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|  | Diagram  Description automatically generated | **FORM: Multi-Center Supplement** |

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| --- | --- |
| **Date:** |       |
| **FHIRB #:** |       |
| **RG #:** |       | **Protocol #:** |       |
| **Principal Investigator:** |       |
| **Study Title:**  |       |

Instructions:

Complete and attach this form in Hutch IRB when submitting a new study that involves, or a Modification that changes, one or more of the following:

* Fred Hutch is serving as the Coordinating Center for a multi-site trial
* Fred Hutch IRB is asked to review on behalf of one or more sites ***outside*** the Fred Hutch/UW/Seattle Children’s Cancer Consortium.

This form is no longer required to be re-submitted with each Continuing Review.

*Note: Each site outside the Cancer Consortium relying on Fred Hutch IRB will also need to submit a separate Participating Site Supplement after the main application is approved.*

1. Are you serving as the overall [Coordinating Center](https://extranet.fredhutch.org/en/u/irb/glossary.html#coordinating_center) for this multi-center trial?

[ ]  Yes

[ ]  No → Provide the name of the Coordinating Center

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2. Will Fred Hutch IRB be serving as the single IRB ([sIRB](https://extranet.fredhutch.org/en/u/irb/glossary.html#sirb)) or lead IRB for this research?

[ ]  Yes

[ ]  No

3. Are your coordinating center or sIRB operations described in a separate manual of operations or similar document?

[ ]  Yes → Attach the manual in Hutch IRB. For questions 4 through 10 refer to specific page numbers in the manual where answers to each question can be found.

[ ]  No → Provide detailed responses below.

**☞** Coordinating Centers: Continue to question 4.
If not a Coordinating Center: Skip to question 7.

4. Describe the method for determining that the privacy of participants and the confidentiality of data are adequately maintained by the Coordinating Center. Include a description of the collection of data, transfer or transmission of data to the coordinating center, analysis at the center (if any), and storage of the data at the coordinating center. Specific details on encryption, electronic transmission, use of shared or cloud computing, and other technology protections should be discussed.

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5. If you will be using laboratories outside of Fred Hutch/UW/Seattle Children’s Cancer Consortium, describe how the information and/or biospecimens will be de-identified and how the confidentiality of the participants will be protected:

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6. Describe the procedure for how the Coordinating Center will confirm the study procedures, and subsequent amendments, are reviewed and approved by the IRB of record before study procedures are initiated at the participating site:

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7. Describe the method for confirming informed consent is obtained from each participant in compliance with federal, local, and if applicable, international regulations:

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8. Describe the overall management, data analysis, and Data Safety and Monitoring (DSM) systems used to oversee the entire study, including the management and analysis of adverse event reporting from participating sites, unexpected problems, or interim results for this study:

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9. Describe the plan for the development of sample protocols and informed consent documents and distribution to each participating site:

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10. Describe the process for ensuring that any substantive modifications made by the participating sites to the sample consent information related to risks, alternatives, or procedures is appropriately justified and not inconsistent with the consent language used by other participating sites:

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11. Describe the procedure for determining that each participating site has an applicable FWA registered with OHRP:

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12. List all current participating sites and their IRB in the following table.

*This list only needs to be updated when submitting a Multi-Center Supplement for another purpose (e.g., if you need to change something else in this form); updates to the list of participating sites do not require a separate modification form just to update the list.*

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| **Site Name** (e.g., Duke, Overlake Hospital, etc.) | **Site Investigator**  | **Site FWA Number, if applicable:** | **IRB of Record** (e.g., Fred Hutch, Duke IRB, NCI CIRB, Western IRB, etc.)  |
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*Unlock the form and add additional rows if necessary.*

13. Are any of the participating sites located outside of the United States?

[ ]  Yes → Explain in detail how you will ensure research conducted at the foreign site complies with local regulation, law, and policies:

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[ ]  No

14. Study-Wide Ethnic, Racial and Gender Enrollment information:

**Table 14.a**

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| STUDY-WIDE ENROLLMENT:Number of Participants (*must provide exact numbers—i.e., no ranges)* |
| Ethnic Categories | Sex/Gender |
|  | Females | Males | Total |
| Hispanic or Latino |       |       |       |
| Not Hispanic or Latino |       |       |       |
| Unknown (individuals not reporting ethnicity) |       |       |       |
| **Ethnic Categories: Total of All Participants\*** |       |       |       |
| **Racial Categories** |
| American Indian/Alaska Native |       |       |       |
| Asian |       |       |       |
| Native Hawaiian or Other Pacific Islander |       |       |       |
| Black or African American |       |       |       |
| White |       |       |       |
| Unknown or Not reported |       |       |       |
| More Than One Race |       |       |       |
| **Racial Categories: Total of All Participants\*** |       |       |       |

**\*** Numbers in “Ethnic Categories: Total of All Participants” row must be equal to the numbers in the “Racial Categories: Total of All Participants” row.

Comments:

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14.b. If the anticipated Ethnic/Racial/Gender data is not available, explain:

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14.c. Provide the basis for the above ethnic and racial study wide enrollment targets.

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