|  |  |  |
| --- | --- | --- |
|  | Diagram  Description automatically generated | **FORM: Continuing Review Supplement** |

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

Instructions

This form is to be used when Fred Hutch is serving as the IRB of Record.

For multi-site studies, each participating site ***outside*** the Cancer Consortium must submit a P-Site Continuing Review Supplement. A separate P-Site Continuing Review Supplement is also required if the lead PI does not have oversight of the site PI or the conduct of the research at the site.

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.

**CAUTION:** If you have significant or complex modifications to make to the study, you are strongly encouraged to submit the Modification separately from the Continuing Review, so that a disapproval of a Modification does not force your study’s approval to lapse. Once a “MODCR” combination is submitted, they cannot be separated. Contact IRO@fredhutch.org to discuss options.

1. Current Status

1.1 Indicate the status of the research for the upcoming review period.

Note: If the status is different from the last approved submission, include an explanation in Question 2.1 below.

Refer to guidance as needed: <https://extranet.fredhutch.org/en/u/irb/submissionstotheirb/study-status.html>

[ ]  Initial Approval with Minor Modifications

[ ]  Research not yet started at this location.

[ ]  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.

[ ]  Closed – Final CR – requesting to close this study now.

2. General Information

2.1 Provide a summary of your research progress to date, including any interim findings since your last continuing review (CR).

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2.2 Do all members of the research team 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, please explain:

|  |
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|       |

**Reminder:** The PI is responsible for ensuring every member of the study team 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 Is all funding information in Hutch IRB current?

[ ]  Yes

[ ]  No → Submit a Modification to update the study record in Hutch IRB (including if a no-cost extension was granted).

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2.4 *Federally funded clinical trials initially approved on or after January 21, 2019:* After a clinical trial is closed to recruitment and no later than 60 days after the last study visit by any participant, one IRB-approved consent form must be posted to ClinicalTrials.gov or Regulations.gov (docket folder HHS-OPHS-2018-0021). Have you posted a consent form?

[ ]  Yes

[ ]  No → This is not a federally funded [clinical trial](https://extranet.fredhutch.org/en/u/irb/glossary.html#ClinicalTrial)

[ ]  No → This federally funded clinical trial is still open to recruitment and/or participants are still having study visits

[ ]  No → The sponsor, coordinating center, or another entity has confirmed they will be posting the consent form for this federally funded clinical trial.

[ ]  N/A → This federally funded clinical trial was initially approved before January 21, 2019.

2.5 Does this research involve 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 repository released information or biospecimens since your last CR?

[ ]  Yes → Please 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.

|  |  |  |  |
| --- | --- | --- | --- |
| IRB # (if Fred Hutch) or study # | Name of Principal Investigator | Name of Outside Institution | Brief Description of Study’s Objective(s) |
|       |       |       |       |
|       |       |       |       |

[ ]  No

3. Enrollment

3.1 Enrollment Table:

* **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.
* Studies only enrolling within the Cancer Consortium: Complete **only** the local enrollment row.
* Studies enrolling outside the Cancer Consortium: Both **local and study-wide** enrollment numbers must be provided.
* For studies 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 studies 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** answer question 3.1.b, until the study is in data analysis. Then skip to Section 4.

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

3.1.a. Explanations of numbers above (optional) or explanation for why some of the requested information is not available:

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

[ ]  Yes → Please 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 has been in data analysis for at least a year)

[ ]  Unknown → Please explain:

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

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

[ ]  Yes → Please describe 1) why enrollment is lower than projected, 2) your plans to improve enrollment, and 3) whether or not low enrollment will affect your 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.

|  |
| --- |
| **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 study **locally** on track to meet anticipated local ethnicity, race and gender goals described in your initial application?

[ ]  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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|       |

3.3 Study-Wide Ethnic, Racial and Gender Enrollment Table

3.3.a. **Only if Fred Hutch IRB is the Coordinating Center or Single IRB**, complete table below for study-wide enrollment (otherwise, skip to question 4).

|  |
| --- |
| CURRENT ENROLLMENT STUDY-WIDE: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 study-wide “Total Enrolled” number put in question 3.2 (Column C) above.*

Comments:

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| --- |
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3.3.b. Is your study overall on track to meet anticipated local ethnicity, race and gender goals described in your initial application?

[ ]  Yes

[ ]  No → Describe your plans to meet the anticipated enrollment goals in relation to ethnicity, race, and gender for this upcoming 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 **Explanation of unchecked items.** The Hutch IRB Continuing Review SmartForm asks you to consider a series of statements and to indicate which ones apply to your study. Provide a summary explanation of the items you left **unchecked**. If you need to provide a longer description, a separate memo may be included. Specifically, you should provide a summary explanation in the boxes below if:

4.1.a. Subjects **DID** experience harm.

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4.1.b. Anticipated adverse events **DID** take place with greater frequency or severity than expected.

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4.1.c. Subjects **DID** withdraw from the study.

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4.1.d. [Unanticipated problems involving risks to subjects or others](https://extranet.fredhutch.org/en/u/irb/glossary.html#unanticipatedproblems) **DID** occur.

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4.1.e. Complaints about the study **DID** occur.

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4.1.f. Publications in the literature relevant to risks or potential benefits **DID** occur.

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4.1.g. Interim findings **HAVE** been identified.

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| --- |
|       |

4.1.h. Multi-center trial reports **WERE** issued (e.g., cooperative group annual study reports).

|  |
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4.1.i. Data safety monitoring reports **WERE** issued (including DSMB, DSMC, etc.).

|  |
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|       |

4.1.j. Regulatory actions **DID** occur that could affect safety and risk assessments (e.g., FDA 483 issued).

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4.1.k. Other relevant information regarding this study **DID** become available, especially information about risks.

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4.1.l. In the opinion of the PI, the risks and potential benefits **HAVE** changed.

|  |
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4.1.m. All modifications to the protocol have **NOT** been submitted to the IRB**.**

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4.1.n. All problems that require prompt reporting to the IRB have **NOT** been submitted (e.g., serious noncompliance, an accumulation of minor noncompliance, etc.).

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4.2. Have any monitors or auditors raised any concerns about your study 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 → Please list the dates of the report and when they were provided to the IRB:

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[ ]  No → Please 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 → If yes, explain:

|  |
| --- |
|       |

[ ]  No

4.4. Have there been any serious or continuing noncompliance events submitted to the IRB since your last Continuing Review?

[ ]  Yes → If yes, explain:

|  |
| --- |
|       |

[ ]  No