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|  | Diagram  Description automatically generated | **FORM – Translated Materials Modification Supplement**  |

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| --- | --- |
| **Date:** |       |
| **FHIRB #:** |       |
| **Study Title:**  |       |
| **Site Name**, if applicable: |       |
| **Principal Investigator** (or site PI): | First Name:       | Middle Initial:       | Last Name:       |

Instructions

* Use this form when submitting **ONLY** translated materials for IRB review. If there are other aspects to your submission, including revisions to the English versions, a completed [*HRP-252 - FORM - Modification Supplement*](https://extranet.fredhutch.org/f/irb/research-modification.html) is required instead of this form.
* Create a Modification submission in Hutch IRB for “Other parts of the study” and attach this form.
* Refer to [*HRP-129 - POLICY - Use of Interpreter Services and Translated Documents*](https://extranet.fredhutch.org/u/irb/policies-and-procedures.html#language).

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[**1. Submission**](#_Toc173745265) **Information**

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1. Submission Information
2. Select one of the following:

[ ]  This is a new translation, not previously submitted to the IRB.

[ ]  This is a revised translation.

[ ]  This submission includes both new translations and revised translations.→ Describe below.

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|       |

NOTE: If submitting a *revised* translated consent form, the re-consent plan approved for the corresponding English consent form version must be followed.

1. What material are you submitting in translation?

[ ]  Consent form(s)

[ ]  Other:

|  |
| --- |
|       |

1. Is this submission related to the **short form consent process**? For example, a translated consent form is being submitted after the short form consent process was used to consent a non-English speaker.

[ ]  Yes → What date did the participant consent using the short form consent?

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|       |

If you are submitting the translation of the full consent form more than 30 days after the short form consent process, provide an explanation for the delay:

|  |
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|       |

[ ]  No

2. Required Attachments

NOTE: Do **not** use this form if you are also submitting new or revised English documents for IRB review, or changing anything else on the study. Instead, use [*HRP-252 - FORM - Modification Supplement*](https://extranet.fredhutch.org/f/irb/research-modification.html)*.*

**[ ]  Translated document(s):** The translation must be a complete translation of the document(s) provided to the IRB in English. The translation may not omit or contain information that is not present in the IRB-approved English versions. (Note that institution names should generally not be translated.)

[ ]  **Translation Certificate(s):** A translation certificate should include:

* A citation and/or document name of the IRB-approved English version that was translated (version and date is preferred to be included)
* List of the source and target languages
* FHIRB# and PI name and/or title of the research study
* An attestation that the translator is fluent in both languages/otherwise able to translate, and that the document is an accurate representation of the English version.

Note: If a standard translation certificate from the translation vendor is unavailable, the person providing the translation service may instead complete [*HRP-280 - FORM - Translation Certificate*](https://extranet.fredhutch.org/f/irb/translation-certification-form.html)*.*

3. PI Acknowledgement and Signature

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

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

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

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| Name of Investigator or Designee\* |  | Signature of Investigator or Designee\* |  | Date |

[ ]  \*I am signing this form as a designee. By checking this box, I affirm the PI (or site PI) is aware of this submission and has given me permission to submit on their behalf. I will save documentation of the PI’s/site PI’s permission to submit this form.