Fred Hutch Cancer Center

Institutional Review Board

Policy/Procedure

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Responsible Office:	Institutional Review Office (IRO)
Responsible Official / Approved By:	Meghan Scott, IRO Director

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6.00	04-12-2010
5.00	07-31-2009
4.00	01-14-2008
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1.00	11-07-2006

POLICY STATEMENT

It is the policy of the Fred Hutchinson Cancer Center (Fred Hutch) that Principal Investigators (PIs) wishing to conduct research activities, must submit an application to the Institutional Review Office (IRO) prior to initiating the research activity. PIs may not independently determine that a research project does not involve human research participants (also referred to as “human subjects”), with the exception of

research that exclusively involves de-identified information or biospecimens obtained from an IRB pre-reviewed source. No research, subject to the Fred Hutch Human Research Protection Program (HRPP), may proceed without review and approval by an IRB even if it has been approved by some other Fred Hutch department or official.

DEFINITIONS

See *HRP-001 - SOP - Glossary of Terms and Acronyms* for full definitions of the following:

Designated Reviewer

Exempt

Expedited Review

FDA-regulated Research

Full Committee Review

Human Subjects **(also known as Human Research Participants)**

Interaction

Intervention

IRB Pre-Reviewed Sources **(of de-identified human specimens and/or data)**

Limited IRB Review

Minimal Risk

Not Human Research **(NHR) (also known as Not Human Subjects Research)**

Private Information

Research

Research Not Involving Humans Subjects

Test Article

PRINCIPLES/OVERVIEW

The Fred Hutch IRB follows policies and procedures for conducting initial review for all research activities. These policies and procedures also describe the documents required to ensure that the IRB reviews relevant information to evaluate the research study in accordance with the regulations.

INDIVIDUALS AFFECTED BY THIS POLICY

The contents of this policy apply to IRO staff, IRB members, employees of Fred Hutch, and investigators from other institutions who submit research studies to the Fred Hutch IRB for review and approval.

PROCEDURES

1. **Type of research activities**

   The four classifications of research activities are:

   - Research Not Involving Human Subjects
   - Exempt from IRB review
   - Minimal Risk
   - More than minimal risk

2. Review process of Research Not Involving Human Subjects

NHR determinations are only made for investigators whose primary appointment is at Fred Hutch. If an investigator's primary appointment is at another institution, he/she should contact that institution's IRB for assistance.

a. If the proposed research exclusively involves de-identified human information and/or human biospecimens obtained from a source on the *HRP-151 - IRB Pre-Reviewed Sources of De-Identified Human Specimens and/or Data* list, the research activity is presumptively considered to be Research Not Involving Human Subjects and the PI does not need to submit the research activity for review and independent determination of Not Human Research (NHR) by IRO staff or a Designated Reviewer. A list of *HRP-151 - IRB Pre-Reviewed Sources of De-Identified Human Specimens and/or Data* can be found at https://extranet.fredhutch.org/en/u/irb/submissionstotheirb/research-not-involving-human-subjects.html.

   In general, de-identified data and/or specimens which are available for purchase from a commercial vendor (e.g., ATCC) or available to researchers through a government administered data or specimen repository (e.g., dbGaP, CHTN) will have appropriate safeguards against releasing identifiable information such that any research exclusively using information and/or biospecimens obtained from the resource would be considered Not Human Research. Researchers may request additional sources be evaluated by the IRO Director or IRO Assistant Director and the IRB Chair or designee. The IRO staff will follow the *HRP-375 - WORKSHEET - Presumptive Not Human Research (NHR) Sources.* After a source is added to the list of *HRP-151 - IRB Pre-Reviewed Sources of De-Identified Human Specimens and/or Data*, future research exclusively utilizing data or specimens from the source can presumptively be considered Research Not Involving Human Subjects.

b. If the proposed research involves de-identified information and/or human biospecimens from any other source (e.g., another research study or data repository), the research must be submitted to the IRO for a formal determination of NHR. The IRB tracks NHR determinations in Hutch IRB. For legacy NHR determinations prior to the launch of Hutch IRB, these projects are located in IR File 6007.

c. A PI who believes that he/she is carrying out this type of activity on information or biospecimens obtained from a source not on the *HRP-151 - IRB Pre-Reviewed Sources of De-Identified Human Specimens and/or Data* list creates and submits a New Study in Hutch IRB, attaching *HRP-262 - FORM - Not Human Research Determination* and any other required attachments to the study record. IRO staff will pre-review the submission using the *HRP-365 - WORKSHEET - Not Human Research Determination*. If the research activity qualifies for a NHR determination, IRO staff will and make the NHR determination. Alternatively, IRO staff can forward the documents to a designated IRB member to make an NHR determination.

d. If IRO staff or the Designated Reviewer determines the research is Not Human Research, a formal written decision will be sent to the PI, Primary Contact, and PI Proxies. These individuals will receive an automated email notification from Hutch IRB that provides a link to the submission, where the formal result letter is available for download.

e. If IRO staff or the Designated Reviewer determines the research does involve Human Subjects, the IRB Analyst will request clarifications through Hutch IRB, requesting the PI to submit the appropriate IRB application form.

f. The turnaround time for review of these activities is outlined in *HRP-150 - IRB Turnaround Times*.

3. Review process for new applications Exempt from IRB review

Exempt determinations are only made for investigators whose primary appointment is at Fred Hutch. If an investigator's primary appointment is at another institution, he/she should contact that institution's IRB for assistance.

a. If the PI evaluates that his/her research activity qualifies for Exempt status (per *HRP-275 - FORM - Exempt*), the PI creates and submits a New Study in Hutch IRB, attaching *HRP-250 - FORM - IRB Application (Contact)* or *HRP-251 - FORM - IRB Application (No Contact)* as appropriate, along with the associated *HRP-275 - FORM - Exempt.*

b. The IRB Analyst pre-reviews the submission following either *HRP-360 - WORKSHEET - IRB Application (Contact)* or *HRP-361 - WORKSHEET - IRB Application (No Contact)* as appropriate, and reviews the information included in the protocol and other submission materials to determine whether it reflects the type of exemption selected by the PI. The IRB Analyst will assign the submission a Designated Reviewer to make the final determination whether:

- Information provided by the PI justifies the selected exemption category;
- The research meets the ethical principles of conducting research;
- Participants are protected; and
- When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data[1].

c. If the research falls into one or more Exempt Categories:

- The research can be assumed to involve no more than minimal risk unless it is determined otherwise by the Designated Reviewer;
- It is the Fred Hutch IRB's policy not to grant an Exempt determination for research activity that involves more than minimal risk even if the research falls into one or more Exempt Categories.

d. When the research involves children as participants, Exempt Categories 1, 4, 5, and 6 may be applied. There are limitations or exclusions of children in Exempt Categories 2 and 3 as follows (see *Exempt Checklist* [048] for further details): [2]

- Exempt Category 3 does not apply to research involving children.
- Exempt Category 2 procedures are limited to:
  - Educational tests (cognitive, diagnostic, aptitude, achievement); or
  - Observation of public behavior where the investigator(s) do <u>not</u> participate in the activity being observed.

Note: Children may <u>not</u> be included in Exempt Category 2 if the information obtained is recorded by the investigator in such a manner that the identity of the human participants can readily be ascertained, directly or through identifiers linked to the participants.

e. The Designated Reviewer will record the applicable Exempt Categories in Hutch IRB to document their determination.

- Approval dates are given using *HRP-302 - WORKSHEET - Approval Intervals*.

f. A formal written decision will be sent to the PI, Primary Contact, and PI Proxies. These individuals will receive an automated email notification from Hutch IRB that provides a link to the submission, where the formal result letter is available for download. If the Designated Reviewer determines that the new application does not meet one of the Exempt Categories, the IRB Analyst will request clarifications through Hutch IRB, requesting the PI to submit the appropriate IRB application. The Designated Reviewer conducting limited IRB review may not disapprove research using the expedited procedure.

g. Activities involving the following may not be considered Exempt from IRB review:

- Cancer Surveillance System (CSS) used to obtain names of potential study subjects.
- Vulnerable Population: Prisoners (except for research aimed at involving a broader subject population that only incidentally includes prisoners) and individuals with impaired decision-making capacity not competent to provide informed consent.[3]
- Accessing Washington state records.[4]

[1] HHS: 45 CFR 46.104(2)(iii), __.104(3)(i)(c)
[2] HHS: 45 CFR 46.104(b)(3)
[3] HHS: 45 CFR 46.104(b)(2)

- FDA regulated drugs/devices/biologics, except in emergency situations and taste and food quality studies.[5]
- There is a possibility that state or local laws, including tribal laws, are in effect or could come into effect which override the Federal Regulations and change an activity from one type of status to another (e.g., from Exempt to Minimal Risk).

h. The turnaround time for review of these activities is outlined in *HRP-150 - IRB Turnaround Times*.

i. Once an Exempt determination is made, there are no ongoing review requirements (i.e., no Continuing Review is required), including studies that were determined to be Exempt under a limited IRB review process.

j. When changes to research are proposed, including but not limited to changes that may impact privacy/confidentiality, the changes will require IRB review and approval prior to implementation of the modification to ensure the research continues to qualify for Exempt status. Additionally, when new funding is added to an existing Exempt study, the funding source document (FSD) will be reviewed against the Exempt application to determine if the Exempt status needs to change. See *IRB Policy 2.5 Modifications to On-Going Activities* (025) for instructions on how to submit.

4. Review process for new Minimal Risk applications

See IRB glossary for definition of minimal risk research. Note that biopsies and scans involving contrast dye are *not* considered minimal risk procedures.

a. If the PI evaluates that his/her research activity qualifies for Expedited Review (per *HRP-276 - FORM - Expedited Review*), the PI creates and submits a New Study in Hutch IRB, attaching following completed documents to the submission for IRB review:

- *HRP-250 - FORM - IRB Application (Contact)* or *HRP-251 - FORM - IRB Application (No Contact)* as appropriate.
- *HRP-276 - FORM - Expedited Review.*
- Other supporting documents and supplements as directed in the IRB application or study SmartForm.

b. The study SmartForm, IRB application form, and associated attachments, collect all the relevant information needed by the IRB to determine the following requirements are satisfied:

- Risks to participants are minimized.
- Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result.
- Selection of participants is equitable.
- Informed consent will be sought from each prospective participant or the participant's legally authorized representative.
- Informed consent will be appropriately documented.
- The research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.
- There are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.[6]
- If the study targets vulnerable populations to participate, information on the additional safeguards that will be used to protect the rights and welfare of this participant group who are likely to be more vulnerable to coercion and undue influence, or other vulnerabilities.[7]

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[4] RCW Chapter 42.48: Washington "state agency" records means records from: (a) The department of social and health services; (b) the department of corrections; (c) the department of health; or (d) the department of children, youth, and families.
[5] FDA: 21 CFR 56.104(c)-(d)
[6] HHS: 45 CFR 46.111(a)1-8; FDA: 21 CFR 56.111(a)1-7

- The investigator(s) are qualified, and the research site(s) are adequate, to conduct the research.

c. The IRB Analyst pre-reviews a new study submission following either *HRP-360 - WORKSHEET - IRB Application (Contact)* or *HRP-361 - WORKSHEET - IRB Application (No Contact),* as appropriate, and reviews the information included in the application to assess whether it reflects the expedited review research category selected by the PI.

d. The IRB Analyst also conducts an initial review of the FSD (if one was submitted) to confirm that the FSD matches the information entered in the Funding Sources pages of the SmartForms. The IRB Analyst assigns the submission to a Designated Reviewer to make the final determination whether the research activity qualifies as a Minimal Risk study eligible for Expedited Review. The *IRB Member Checklist* (071) is used by the Designated Reviewer to ensure that all the relevant information is included.

e. The Designated Reviewer will determine the frequency of review by considering information in the *IRB Member Checklist* (071) about studies that may require IRB review more often than once a year. For research studies subject to only the 2018 requirements of the Common Rule, and not FDA-regulated research, Continuing Review of the research will not be required unless the Designated Reviewer determines otherwise and documents their rationale accordingly. When Continuing Review of Minimal Risk research is not required, an annual Status Report email will be sent as outlined in *IRB Policy 2.28 Status Reports for IRB Files* (0403).[8]

f. Special considerations – see Section 6.

g. If the Designated Reviewer determines that the new application meets one of the expedited review research categories, the reviewer will record the applicable Expedited Categories in Hutch IRB to document their determination. IRO staff will complete the post-review steps outlined in either *HRP-360 - WORKSHEET - IRB Application (Contact)* or *HRP-361 - WORKSHEET - IRB Application (No Contact),* as appropriate.

- Approval dates are given per *IRB Policy 1.8 Approval Date Guidelines and Turnaround Times* (06) and using *HRP-302 - WORKSHEET - Approval Intervals*.

h. A formal written decision will be sent to the PI, Primary Contact, and PI Proxies. These individuals will receive an automated email notification from Hutch IRB that provides a link to the submission, where the formal result letter is available for download. All new study submissions approved by Expedited Review, will be reported to the IRB on the "Expedited Submissions Approved in the Last 45 Days" report on the meeting workspace. The IRB members are given an opportunity to request Full Committee Review and/or to review additional documents of any items that underwent Expedited Review.

i. If the Designated Reviewer determines that the new application does not meet one of the expedited review research categories, the IRB Analyst notifies the PI that the application requires Full Committee Review. The Expedited Reviewer may not disapprove research using the expedited procedure.

j. The turnaround time for review of these activities is outlined in *HRP-150 - IRB Turnaround Times.*

k. All FDA-regulated research studies and studies subject to the pre-2018 requirements of the Common Rule will undergo continuing review, at least once a year. See *IRB Policy 2.2 Continuing Review* (010).

l. Minimal Risk research studies that qualify for Expedited Review and are subject to the 2018 requirements of the Common Rule do not undergo continuing review, unless otherwise determined by the Designated Reviewer. When continuing review is not required, a Status Report email will be sent once a year. See *IRB Policy 2.8 Status Reports for IRB Files* (0403).

m. Investigators with a primary appointment at the University of Washington should submit all minimal risk research to the UW IRB, unless single IRB requirements apply or as otherwise agreed to with the Fred Hutch Institutional Review Office.

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[7] HHS: 45 CFR 46.111(b); FDA: 21 CFR 56.111(b)
[8] HHS: 45 CFR 46.108(a)(3), __.109(f)(1)(i), __.115(a)(3); FDA: 21 CFR 56.108(a)(2), __.109(f)

5. Review process for new more than minimal risk applications

a. If the PI evaluates that his/her research activity does not qualify as a Not Human Research, Exempt or Minimal Risk activity, the PI creates and submits a New Study in Hutch IRB, attaching the following documents to the submission for full IRB review:

- *HRP-250 - FORM - IRB Application (Contact)* or *HRP-251 - FORM - IRB Application (No Contact)* as appropriate.
- Other supporting documents and supplements as directed by the study SmartForm or IRB application.

b. The study SmartForm, IRB application form, and associated attachments, collect all the relevant information needed by the IRB to determine the following requirements are satisfied:

- Risks to participants are minimized.
- Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result.
- Selection of participants is equitable.
- Informed consent will be sought from each prospective participant or the participant's legally authorized representative.
- Informed consent will be appropriately documented.
- The research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.
- There are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.[9]
- If the study targets vulnerable populations to participate, information on the additional safeguards that will be used to protect the rights and welfare of this participant group who are likely to be more vulnerable to coercion and undue influence, or other vulnerabilities.[10]
- The investigator(s) are qualified, and the research site(s) are adequate, to conduct the research.

c. The IRB Analyst pre-reviews the new study submission using either *HRP-360 - WORKSHEET - IRB Application (Contact)* or *HRP-361 - WORKSHEET - IRB Application (No Contact),* as appropriate, to confirm that the submission is complete and all relevant documents were attached.

d. Special considerations – see Section 6.

e. The Fred Hutch IRB uses the primary review system (*IRB Policy 1.6 Meeting and Meeting Records* [024]). The primary reviewers are responsible to review all the materials as noted in *IRB Policy 1.6 Meeting and Meeting Records* (024) that are posted in Hutch IRB to perform an in-depth review of the materials. However, only the primary reviewers are responsible for reviewing the FSD(s).

All IRB members have access to the same materials in Hutch IRB. When an IRB member is not a primary reviewer, they are expected to review the study SmartForm, IRB Application form, current protocol, and consent or assent forms in enough depth to discuss the information at the convened meeting. All IRB members have access to the *IRB Member Checklist* (071). Any IRB member may request additional information.

f. IRB Committee Deliberations/Actions:

- The primary reviewers summarize their review for the committee. The IRB will vote to take one of the actions outlined in *IRB Policy 1.6 Meeting and Meeting Records* (024).[11]

[9] HHS: 45 CFR 46.111(a)1-8; FDA: 21 CFR 56.111(a)1-7
[10] HHS: 45 CFR 46.111(b); FDA: 21 CFR 56.111(b)
[11] HHS: 45 CFR 46.109(a); FDA: 21 CFR 56.109(a)

- For specific information regarding IRB Committee deliberations and actions, please see *IRB Policy 1.6 Meeting and Meeting Records* (024).

g. Notifying PIs of the IRB Committee's decisions:

- The IRB will provide a written decision indicating that the IRB has approved the research, requires modifications to secure approval, or has deferred or disapproved the research. A formal written decision will be sent to the PI, Primary Contact, and PI Proxies. These individuals will receive an automated email notification from Hutch IRB that provides a link to the submission, where the formal result letter is available for download.
- For deferrals or disapprovals, IRO staff emails the PI and/or contact person within 24 hours after the meeting to inform them of this determination. The email also informs them that the details of the review will be forwarded to them in the result letter as outlined in *HRP-150 - IRB Turnaround Times*.
- The IRO staff completes the post-review steps described in either *HRP-360 - WORKSHEET - IRB Application (Contact)* or *HRP-361 - WORKSHEET - IRB Application (No Contact),* as appropriate.
- Approval dates are given per *IRB Policy 1.8 Approval Date Guidelines and Turnaround Times* (06) and using *HRP-302 - WORKSHEET - Approval Intervals*.

h. The turnaround time for review of activities requiring Full Committee Review depends on the IRB Committee's determination. Specific turnaround times are given per the *IRB Policy 1.8 Approval Date Guidelines and Turnaround Times* (06) and according to *HRP-150 - IRB Turnaround Times.*

i. All FDA-regulated research studies and studies subject to the pre-2018 requirements of the Common Rule will undergo continuing review, at least once a year unless the IRB determines more frequent review is required. See *IRB Policy 2.2 Continuing Review* (010). The IRB Committee considers information in the *IRB Member Checklist* (071) about studies that may require IRB review more often than once a year[12] .

j. Research studies that initially received Full Committee Review and are only subject to the 2018 requirements of the Common Rule undergo continuing review, at least once a year unless the IRB determines more frequent review is required. If the research study has progressed to the point that the status is "closed to accrual, in long-term follow-up only" or "closed to accrual, in data analysis only," continuing review of the research will no longer be required. When continuing review is no longer required, a Status Report email will be sent once a year. See *IRB Policy 2.28 Status Reports for IRB Files* (0403). However, the IRB may determine that continuing review must occur even if the study meets the criteria under the 2018 Requirements of the Common Rule for not needing continuing review. In that case, the IRB's decision will be documented and rationale provided to the investigator. [13]

6. Special Considerations for studies that are minimal risk or more than minimal risk:

- Accessing Medical Records from UW prior to obtaining consent: Studies accessing medical records from the UW prior to obtaining consent must have an IRB-approved Waiver of Consent and Waiver of HIPAA Authorization. Studies must also complete a UW Confidentiality Agreement with UW Human Subject's Division or other appropriate UW records custodian, after receiving IRB approval from Fred Hutch.
- Cancer Surveillance System (CSS): Studies involving the use of identifiable CSS data (e.g., data with names, addresses, SSNs, other identifiers) to recruit CSS patients must comply with the CSS-approved process to approach and recruit participants. Research involving recruitment of participants through CSS undergoes review by a convened meeting.
- Certificate of Confidentiality (CoC) See *IRB Policy 2.12 Privacy and Confidentiality* (030) for information.

[12] HHS: 45 CFR 46.108(a)(3); FDA: 21 CFR 56.108(a)(2)
[13] HHS: 45 CFR 46.109(f)(1)(iii)

- ClinicalTrials.gov registration: NIH-funded clinical trials and FDA-regulated applicable clinical trials must be registered with and reported on www.clinicaltrials.gov. For more information regarding registration (and what an applicable clinical trial is) see https://clinicaltrials.gov/ct2/manage-recs, 42 CFR 11, and https://grants.nih.gov/policy/clinical-trials/reporting/index.htm. Contact Fred Hutch Clinical Research Support or Institutional Review Office with questions.
- Community-Based Participatory Research (CBPR): Studies involving CBPR must provide information on the involvement of community members in the research process, including design and implementation of the research and the dissemination of results, for the IRB's consideration. The IRB will consider if consultants with expertise in CBPR are needed to assist with the review and provide additional guidance and education to the IRB when reviewing CBPR studies.
- Department of Health and Human Services (DHHS): When research is funded by DHHS, if there is a DHHS-approved sample consent document and/or a DHHS-approved protocol, a complete copy of these documents will be provided to the IRB or designated reviewer for review as part of the new study submission.
- Clinical intervention: Studies involving clinical intervention may require review by Scientific Review Committee (SRC) and/or disease group review meetings prior to IRB submission.
- Compensation for Participation: Studies involving compensation to research participants such as in the form of money or other incentives must provide the following information:
    - amount of compensation;
    - the form of compensation;
    - the reason for compensation;
    - if the compensation will be prorated.

  This information allows the IRB to determine whether the:
    - inducement is so substantial as to persuade a potential participant to take a risk when otherwise he or she would not have done so
    - research participant is a member of a "captive" population, vulnerable to inducement (e.g., institutionalized participants, student subjects in a PI's class or department)
- Conflict of Interest Management Plans: If the PI indicates on the application a Conflict of Interest Management Plan has been established, the plan should be included for the IRB's review. For non-Fred Hutch investigators, IRB staff will contact the PI, PI Proxy (if applicable), and Primary Contact to obtain a copy of the conflict management plan. For Fred Hutch investigators, IRB staff will contact the Fred Hutch COI Office for the conflict management plan. The IRB will consider and determine if the management plan is appropriate to approve the research.
- Hutchinson Center Research Institute in Uganda (HCRI-U) and Hutchinson Center Research Institute in South Africa (HCRISA): As these are component entities of Fred Hutch, all research projects conducted at HCRI-U and HCRISA are reviewed by Fred Hutch IRB in addition to dual review by a local IRB and any other reviews which may be required. Unless the IRO Director or IRO Assistant Director in consultation with an IRB Chair determines otherwise, IRO staff will obtain a consultant review from an individual with appropriate local context knowledge prior to Fred Hutch IRB review of research conducted at HCRI-U and HCRISA. See *IRB Policy 1.3 IRB Committee Structure* (019) for specific information regarding consultants.
- Consultant: When it is determined that expertise and knowledge are needed that do not exist currently with the IRB membership (e.g., cultural appropriateness, vulnerable population), consultants are invited to review and provide comments to the IRB or designee. See *IRB Policy 1.3 IRB Committee Structure* (019) for specific information regarding consultants.
- Multi-center Research: When the research involves performance sites outside the Fred Hutch/UW/SCH Cancer Consortium for which Fred Hutch IRB will be the IRB of record,

additional information about the site will be evaluated by the IRB to ensure the investigators at the site are qualified, and the site is adequate, to perform the research procedures. See *IRB Policy 2.14 Multi-Center Study Coordination – IRB Review and Oversight* (027).

- Single IRB (sIRB), Coordinating Center and/or Operations Center activity: When Fred Hutch serves as the sIRB, overall coordinating center or operations center, *HRP-254 - FORM - Multi-Center Supplement* must be completed and attached to the study in Hutch IRB. See *IRB Policy 2.14 Multi-Center Study Coordination – IRB Review and Oversight* (027).
- Department of Defense (DoD): When a study involves DoD or one of its component agencies (e.g., Department of Army), *HRP-263 - FORM - Department of Defense Supplement* must be completed and attached to the study in Hutch IRB. See *IRB Policy 2.26 Research Involving Department of Defense Components* (0298).
- Children in Research: When a study involves children, *HRP-264 - FORM - Children Supplement* must be completed and attached to the study in Hutch IRB. See *IRB Policy 2.15 Research Involving Special Populations* (033).
- Genomic Data Sharing Studies (GDS): When a study involves Fred Hutch depositing data from any Genomic Data Sharing Studies (GDS) or other genetic information research directly into a repository whose purpose is to share data with a wider research community (e.g., dbGaP), *HRP-268 - FORM - Genomic Data Sharing Supplement* must be completed and attached to the study in Hutch IRB.
- HIPAA: When a study requests a complete or partial waiver or an alteration of HIPAA Authorization, *HRP-257 - FORM - HIPAA Supplement* must be completed and submitted.
- International performance sites: When a study requests to enroll research participants from countries outside the United States, *HRP-266 - FORM - International Research Performance Site Assessment Supplement* must be completed and attached to the study in Hutch IRB.
- IND/IDE: A study involving the use of an investigational drug/biologic/device may require an IND/IDE. For research involving the use of a device, mobile medical application, or *in vitro* diagnostic test, *HRP-258 - FORM - Device Supplement* must be completed and attached to the study in Hutch IRB.
    - Patient accrual cannot begin until the IND/IDE documentation is received by the IRB.
- Prisoners: A study involving prisoners is considered more than minimal risk. *HRP-265 - FORM - Prisoner Certification Checklist for Investigator* must be completed and attached to the study in Hutch IRB for a study that may enroll prisoners.
- Repository, Registry or Databank*:* For a study establishing a repository, registry or databank at Fred Hutch, *HRP-267 - FORM - Repository or Registry Supplement* must be completed and attached to the study in Hutch IRB. A Fred Hutch/UW Cancer Consortium PI establishing a repository, registry or databank at UW must also complete and submit this supplement when Fred Hutch is the IRB of record.
- Radiation Safety Review Requirements: Studies involving radiation procedures may require Radiation Safety Committee review.
- University of Washington Cancer Consortium studies: The Zipline Authorization Form must be submitted.
- Seattle Children's: For research where Seattle Children's (SCH) is engaged, an "Acknowledgement of Reliance on an External IRB" letter from SCH must be attached to the study in Hutch IRB.
- Waiver of Consent: When the study is requesting a waiver of consent or alteration of consent, *HRP-256 - FORM - Consent Supplement* must be completed and attached to the study in Hutch IRB.
- Other: The IRO Staff also conduct additional administrative procedures and institutional reviews relating to IRB applications as directed by the institution per either *HRP-360 - WORKSHEET - IRB Application (Contact)* or *HRP-361 - WORKSHEET - IRB Application (No Contact),* as appropriate. Additional administrative tasks include but are not limited to:

- Assigning Business Development as an ancillary reviewer on applicable studies for Institutional Conflict of Interest Review.
- Data entry of Conflict of Interest information into Hutch IRB for use by Office of General Counsel.
- Assigning Office of General Counsel as an ancillary reviewer for the review of final, signed clinical trials agreements against the IRB-approved consent form.

SUPPORTING DOCUMENTS

IRB Policy 1.3 IRB Committee Structure (019)
IRB Policy 1.6 Meeting and Meeting Records (024)
IRB Policy 1.8 Approval Date Guidelines and Turnaround Times (06)
IRB Policy 2.2 Continuing Review (010)
IRB Policy 2.5 Modifications to On-Going Activities (25)
IRB Policy 2.12 Privacy and Confidentiality (030)
IRB Policy 2.14 Multi-Center Study Coordination – IRB Review and Oversight (027)
IRB Policy 2.15 Research Involving Special Populations (033)
IRB Policy 2.26 Research Involving Department of Defense Components (0298)
IRB Policy 2.28 Status Reports for IRB Files (0403)
IRB Member Checklist (071)
HRP-001 - SOP - Glossary of Terms and Acronyms
HRP-150 - IRB Turnaround Times
HRP-151 - IRB Pre-Reviewed Sources of De-Identified Human Specimens and/or Data
HRP-250 - FORM - IRB Application (Contact)
HRP-251 - FORM - IRB Application (No Contact)
HRP-254 - FORM - Multi-Center Supplement
HRP-256 - FORM - Consent Supplement
HRP-257 - FORM - HIPAA Supplement
HRP-258 - FORM - Device Supplement
HRP-262 - FORM - Not Human Research Determination
HRP-263 - FORM - Department of Defense Supplement
HRP-264 - FORM - Children Supplement
HRP-265 - FORM - Prisoner Certification Checklist for Investigator
HRP-266 - FORM - International Research Performance Site Assessment Supplement
HRP-267 - FORM - Repository or Registry Supplement
HRP-268 - FORM - Genomic Data Sharing Supplement
HRP-275 - FORM - Exempt
HRP-276 - FORM - Expedited Review
HRP-302 - WORKSHEET - Approval Intervals
HRP-360 - WORKSHEET - IRB Application (Contact)
HRP-361 - WORKSHEET - IRB Application (No Contact)
HRP-365 - WORKSHEET - Not Human Research Determination
HRP-375 - WORKSHEET - Presumptive Not Human Research (NHR) Sources

REFERENCES

42 CFR 11
45 CFR 46.104
45 CFR 46.108

45 CFR 46.109

45 CFR 46.111

45 CFR 46.115

21 CFR 56.104

21 CFR 56.108

21 CFR 56.109

21 CFR 56.111

Revised Code of Washington (“RCW”) Chapter 42.48

OHRP Guidance: Coded Private Information or Biological Specimens

OHRP Guidance: Engagement of Institutions in Research

OHRP Guidance: Human Subject Regulations Decision Charts

OHRP Guidance at 45 CFR46.101(b)(5): Exemption for Research and Demonstration Projects on Public Benefit and Service Programs

OHRP Guidance on Involvement of Prisoners in Research

OHRP compliance Activities: common Findings and Guidance #3, #4, #14, #15 17, #26, #27, #28, #29, #30, #72

NIH Requirements for Registering & Reporting NIH-Funded Clinical Trials in ClinicalTrials.gov https://grants.nih.gov/policy/clinical-trials/reporting/index.htm

NIH Policy for Issuing Certificates of Confidentiality https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html

FDA Information Sheets: Frequently Asked Questions: IRB Records

FDA Information Sheets: Frequently Asked Questions: IRB Procedures

FDA Guidance: IRB Responsibility for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether and IND/IDE is Needed