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|  | Diagram  Description automatically generated | **FORM - Modification Supplement** |

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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:**

1. Create a Modification submission in Hutch IRB.
2. Complete and attach this Supplement to your Modification submission in Hutch IRB, to provide supporting information. This supplement is **required** for Modifications that affect “Other parts of the study.”

Note: You do **not** need to attach this form to make administrative Modifications to “Study team member information,” nor for updates to studies reviewed by an External IRB.

1. Have you consulted with anyone in the IRO about this Modification? Who and when?

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2. Does this modification involve changes to any of the following aspects of the research? For each selection made below, include a thorough description and rationale of the change in the SmartForm “Summarize the modifications” question. *(Check all that apply.)*

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

3. 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 and include a comment in the SmartForm noting the rush request.

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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4. Does the Modification provide updated risk information? (Check only one)

*Note:* If submitting an updated Investigator’s Brochure (IB) even if no risk changes, attach the updated IB, the tracked IB/Summary of Changes, and the **cover letter/cover email provided by the Sponsor** in Hutch IRB.

Yes → Updated risk information is already described in the current consent form. Explain where the information is found in the consent form (e.g., page, section)

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Yes → However, in the PI’s opinion the updated risk information does not need to be communicated to participants. Justify below (e.g., research is in long term follow-up phase and the updated risk are acute and only apply during treatment):

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Yes → Updated risk information will be communicated to participants as outlined below.

No → Changes do not contain any updated risk information.

5. 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.*

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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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.a-c.

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.a-c.

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.a-c. Attach the letter, email, or phone script to the study in Hutch IRB.

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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5.a 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.a.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.b 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.c Describe who on the research team will communicate new information to participants (e.g., 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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6. Indicate the date you received each updated document from the sponsor. (Review[*IRB Policy 2.5* *Modifications to On-Going Activities*](https://extranet.fredhutch.org/en/u/irb/policies-and-procedures/_jcr_content/leftParsys/download_21/file.res/IRB-Modifications-Ongoing-Activities-Policy.pdf) (025) for information about submission timeline requirements.)

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7. Modification is obtaining information and/or specimens from **a new source**, other than what is provided to you directly by the enrolled human research participant:

7.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 attach 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 your 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). Fred Hutch researchers, review <https://centernet.fredhutch.org/cn/u/business-dev/form-questionnaire.html> or contact Business Development at [MTA@fredhutch.org](mailto:MTA@fredhutch.org) for more information. UW researchers, contact the Agreements Group at [mta-group@uw.edu](mailto:mta-group@uw.edu).
2. If this project involves the use of information and/or biospecimens that are covered by a Certificate of Confidentiality (CoC), you should be aware the CoC protections extend to the information and/or biospecimens permanently. When you receive such biospecimens or data, you are 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.
3. Per UW Medicine policy, the UW Medicine eCare/MyChart system may not be used for research recruitment purposes. Additionally, researchers may not use UW Medicine’s Epic Care Everywhere data for research purposes unless the clinical data is necessary for patient/participant safety activities. This means Care Everywhere data cannot be used for recruitment, data abstraction, or any research activities other than those necessary for patient/participant safety.

7.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

8. Modification involves a **new Principal Investigator**. If no, skip to the next question.

Attach a memo from the new Principal Investigator indicating agreement to fulfill the responsibilities and role of the PI on this research study and confirmation of who should serve as a PI Proxy.

For a new PI with a primary appointment at UW, the UW PI must be a Cancer Consortium [member](https://www.cancerconsortium.org/membership.html).

For any study document listing the PI, revise existing documents and use the “Update” function in Hutch IRB to attach the revised documents.

9. Does the modification need to be reviewed by the Cancer Consortium Scientific Review Committee (SRC)?

For questions about SRC, email [PRMS@fredhutch.org](mailto:PRMS@fredhutch.org) or see <https://www.cancerconsortium.org/research-support/clinical-research-support/forms-templates-documents.html#renew-modify>.

Yes → Attach SRC approval documentation along with this form in Hutch IRB. The Modification cannot be scheduled for IRB review without documentation of SRC approval.

No. This study is not subject to SRC review.

No. Although this study is subject to SRC review, this Modification does not involve changes to design, eligibility, therapy, or risk/benefit ratio.

No. Although this study was subject to SRC review initially, it is an industry-sponsored or NCTN trial and SRC review of Modifications is not required.

10. **Additional ancillary reviews** may be required. Identify any other ancillary approvals that are required for this research by checking applicable boxes. *Refer to* [*HRP-309 - WORKSHEET - Ancillary Review Matrix*](https://extranet.fredhutch.org/en/f/irb/ancillary-review-matrix.html) *for additional information on how to apply for approval from these ancillary groups.*

Attach the ancillary approval documentation to the “Other attachments” question on either the “Study-Related Documents” or the “Local Site Documents” page within the study SmartForm in Hutch IRB.

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| **ANCILLARY APPROVAL REQUIRED** | **RESEARCH FOR WHICH THIS IS REQUIRED & HOW TO SUBMIT** |
| **REQUIRED BEFORE IRB APPROVALS CAN BE ISSUED** | |
| Cancer Surveillance System (CSS)  Pending | Required if this Modification involves adding confidential identifying information from the CSS database as a new data source.  In Hutch IRB, attach the CSS letter of support to the submission under “Other attachments.” |
| Governance, Risk, and Compliance (GRC) (formerly ISO)  Pending | Required if this Modification involves changes to 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).  Or, required if this Modification involves a new request for the use of e-consent (exception: use of Florence e-consent does not require GRC review).  Contact Governance, Risk, and Compliance (GRC) at [grc@fredhutch.org](mailto:grc@fredhutch.org) to obtain a security risk assessment and attach it under “Other attachments” in Hutch IRB. |
| Institutional Biosafety Committee (IBC)  Pending  Also indicate which apply:  UW IBC  Fred Hutch clinical IBC (for human gene trials)  Other: | Required if this Modification involves a change in the location where a relevant product is being administered, you may need additional IBC review. **Each** research site administering a relevant study product would need its own IBC review (if the 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).  To confirm whether IBC review is required for this modification, contact the Fred Hutch Environmental Health & Safety at 206.667.4866 or [ehs@fredhutch.org](mailto:ehs@fredhutch.org), or contact the IBC for the institution involved.  In Hutch IRB, attach the IBC approval documentation to the submission under “Other attachments.” |
| Radiation Safety  Pending  Also indicate which apply:  Joint HSRAC for UW or FHCC  Seattle Children’s RSC  Fred Hutch Radiation Safety  Other: | Required if this Modification involves a change to 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) 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.  In Hutch IRB, attach the approval documentation to the submission under “Other attachments.” |
| UW Radioactive Drug Research Committee (RDRC)  Pending | If applicable, obtain confirmation from the RDRC that the study will be conducted in accordance with 21 CFR 361.1 and does not require an IND.  In Hutch IRB, attach the approval documentation to the submission under “Other attachments.” |
| Total Body Irradiation  Pending | Required if the study is adding a new use of Total Body Irradiation procedures (even if considered standard of care).  This is a review by the University of Washington Radiation Oncology department. Contact 206.598.4100 or [ROinfo@uw.edu](mailto:ROinfo@uw.edu) with questions.  In Hutch IRB, attach documentation of protocol approval to the submission under “Other attachments.” |
| Adding University of Washington as an engaged institution | If the new PI has a primary appointment at UW (when the prior PI had a Fred Hutch primary appointment), **OR** if UW as an institution will newly be engaged in the research: Documentation of UW Zipline authorization to rely on the Fred Hutch IRB must be included.  For more info: <https://www.washington.edu/research/hsd/is-the-uw-irb-the-right-irb/how-to-ask-for-a-non-uw-irb/>  In Hutch IRB, attach the Zipline authorization to the submission under “Other attachments.” |
| Adding Seattle Children’s as an engaged institution | For research where Seattle Children’s (SCH) is newly engaged, an “Acknowledgement of Reliance on an External IRB” letter from SCH must be included as part of your submission to the Fred Hutch IRB.  For instructions on how to obtain this letter, please review Section A of the [SCH-FH Guidance for Relying](https://extranet.fredhutch.org/en/u/irb/submissionstotheirb/_jcr_content/leftParsys/download_copy/file.res/SCH-FH%2520Guidance%2520for%2520Relying%252005.01.22.pdf).  In Hutch IRB, attach the SCH letter to the submission under “Other attachments.” |

11. **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.

If the Modification involves *adding* a new Supplement: Attach the new Supplement to the “Other documents” section (except as indicated below).

If the Modification involves revising an *existing* Supplement already in Hutch IRB: Revise your 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 RESEARCH  THAT ARE CHANGING WITH THIS MODIFICATION** | **SUPPLEMENT NAME AND LINK** |
|  | **Children**  This includes research procedures, enrollment, and accessing identifiable information or identifiable biospecimens about minors. | [*HRP-264 - FORM - Children Supplement*](https://extranet.fredhutch.org/en/f/irb/children-supplement.html) |
|  | **Department of Defense (DoD)**  The research involves 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) |
|  | **Drug, biologics, food, or dietary supplement**  Procedures involve the evaluation of any drug, biologic, botanical, food, or dietary supplement.  *Note: In Hutch IRB, attach the Drug Supplement to the Drugs SmartForm page, under “Attach files.”* | [*HRP-259 - FORM - Drug Supplement*](https://extranet.fredhutch.org/en/f/irb/drug-supplement.html) |
|  | **Genomic data sharing**  Genomic data are being collected and are planned to be deposited into a public database (such as the NIH dbGaP database) for sharing with other researchers, and Fred Hutch is being asked to provide the NIH-required [Institutional Certification](https://sharing.nih.gov/genomic-data-sharing-policy/institutional-certifications/completing-an-institutional-certification-form) or to ensure that the consent forms allow such sharing. | [*HRP-268 - FORM - Genomic Data Sharing Supplement*](https://extranet.fredhutch.org/en/f/irb/genomic-data-sharing-supplement.html) |
|  | **International research**  The PI on this application 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) |
|  | **Medical devices**  Studies that:   * Evaluate a device, including a software function (this may include medical mobile applications), or * Use an unapproved *in vitro* diagnostic test; or * Use an unapproved *in vitro* diagnostic test for decision-making (e.g., eligibility determination or treatment assignment) or data analysis (e.g., response assessment) * Use a humanitarian use device (HUD)   *Note: In Hutch IRB, attach the Device Supplement to the Devices SmartForm page, under “Attach files.”* | [*HRP-258 - FORM - Device Supplement*](https://extranet.fredhutch.org/en/f/irb/device-supplement.html) |
|  | **Multi-site or collaborative study, or serving as the coordinating center**  The Fred Hutch IRB is being asked to review on behalf of one or more non-Cancer Consortium institutions.  Note: Each new site outside Fred Hutch and the Cancer Consortium relying on Fred Hutch IRB will need to submit a separate Participating Site Application after this Modification is approved. | [*HRP-254 - FORM - Multi-Center Supplement*](https://extranet.fredhutch.org/en/f/irb/multi-center-supplement.html) |
|  | **Prisoners**  This includes research procedures, enrollment, and accessing identifiable information or identifiable biospecimens about prisoners. | [*HRP-265 - FORM - Prisoner Certification Checklist for Investigator*](https://extranet.fredhutch.org/en/f/irb/investigator-prisoner-certification-checklist.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) |
|  | **Transfer of IRB oversight**  This study is being transferred from another IRB. | [*HRP-260 - FORM - Transfer Supplement*](https://extranet.fredhutch.org/en/f/irb/transfer-of-irb-oversight.html) |
|  | **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) |
|  | **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 THE ABOVE ARE CHANGING WITH THIS MODIFICATION** |  |