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|  | Diagram  Description automatically generated | **FORM: Transfer Supplement** |

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

**Name and Address of Previous IRB:**

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The following documents must be submitted to Fred Hutch IRB for review:

[ ]  Fred Hutch IRB Application (for study transfer) or Fred Hutch Participating Site Application (for site transfer if Fred Hutch already reviews the study) with associated supplement forms and attachments as required

[ ]  Most recent version of protocol (for study transfer) (Dated:      )

[ ]  Amendments (Dates of those included:      ), if not incorporated in protocol (for study transfer)

[ ]  Transferring IRB’s original application form and subsequent continuing review report forms showing research progress, and any unanticipated problems

[ ]  Any meeting minutes where the research was discussed by the transferring IRB

[ ]  IRB-conducted audit reports

[ ]  Any IRB correspondence with the Investigator, FDA, OHRP, or sponsor

[ ]  Most recently approved consent form(s) approved by the transferring IRB

[ ]  Advertisements currently being used for recruitment

[ ]  Product information (Investigator’s Brochures, package inserts, device manuals for the test article(s)). (Dated:      )
Note: If transferring IRB has most recently reviewed a prior version of the product information, submit that as well.

[ ]  Fred Hutch IRB Transfer Agreement

**Reason for Transfer to Fred Hutch IRB:**

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Date of initial approval by the previous IRB:

Date approval expires:

Summary of Study Activity Prior to Transfer

**At your site:**

1. Has the study begun?

[ ]  Yes [ ]  No

1. Total subjects enrolled (signed consent form):
2. Do you intend to enroll any more subjects?

[ ]  Yes [ ]  No

1. Are any subjects still on active treatment?

[ ]  Yes [ ]  No

**Comments:**

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1. Are all study interventions complete and the remaining activity limited to [long-term follow-up](https://extranet.fredhutch.org/en/u/irb/glossary.html#longtermfollowup) or data analysis?

[ ]  Yes [ ]  No

1. Has any new risk or benefit information become available that was not reported to the previous IRB?

[ ]  Yes\* [ ]  No

\*If yes, submit a memo with your application explaining the new risk or benefit information.

1. Have there been any [Unanticipated Problems involving Risks to Subjects or Others](https://extranet.fredhutch.org/en/u/irb/glossary.html#unanticipatedproblems) associated with the research during the time it was overseen by the transferring IRB?

[ ]  Yes\* [ ]  No

\*If yes, describe the problem and actions taken, if any, as a result of the unanticipated problem (attach a separate page if necessary) and **submit any IRB correspondence from the previous IRB related to the unanticipated problem**.

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1. Have there been any [Serious or Continuing Noncompliance](https://extranet.fredhutch.org/en/u/irb/glossary.html#noncompliance) events associated with the research?

[ ]  Yes\* [ ]  No

\*If yes, describe the problem and actions taken, if any, as a result of the serious or continuing noncompliance (attach a separate page if necessary) and **submit any IRB correspondence from the previous IRB related to the event**.

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1. Have there been any subject complaints related to this research?

[ ]  Yes\* [ ]  No

\*If yes, describe the complaint and actions taken, if any, as a result of the complaint, and **submit any correspondence from the previous IRB related to the complaint** (attach a separate page if necessary).

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1. Did the previous IRB ever suspend accrual, suspend approval, or terminate approval of this research?

[ ]  Yes\* [ ]  No

\*If yes, provide information on the reason for the Board action, the steps taken to resume the research **and copies of any correspondence related to the suspension** (attach a separate page if necessary).

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