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

|  |  |  |
| --- | --- | --- |
|  | Diagram  Description automatically generated | **FORM - Continuing Review Supplement – Participating Site** |

INSTRUCTIONS

This form is to be used for a Participating Site ***outside*** the Fred Hutch/University of Washington/Seattle Children’s Cancer Consortium when the site is relying on the Fred Hutch IRB.

If this is your first Continuing Review (CR), where this form refers to “since your last CR” consider the information since your initial IRB approval.

The lead study team at Fred Hutch can pre-fill any study-wide information and have the pSite confirm and add site-specific information. It is strongly recommended that the lead study team identify **a specific date** on which the enrollment numbers should be based, so that all sites on the study are reporting enrollment numbers as of a specific date (even if sites are completing and signing a Continuing Review Supplement on different dates).

1. CURRENT STATUS

1.1 Indicate the status of the research at your site for the upcoming review period.

[ ]  Initial Approval with Minor Modifications

[ ]  Research not yet started at this site.

[ ]  Approved (Open to enrollment of new participants / Open to the collection of specimens or records)

[ ]  Closed to Enrollment – enrollment is temporarily on hold.

[ ]  Closed to Enrollment – clinical interventions, surveys, or similar participant interactions continuing.

[ ]  Closed to Enrollment – remaining activity limited to collection of participant [long-term follow-up](https://extranet.fredhutch.org/en/u/irb/glossary.html#longtermfollowup) data.

[ ]  Closed to Enrollment – remaining activities limited to analysis of information/biospecimens already collected.

Notes:

* If the status is different from the last approved submission for this site, include an explanation in Question 2.1 below.
* Refer to [Guidance: Study Status](https://extranet.fredhutch.org/en/u/irb/submissionstotheirb/study-status.html) as needed.
* If this site is closing completely, fill out [*HRP-898 - FORM - Closure - Participating Site*](https://extranet.fredhutch.org/en/f/irb/closure-participating-site.html) instead. Follow the instructions on that form for how to submit.

2. GENERAL INFORMATION

2.1 Provide a summary of your research progress to date at this site.

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2.2 Do all members of the research team at this site have current training on Human Subject Protections and if applicable Good Clinical Practices (GCP) per [*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)?

[ ]  Yes

[ ]  No, explain:

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**Reminder:** The site PI is responsible for ensuring every member of the study team at this site receives and maintains required training per [*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).

2.3 Has any site-specific funding changed or been extended since your last approval?

[ ]  Yes → Describe and complete [*HRP-252 - FORM - Modification Supplement*](https://extranet.fredhutch.org/en/f/irb/research-modification.html).

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[ ]  No

[ ]  N/A → This site has no site-specific funding.

2.4 Conflict of Interest:Do any investigators or study team members have a financial conflict of interest subject to a conflict management plan that was not previously reported to the IRB?

[ ]  Yes → Attach the conflict management plan*.*

[ ]  No

Note:  If the new or updated management plan requires changes (such as updates to the consent form language or a change in who can consent participants), you must also complete [*HRP-252 - FORM - Modification Supplement*](https://extranet.fredhutch.org/en/f/irb/research-modification.html).

2.5 Does this *site* oversee the ongoing maintenance of a repository of information or biospecimens for purposes of storing or using for, or sharing with, other research projects?

[ ]  Yes

[ ]  No

2.5.a Has the site’s repository released information or biospecimens since your last CR?

[ ]  Yes → Complete the table below for all new research projects receiving information or biospecimens from your repository since your last CR. Include a copy of each confidentiality pledge, or other similar document, signed by an Investigator accessing the repository or registry.

|  |  |  |  |
| --- | --- | --- | --- |
| Study # | Name of PI | Name of Institution | Brief Description of Study’s Objective(s) |
|       |       |       |       |
|       |       |       |       |

[ ]  No

3. ENROLLMENT

3.1 Enrollment Table for this Site:

* **For the first three columns: A (Total Consented) minus B (Not Eligible or Not Enrolled) should equal C (Total Enrolled).**
	+ - * + Note that “Not Eligible or Not Enrolled” would encompass anyone who consented but did not start treatment, for example: screen failure, withdrew after consenting, etc.
* For sites without direct participant contact: Enrollment should reflect numbers of data subjects (distinct individuals from whom you have information or biospecimens) and should be listed in column C. Indicate “Not Applicable” or N/A for any columns that do not apply.
* For sites that have been closed to enrollment for more than one year, you only need to fill out the enrollment table with your last enrollment information **and** question 3.1.b, until the site is in data analysis. Then skip to Section 4.

|  |  |
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| **Cumulative Enrollment Totals for this Site** | **Projected and Actual Enrollment Goals for this Site***For D and E, refer to your last Continuing Review (or initial P-Site form if this is your first year CR)* |
|  | **A.** Total Consented | **B.** Not Eligible/ Not Enrolled (for any reason) | **C.** Total Enrolled on Study at this Site | **D.** Overall Site Enrollment Goal | **E.** Projected Enrollment for Last Approval Period | **F.** Actual Enrollment for Last Approval Period | **G.** Projected Enrollment for Next Approval Period |
| **Local** |       |       |       |       |       |       |       |

3.1.a. Explanations of numbers above (optional):

3.1.b. Have there been any deaths of study participants at this site (for any cause) since the study's inception?

[ ]  Yes → Specify the number of deaths and the apparent cause of each. Indicate whether the death was related or unrelated to the study product, treatment or procedure:

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[ ]  No

[ ]  N/A (retrospective study involving only information and/or biospecimens)

[ ]  N/A (study at this site has been in data analysis for at least a year)

[ ]  Unknown → Explain:

|  |
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Sites that have been closed to enrollment for more than one year: Skip to Section 4.

3.1.c Was enrollment at this site since the last CR lower than projected?

[ ]  Yes → Describe 1) why enrollment is lower than projected at this site, 2) your plans to improve enrollment at this site, and 3) whether or not low enrollment at this site will affect the ability to complete the study’s research objectives.

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[ ]  No

3.2 Local Ethnic, Racial and Gender Enrollment Table

3.2.a. Complete table below for **local** enrollment.

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

\* *These totals must equal local “Total Enrolled” number put in Question 3.1 (Column C) above.*

Comments (optional):

|  |
| --- |
|  |

3.2.b. Is your site on track to meet anticipated local ethnicity, race and gender goals described in your initial Participating Site form?

[ ]  Yes

[ ]  No → Describe your plans to meet the anticipated enrollment goals in relation to ethnicity, race and gender for this current approval period.

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[ ]  N/A → Information is not available; explain.

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4. EVENTS IN THE PAST YEAR

4.1 **Check the items that are true for this site since the last IRB approval** (initial review or last continuing review):

[ ]  NO subjects experienced unexpected harm

[ ]  If subjects did experience harm, describe:

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[ ]  Anticipated adverse events have NOT taken place with greater frequency or severity than expected

[ ]  If anticipated adverse events have taken place with greater frequency or severity than expected, describe:

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[ ]  NO subjects withdrew from the study

[ ]  If subjects withdrew from the study at this site, describe:

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[ ]  NO [unanticipated problems involving risks to subjects or others](https://extranet.fredhutch.org/en/u/irb/glossary.html#unanticipatedproblems)

[ ]  If unanticipated problems involving risks to subjects or others occurred at this site, describe:

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[ ]  NO complaints about the study

[ ]  If complaints about the study occurred at this site, describe:

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| --- |
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[ ]  NO publications in the literature relevant to risks or potential benefits

[ ]  If there were publications in the literature relevant to risks or potential benefits, describe:

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| --- |
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[ ]  NO interim findings

[ ]  If there were interim findings, describe:

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| --- |
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[ ]  NO multi-center trial reports (e.g., cooperative group annual study reports)

[ ]  If there were multi-center trial reports, describe:

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|       |

[ ]  NO data safety monitoring reports for this site (including DSMB, DSMC, etc.)

[ ]  If there were data safety monitoring reports issued for this site, describe:

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| --- |
|       |

[ ]  NO regulatory actions that could affect safety and risk assessments (e.g., FDA 483 issued)?

[ ]  If there were any regulatory actions taken for this site that could affect safety and risk assessments, describe:

|  |
| --- |
|       |

[ ]  NO other relevant information regarding this study, especially information about risks

[ ]  If other relevant information regarding this study became available, especially information about risks, describe:

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| --- |
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[ ]  In the opinion of the site PI, the risks and potential benefits are unchanged

[ ]  If in the opinion of the site PI, the risks and potential benefits have changed, describe:

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| --- |
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[ ]  All modifications to the protocol have been submitted to the IRB

[ ]  If any modifications to the protocol have NOT been submitted to the IRB, describe:

|  |
| --- |
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[ ]  All problems that require prompt reporting to the IRB have been submitted

[ ]  If any problems that require prompt reporting to the IRB haveNOTbeen submitted (e.g., serious noncompliance, an accumulation of minor noncompliance, etc.), describe:

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4.2 Have any monitors or auditors raised any concerns about this study at your site that required a report from you to the IRB, FDA, or other regulatory agencies since your last CR? These may include Form FDA 483; sponsor, industry, or institutional monitoring findings; or other findings from external reviews of this study.

[ ]  Yes → Respond to Question 4.2.a.

[ ]  No → Go to Question 4.3

4.2.a. Have these reports been submitted to the IRB?

[ ]  Yes → List the dates of the report and when they were provided to the IRB:

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| --- |
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[ ]  No → Submit a copy of the report, or summary of the issue, and your corrective action plan.

4.3 Have there been any regulatory or disciplinary actions against the investigator (e.g., investigator debarment, disqualification, revoked medical licenses, regulatory warning letters, etc.) in the last approval period?

[ ]  Yes → Explain:

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|       |

[ ]  No

5. SITE PI ACKNOWLEDGMENT AND SIGNATURE

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| --- | --- |
| **Study Title:**  |       |

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

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

B. This submission accurately indicates whether the site PI or any study team members have a conflict management plan; and

C. The site PI will conduct this research in accordance with requirements in the [*HRP-103 - Investigator Manual*](https://extranet.fredhutch.org/en/u/irb/policies-and-procedures.html#investigator_manual).

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|       |  |  |  |       |
| 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.