Application for Translation Review

OMB #0925-0753 Expiration Date: 05/31/2027

The purpose of the information collection is to conduct reviews of clinical trial studies. NCI guidelines mandate the participation of institutions in the CIRB for Network group studies. You are being requested to complete this instrument so that we can conduct activities involved with the operations of the NCI CIRB Initiative. Although your participation in Network group research and completion of the forms is voluntary, if you wish to participate in the CIRB, you must complete all questions on the form. The information you provide will be combined for all participants and reported as summaries. It will be kept private to the extent provided by law.

NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892- 7974, ATTN: PRA (0925-0753). Do not return the completed form to this address.

Study ID Number

Study Title

Study Chair

Protocol Version Date

**To be Completed by the CTSU or Study Team:**

1. Indicate the type of translation for review: (Required)

[ ]  Spanish Consent Form Translation from CTSU.

[ ]  Spanish or Other Language Consent Form Translation from Study Team.

[ ]  Translation of CIRB-approved materials by the Study Team (includes documents created by the Study Team OR obtained from an Outside Source and then translated (or modified) or by the Study Team).

[ ]  Translations by an Outside Source created by an Outside Source being used as provided by Study Team.

For more information on the types of translation submissions please go to this link on the CIRB website (Quickguide for Study Team-To be added).

**Spanish Consent Form Translation from CTSU**

This application is to be used for Spanish consent form translations submitted by the CTSU.

What’s the Protocol Version Date (PVD) of the consent form(s) you’re submitting? (Required)

How many Consent Forms are being submitted for this study for CIRB review? (Required)

[ ]  One consent form

 [ ]  Two or more consent forms

If more than one consent form, please name them.

Examples: (main) and Addendum.

 Phase I and Phase II

 Was the Protocol Version Date the only change made to the consent form? (Required)

[ ]  Yes

[ ]  No

If Yes and there are multiple consent forms, identify the consent forms where the only change was the PVD. (Required)

Attach the translated Spanish consent form(s). (Required) *Attachment*

Attach the certificate(s) of accuracy.

Note: Ensure that the certificate of accuracy lists the study number, consent form(s) and the consent form(s) Protocol Version Date (PVD) for the submission. (Required) *Attachment*

Do you have any additional information for the CIRB to consider when reviewing this translation submission? (Required)

[ ]  Yes

[ ]  No

Provide the information below. (Required)

**Spanish or Other Language Consent Form Translation from Study Team**

This application is to be used for any other language consent form translations submitted by the Study Team.

What’s the Protocol Version Date (PVD) of the consent form(s) you’re submitting? (Required)

How many consent form(s) are being submitted for this study for CIRB review? (Required)

[ ]  One consent form

 [ ]  Two or more consent forms

If more than one consent form –name them.

Examples: (main) and Addendum.

 Phase I and Phase II

Was the Protocol Version Date the only change made to the translated document(s)? (Required)

[ ]  Yes

[ ]  No

If Yes and there are multiple consent forms, identify the consent forms where the only change was the PVD.

 Attach the translated consent form(s). (Required) *Attachment*

For this submission, what language(s) have the consent form(s) been translated into for CIRB review? (Required)

 Attach the certificate(s) of accuracy.

Note: Ensure that the certificate of accuracy lists the study number, consent form(s) and the consent form(s) Protocol Version Date (PVD) for the submission. (Required) *Attachment*

Attach a copy of the CIRB approval letter for the English version of the Translated consent form(s) being submitted. (Required) *Attachment*

Do you have any additional information for the CIRB to consider when reviewing this translation submission? (Required)

[ ]  Yes

[ ]  No

Provide the information below. (Required)

How do you want your documents posted?

If this is a CP-CTNet Study, select "N/A"

[ ]  Word

[ ]  PDF

[ ]  N/A

If document-specific, specify type:

Do you want your documents posted upon approval of Translation review?

If this is a CP-CTNet Study, select "N/A"

[ ]  Yes

[ ]  No

[ ]  N/A

If no, indicate when posting should occur?

**Translation by the Study Team of materials already approved by the CIRB**

This application is to be used for translations of documents created by the Study Team OR obtained from an outside source and translated (or modified) by the Study Team.

NOTE: The English version must be approved prior to submission of the translation. The Study Team is responsible for ensuring that the translation is an accurate translation of the approved English version.

Document(s) created/translated by the Study Team, and/or outside source document(s) translated by the Study Team, and/or outside source materials modified and translated by the study team.

Provide a list of translated documents. For each item in this submission, name the language, the type/name of document and the “versioning” per document being submitted for CIRB review.

Note: Your translated documents might have a version date or version number or a combination of both. Please be sure to tell us what “versioning” is used for each translated document.

Examples:

Spanish DRUG NAME Pill Diary 10/28/22 French Recruitment Brochure version 2.0

Chinese Appointment Card, v1.0, December 11, 2022

Note: If you’re submitting any combination documents, per combination document, list the sub-sections/components. Per listed sub-section/component indicate if an in-house Translation OR if an outside source(d) material OR if an outside source(d) material that your Study Team modified and translated.

Attach the translated document(s). (Required) *Attachment*

Attach the certificate(s) of accuracy.

Note: Ensure the certificate identifies the study number, the names of the documents submitted, the language the documents have been translated into, and the matching “versioning” of each document is listed on the certificate. (Required) *Attachment*

 Attach a copy of the CIRB approval letter for the English version of the Translated document(s). (Required) *Attachment*

Do you have any additional information for the CIRB to consider when reviewing this translation submission?

[ ]  Yes

[ ]  No

Provide the information below.

How do you want your documents posted?

If this is a CP-CTNet Study, select "N/A"

[ ]  Word

[ ]  PDF

[ ]  N/A

If document-specific, specify type:

Do you want your documents posted upon approval of Translation review?

If this is a CP-CTNet Study, select "N/A"

[ ]  Yes

[ ]  No

[ ]  N/A

If no, indicate when posting should occur?

**Translation by an Outside Source being used as Provided**

This application is to be used for translations of documents created and translated by an Outside Source with no modification by the Study Team.

Provide a list of the Outside Sourced instrument(s)/document(s) to be used in your Study, name the language, the Outside Sourced document name, and any “versioning” information used by the Outside Source

Outside Source Examples: Any instruments from FACIT, (FACT-G) PROMIS, (Fatigue 7a), EORTC (QLQ-C30), a PRO-CTCAE, DNA

Genotek (OMNIgene Stool collection instructions), etc.

Examples of how to list your Outside Source materials: Spanish EPIC50 Expanded Prostate Cancer Index (Composite) Bowel Assessment (Version 1)

French PRO-CTCAE, Item Library 1.0

Spanish PROMIS Item Bank v.1.0, Fatigue -Short Form 7a

Attach your Outside Source translated instrument(s)/document(s).

Note: Certificate(s) of Accuracy are not required for these translations. (Required) *Attachment*

If the CIRB has previously approved the English version, attach a copy of the CIRB approval letter for the English version document. (Required) *Attachment*

Do you have any additional information for the CIRB to consider when reviewing this translation submission?

[ ]  Yes

[ ]  No

Provide the information below.

How do you want your documents posted?

If this is a CP-CTNet Study, select "N/A"

[ ]  Word

[ ]  PDF

[ ]  N/A

If document-specific, specify type:

Do you want your documents posted upon approval of Translation review?

If this is a CP-CTNet Study, select "N/A"

[ ]  Yes

[ ]  No

[ ]  N/A

If no, indicate when posting should occur?