**Translation Attestation Form**

**Instructions:** The Principal Investigator is responsible for ensuring that IRB-approved study documents, e.g., recruitment materials and consent forms, are accurately translated into a language understandable to study participants. If any study documents will be administered in languages other than English, the Principal Investigator must:

* Submit a signed copy of this form with the Initial Application.
* Submit a signed copy of this form if, as part of a study modification, there is a request to add new study documents that will be translated.
* Ensure that all translated documents are approved by the local IRB/Ethics Committee (EC) prior to their use in the field.
* Submit the locally-approved, translated documents to the IRB as soon as they become available.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **A. PROTOCOL INFORMATION** | | | | | |
| Initial Review Modification Request (to add new documents) | | | | | |
| Protocol Number: | | |  | | |
| Protocol Title | | |  | | |
| Principal Investigator or Faculty Advisor/ Degree(s): | | | **/** | | |
| **B. LIST OF DOCUMENTS TO BE TRANSLATED** | | | | |  |
| Document Name | Name(s) of Local Reviewing IRB/Ethics Committee | Translated Language(s) | | Person Preparing Translation(s) | Name of Translator |
|  |  |  | | Harvard PI  Local Investigator  Certified Translator  Other, Specify: |  |
|  |  |  | | Harvard PI  Local Investigator  Certified Translator  Other, Specify: |  |
|  |  |  | | Harvard PI  Local Investigator  Certified Translator  Other, Specify: |  |
| **C. PRINCIPAL INVESTIGATOR ATTESTATION AND SIGNATURE** | | | | |  |
| By signing this form, I attest that I understand my responsibility as Principal Investigator to ensure that IRB-approved study documents, e.g., recruitment materials and consent forms, are accurately translated in a language understandable to study participants, and that I will submit locally-approved versions of these materials to the IRB when they become available.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Principal Investigator or Faculty Advisor’s Signature Date | | | | | |
| **D. TRANSLATOR SIGNATURE** | | | | | |
| By signing this form, I confirm that translations of the documents listed above will be accurate and complete.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Translator’s Signature Date | | | | | |