff facilitates ancillary review via Hutch IRB, and this review does not impact IRB review.  |