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|  | Diagram  Description automatically generated | **FORM - Local Context Review** |

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| **Date of Report:** |  | | |
| **Lead Principal Investigator:** |  | | |
| **FHIRB #:** |  | | |
| **RG #:** |  | **Protocol #:** |  |
| **Title of Protocol (if applicable):** |  | | |
| **Site Relying on Fred Hutch for IRB Review:** |  | | |
| **Site Investigator:** |  | | |
| **Local Context Representative:** |  | | |
| **Contact Information for Local Context Representative:** |  | | |

The Fred Hutchinson Cancer Center (Fred Hutch) Institutional Review Board (IRB) invites you to provide local context review of this research activity. The IRB requests your review and comments specifically for local research context for Fred Hutch IRB serving as the single IRB for your institution. Before completing the following Local Context Review questionnaire, please take a moment to determine whether you have a conflict of interest.

Any financial interests, relationship, affiliation or other circumstance that is, or might reasonably be perceived as, a conflict of interest on the part of the consulting local context reviewer must be disclosed. Carefully review [*HRP-050 - POLICY - Conflicting Interests of IRB Members*](https://extranet.fredhutch.org/u/irb/policies-and-procedures.html#conflictinginterests) to determine if you have a conflict of interest with the above referenced study.

# Conflict of Interest Statement:

With the above referenced study, do you have a conflict of interest?

Yes → Describe the conflict of interest below and contact the individual who provided you this form, or the Institutional Review Office at [IRO@fredhutch.org](mailto:IRO@fredhutch.org), so we may arrange for a different Local Context Reviewer.

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No

# Confidentiality Pledge:

In consideration of my access to records and information relating to lead IRB review of the above-referenced protocol at my site, by completing the local context questions and signing below, I agree as follows:

1. I agree not to make use of, disseminate, disclose or in any way circulate beyond reasonably necessary to complete the local context questions any Information provided by Fred Hutch as part of the IRB local context review process, or if applicable, information discussed at the Fred Hutch IRB meeting.
2. I agree to maintain appropriate procedures to ensure that Confidential Information remains confidential to the extent required by this Confidentiality Pledge.
3. I understand and acknowledge that this Agreement may not be amended and that use of Confidential Information in a manner not permitted by this Confidentiality Pledge is not permitted.

# Local Context Questions:

To assist the Fred Hutch IRB review of the above-referenced research study, please respond to the following questions relating to local research context. The necessary study documents are attached for your reference.

## Subject Selection:

Section 3 of the attached [*HRP-893 - FORM - Participating Site Supplement*](https://extranet.fredhutch.org/f/irb/participating-site-supplement.html) describes the selection and recruitment of participants for this research study. Based on the information provided:

1. Does the selection and recruitment process outlined in section 3 comply with local laws and your institutional policies?

Yes

No

1. Do you find the selection and recruitment methods acceptable in the context of your local area?

Yes

No

If you answered “No” to either of these questions or have any comments about local laws or institutional policies on participant selection and recruitment, please explain:

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## Consent Process:

Section 4 of the [*HRP-893 - FORM - Participating Site Supplement*](https://extranet.fredhutch.org/f/irb/participating-site-supplement.html) describes the consenting process and compensation for research participants. Based on the information provided:

1. Does the consent process outlined in Section 4 comply with local laws and your institution’s consent policies?

Yes

No

1. Do the consent documents (and/or waiver of consent or documented consent) comply with local laws and your institution’s consent policies?

Yes

No

1. Is the participant compensation consistent with local laws and your institution’s policies?

Yes

No

1. Do you find the consent process and compensation acceptable in the context of your local area?

Yes

No

If you answered “No” to any of these questions or have any comments about local laws or institutional policies on participant selection and recruitment, please explain:

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## Other Considerations:

1. Are there any other sections of the Participating Site Supplement that are inconsistent with local laws or your institution’s policies?

Yes → Explain:

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No

1. Have there been any recent events in the local community that may have created positive/negative attitudes towards human subjects research?

Yes → Explain:

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No

1. Given the nature of this particular research study, are there any additional factors (community attitudes, ethnic diversity, language, etc.) that may contribute to the acceptability of this research in your area?

Yes → Explain:

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No

1. Add any additional comments that will help the Fred Hutch IRB in its review process:

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| --- | --- |
| Local Context Reviewer Name: |  |
| Local Context Reviewer Title: |  |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Reviewer Signature |  | Date |