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|  | Diagram  Description automatically generated | **FORM: Modification Supplement – Participating Site** |

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| **Date:** |       |
| **FHIRB #:** |       |
| **RG # (required):** |       | **Protocol #:** |       |
| **Principal Investigator:** |       | **Site Investigator (if applicable):** |       |
| **Person filling out this supplement:** |       | **Relying Site (if applicable):** |       |
| **Contact Person:** |       | **Contact Email:** |       |
| **Study Title:**  |       |

**Instructions:**

* This form should be used to modify approval for a participating site outside the Fred Hutch/UW Cancer Consortium that relies on the Fred Hutchinson Cancer Center IRB.
* This form is used in conjunction with Hutch IRB to submit the site’s modification to the Fred Hutch IRB. The site completes this form and any relevant Supplements, and the Cancer Consortium lead study team creates and submits a Modification in Hutch IRB.
* Modifications to enroll special populations who require additional safeguards (children, individuals with impaired decision-making capacity, prisoners, etc.) must be made in the lead file rather than at the site level, because the IRB should consider the protocol and entire study context when assessing the appropriateness of enrolling the special population.
* Answer all questions, except when directed to skip some. If a question is not applicable to the research or if you believe you have already answered a question elsewhere, state “N/A” (and if applicable, refer to the question where you provided the information). If you do not answer a question, the IRB does not know whether the question was overlooked or whether it is not applicable. This may result in unnecessary “back and forth” for clarification.
1. Have you consulted with anyone in the IRO about this site modification? Who and when?

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1. Does this site modification involve changes to any of the following aspects of the research?*(Check all that apply.)*

[ ]  Incorporating Already Approved Lead File Changes to this Participating Site → Provide lead file Mod number:

[ ]  Research Design and/or Resources

[ ]  Participant Selection or Recruitment/Approach Process

[ ]  Consent Process and/or Compensation

[ ]  Methods for Documenting Consent

[ ]  Potential Willingness of Research Participants to Continue to Take Part in This Study

[ ]  Monitoring of the Data being collected

[ ]  Privacy of Research Participants and/or Confidentiality of Research Participants’ Data

[ ]  Funding (Update the Funding page in Hutch IRB)

[ ]  None of the above

1. Does this modification require emergency IRB review within 24-48 hours of the IRO receiving the modification? Only situations involving emergency funding or participants with life-threatening issues that cannot be resolved without this modification will be considered.

**[ ]** Yes → Complete 3.a. – 3.c

**[ ]** No

3.a Provide a justification for how this scenario meets the rush criteria (either it involves emergency funding or patients with life-threatening issues):

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3.b Include the date of the scheduled participant visit or funding deadline that necessitates emergency review:

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3.c How would patient care be adversely affected to wait an additional week for review? (For example, this participant does not have other treatment options.) Explain:

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1. If the site modification involves consent form changes, does it involve updating the site-specific consent form(s) with language that was *already approved* by the IRB in the template consent in the lead file?

[ ] Yes → All language being added to the site-specific consent form(s) was already approved by the IRB in the template consent form.

**[ ]** Yes, in general. However, additional or different language is being added to the site-specific consent form(s). Describe and provide rationale:

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**[ ]** No → All consent form changes that are part of this modification are specific to this site only.

**[ ]** Other → Explain.

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[ ] N/A – No consent changes. Skip to question 6.

1. Re-consenting. Fred Hutch recommends adhering to the re-consenting plan approved in the modification approved in the lead file, including the category of individuals allowed to obtain consent from participants. Will this site follow the re-consenting plan that was approved under the main application?

[ ]  Yes → The consenting plan at this site matches what was approved at the lead file when these changes were made there. Contact the Fred Hutch study team to confirm. Skip to question 6.

[ ]  No → We will have a site-specific consenting plan. Respond to 5.1.a-d.

[ ]  N/A → The changes are site-specific only. Respond to 5.1.a-d.

[ ]  N/A → The site is not consenting.

5.1.a Are modifications going to be communicated to existing or past participants? **Check all that apply**. Review[*IRB Policy 2.11 Informed Consent*](https://extranet.fredhutch.org/en/u/irb/policies-and-procedures/_jcr_content/leftParsys/download_11/file.res/017IRBpolicy2_11InformedConsent.pdf) (017) for information about the IRB’s consent expectations.

*Note: If phone scripts, letters, email, or other documents will be used to communicate new information, attach those to the study in Hutch IRB only if they are site-specific and not already approved at the lead file.*

**[ ]** Yes → **In person re-consent process**: We will formally re-consent some or all participants in person. This means an in‑person re‑consent discussion will be conducted, and an ink-signed consent form obtained from participants. You must also fill in 5.1.b-d.

[ ] Yes → **Remote re-consent process**: We will formally re-consent some or allparticipants via phone or video conferencing technology. This means a remote re-consent discussion will be conducted in which the participant receives a copy of the consent form before the consent discussion. The participant sends back an ink-signed consent form and the individual who conducted the consent discussion also signs. You must also fill in 5.1.b-d.

[ ] Yes → **Notification only**: For some or all participants, we will only notify them of the changes by phone, mail, or email. We will *not* receive a signed consent form back. Describe plan in detail below and address which participants will be notified, how, and when. If a phone discussion is proposed, describe who will call the participants. You must also fill in 5.1.b-d. Provide any site-specific letter, email, or phone script.

[ ] Yes → **Other plan**. Describe plan in detail below, including a specific rationale, which participants, how, when, and who will contact, if applicable.

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[ ]  No → Justify why not (e.g., changes that are unlikely to affect a participant’s willingness to take part, or administrative changes, or changes that only apply to new participants), then go to Question 6.

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5.1.b Describe which participants will receive the new information (e.g., all participants, only participants receiving active treatment, all those who received treatment within the last *xx* months, etc.).

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5.1.b.i. If applicable, list the number of participants who are on active treatment       and the number of participants who have completed treatment within the past six months      .

5.1.c Describe when participants will be informed of the new information (e.g., at their next clinic visit after the revised consent is available).

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5.1.d Describe who on the research team will communicate new information to participants (e.g., site PI or attending physician, sub-investigators who are all MDs with current U.S. licensure, research coordinator, etc.). If a re-consent discussion will be conducted by someone not identified as conducing consent on the initial IRB application, justify below. (For example, “Changes do not include changes to risks or procedures which would require MD expertise to adequately explain the changes.”)

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1. Modification involves the site obtaining information and/or specimens from **a new source**, other than what is provided to the site directly by the enrolled human research participant (and this source was not already approved in the lead file):

6.a. Provide name, address, institution/company, and a brief description of what information and/or biospecimens will be provided from each new source.

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| **Name** | **Address** | **Institution/Company** | **Description** |
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For public or medical record sources, or from sources on the [IRB Pre-Reviewed Sources of De-identified Human Specimens and/or Data](https://centernet.fredhutch.org/cn/u/irb/submissionstotheirb/research-not-involving-human-subjects/_jcr_content/leftParsys/download_f2c7/file.res/Pre-Reviewed-Sources-De-identified-Human-Specimens.pdf): You do not need to attach any other documentation about these sources.

For all other sources: **You must provide supporting documentation** (e.g., a gatekeeper letter, material or data transfer agreement, contract, etc.) from the provider of the information and/or biospecimens. The documentation should acknowledge the site’s use of the information and/or biospecimens for this specific project and should confirm consent was appropriately obtained or waived for future research use.

Important Notes:

1. Receiving information and/or biospecimens from outside your home institution may require a material transfer or data use agreement (MTA/DUA).
2. If this project involves the use of information and/or biospecimens that are covered by a Certificate of Confidentiality (CoC), the site should be aware the CoC protections extend to the information and/or biospecimens permanently. When a site receives such biospecimens or data, the site is obligated to uphold the disclosure restrictions. For example, data from an NIH repository such as dbGaP or biospecimens and/or data collected or generated by another research project covered by a Certificate of Confidentiality.

6.b. Does a new source of biospecimens include human fetal tissue?

[ ]  Yes → Provide information about where the tissue is obtained and attach an attestation (from the provider or third-party supplier) that informed consent was obtained at the time of tissue collection.

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[ ]  No

1. Modification involves a **new Principal Investigator** for this site. If no, skip to the next question.

**NOTE:** If this involves a PI change at a Participating Site outside the Cancer Consortium, contact IRBreliance@fredhutch.org first to determine whether an updated reliance agreement is required.

[ ] Attach the following:

[ ]  A memo from the new site investigator indicating agreement to fulfill the responsibilities and role of the PI on this research study at this site

[ ]  New site investigator’s current *Curriculum Vitae* or resume

[ ]  For sites conducting clinical procedures, a copy of the new site investigator’s current medical license

[ ]  New site investigator’s Documentation of Human Subjects Protection training completed in the last 3 years

[ ]  If the site is conducting a clinical trial (defined in [*IRB Policy 2.20 Training*](https://extranet.fredhutch.org/en/u/irb/policies-and-procedures/_jcr_content/leftParsys/download_36/file.res/IRB-Training-Policy.pdf) (038), documentation of the new site investigator’s Good Clinical Practice training completed in the last 3 years

[ ] For any site-specific document listing the previous site PI, provide revised documents. (Note: the Fred Hutch study team will Update in the Local Site Documents in Hutch IRB.)

8. Does the modification involve review by any of the site’s ancillary committees (e.g., radiation safety committee, scientific review committee, etc.)?

[ ]  Yes → List ancillary reviews and approval dates:

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[ ]  No → Explain:

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[ ]  N/A → Changes do not impact any ancillary reviews at my institution.

**9. Additional Supplement forms** may be required, or you may need to revise an existing Supplement on the study. Identify any IRB Supplements that are required because of this Modification by checking applicable boxes below and completing the Supplement.

*Fred Hutch study team instructions for Hutch IRB submission:*

If the Modification involves *adding* a new Supplement: Attach the new Supplement to the Local Site Documents page in Hutch IRB.

If the Modification involves revising an *existing* Supplement already in Hutch IRB for this site: Revise the Supplement and then click “**Update**” in the study SmartForm to replace the old version with the new clean copy.

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| **CHECK ALL THAT APPLY** | **ELEMENTS OF RESEARCHTHAT ARE CHANGING WITH THIS MODIFICATION** | **SUPPLEMENT NAME AND LINK** |
| [ ]  | **If this site is serving as the coordinating center** | [*HRP-254 - FORM - Multi-Center Supplement*](https://extranet.fredhutch.org/en/f/irb/multi-center-supplement.html) |
| [ ]  | **International research**The site PI is overseeing any research activities to be conducted outside the United States | [*HRP-266 - FORM - International Research Performance Site Assessment Supplement*](https://extranet.fredhutch.org/en/f/irb/intl-research-performance-site-assessment.html) |
| [ ]  | **Repository or Registry**A collection of information and/or biospecimens that are specifically intended to be used, stored, and/or shared for Secondary Research purposes. | [*HRP-267 - FORM - Repository or Registry Supplement*](https://extranet.fredhutch.org/en/f/irb/repository-registry-databank-supp.html) |
| [ ]  | **Site-Specific Department of Defense (DoD) funding or support**The research involves NEW funding, facilities, data, or personnel from the DoD or one of its component entities (e.g., Dept. of Army, DARPA)  | [*HRP-263 - FORM - Department of Defense Supplement*](https://extranet.fredhutch.org/en/f/irb/dod-supplement.html) |
| [ ]  | **Site-Specific Waiver or Alteration of Consent** If requesting to waive some or all elements of consent.If requesting to waive the consent signature (including for e-consent) | [*HRP-256 - FORM - Consent Supplement*](https://extranet.fredhutch.org/en/f/irb/waiver-consent.html) |
| [ ]  | **Site-Specific Waiver or Alteration of HIPAA**If requesting to waive HIPAA for screening purposes or for the entire study.If requesting to waive the HIPAA signature (including for e-consent or non-English speakers) | [*HRP-257 - FORM - HIPAA Supplement*](https://extranet.fredhutch.org/en/f/irb/hipaa-supp-waiver-authorization.html) |
| [ ]  | **NONE OF ABOVE ARE CHANGING WITH THIS MODIFICATION** |  |

SITE PI ACKNOWLEDGMENT AND SIGNATURE

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| **Study Title:**  |       |

As the site Principal Investigator (PI) or designated proxy for this study at this site, I provide assurances for the following:

A. All of the information provided in this submission is complete and correct.

B. The site PI will conduct this research in accordance with requirements in the *HRP-103 - Investigator Manual*.

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| Name of Site Investigator or Designee\* |  | Signature of Investigator or Designee\* |  | Date |

[ ]  \*I am signing this form as a designee. By checking this box, I affirm the site PI is aware of this submission and has given me permission to submit on their behalf. I will save documentation of the site PI’s permission to submit this form.