ORP Forum Table: Limited English-Speaking Participants

IRB considerations for study document translations

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Table discussion leaders:

Dacia Christin (daciac@crab.org), Project Manager, SWOG Latin America Initiative
Angela Norman, Administrator, Cancer Prevention and Control Central CIRB
Renee Green, Local Context Administrator, CIRB

<u>Part 1:</u> Review of Translated Study Documents

Document Type	Typical Documents Used with NCTN Trials	CIRB Approval Required	Local IRB Review Required
Translated Long Informed Consent (ICF)	Spanish (and sometimes French) provided centrally; short form used if no long form available	Yes	No
Translated Short Form Consent on CTSU	Used when no translated long ICF is available on CTSU	No	No
Translated Short Form Consent not on CTSU	Used when no translated long ICF is available and no Short Form Consent available on CTSU	Yes, if the CIRB-approved Short Forms posted to CTSU are not available in the language being needed by the institution	Only if institution wants to use its own short forms which will also need CIRB approval before they can be used
Information sheet with local information not in boilerplate, usually standard of care language	Information required at institution but not permitted in CIRB boilerplate	No	Yes, always
PRO / QoL Instruments	Validated translated instruments	Yes	No. Validated instruments and their translated versions must be provided by the study.

Document Type	Typical Documents Used with NCTN Trials	CIRB Approval Required	Local IRB Review Required
Patient Diaries / Symptom Logs	Logs translated for participants by study sponsor or institution	Yes	Only if the institution creates their own documents to be used for study and gets them translated
Recruitment Materials	Flyers/ads in other languages provided by the sponsor or translated from institution created material	Yes. Locally developed recruitment materials also need to be approved.	Yes, when locally created and translated
Patient Education Materials	Materials tied to protocol participation	Yes	Yes, when created or translated by the institution
HIPAA Authorization	Institutional HIPAA forms	No. Not in CIRB's purview	Maybe. Often required by Institutional Privacy Board, not necessarily the local IRB

Note: Translations requiring CIRB approval are submitted via the IRBManager using the Annual Signatory Worksheet for boilerplate language or the Study-Specific Worksheet if the translated document only applies to a specific study.

<u>Part 2:</u> Guidelines and processes for CIRB submission of local boilerplate template language for translated informed consent forms (ICFs)

Key Principles:

- CIRB permits only **limited local context additions** (e.g., contacts, institutional policies).
- If an institution uses a CIRB-approved English boilerplate language, **that same boilerplate content must appear in translated versions**.
- Both FDA and Common Rule regulations require that consent information be provided **"in language understandable to the subject."** If this condition is not met with existing long form available on CTSU, your site may be able to translate a local version.

Does a CIRB-Approved Translation Exist on CTSU?

If yes (common for Spanish):

- Use the CIRB-approved translation.
- Submit translated boilerplate using the Annual Signatory Institution Worksheet (this can be submitted whenever there is a need for translated boilerplate language).
- For minor dialect differences:
    - Have bilingual staff or interpreters review for comprehension.
    - Address differences through the consent discussion rather than document changes.

If no:

- Contact CIRB before initiating translation to confirm justification.
- Translate the CIRB-approved English ICF.
- Submit via IRBManager using the Study-Specific Worksheet.
    - Translated ICF for the required study
    - Certificate of Accuracy
    - CIRB approval of the English ICF

Example of a Local Boilerplate Approval Process

Note: Steps marked "Per institutional policy" are not part of CIRB approval process and may vary by institution.

1) Obtain CIRB approval of the **English boilerplate before submitting request for non-English language boilerplate ICF.**
2) Identify required local context (law, policy, institutional contacts).
3) Per institutional policy: Complete internal HRPP / legal review.
4) Submit boilerplate via IRBManager using Annual Signatory Institution Worksheet.
5) CIRB review and approval.
6) Per institutional policy: Local reliance acknowledgment.
7) Maintain and update the boilerplate as policies change.

Once approved, CIRB-approved boilerplate may be used across NCTN studies.

Part 3: eConsent in languages other than English

CIRB allows eConsent and remote consent in languages other than English.

- It must be pre-approved (Study-Specific Worksheets or the Signatory Institution Worksheet), documented, and compliant with local laws.
- eConsent must meet the same regulatory standards as paper consent.

Special considerations for non-English speakers:

- Must obtain CIRB approval required for process and ICF translations.
- Platforms used for remote consent must support translations and interpreter workflows.
- Comprehension must be verified (interactive discussion).
- Interpreter involvement must be documented.
- Same signatures must be obtained (patient, witness, person obtaining consent, etc).

Additional Resources:

CIRB, Standard Operating Procedures, August 1, 2024. Available from: FINAL_CIRB_SOPs_1AUG2024.pdf.

CIRB, Guidelines For Permitted Boilerplate Language Additions, May 16, 2024. Available from: https://www.ncicirb.org/guidelines-permitted-boilerplate-language-additions.

CIRB, Institution Q&A, May 1, 2021. Available from: https://www.ncicirb.org/institution-q.

ORP Open Table Forum, Translations and Consent for Non-English Speaking Participants, October 13, 2023. Available from: https://www.swog.org/sites/default/files/docs/2023-10/Fall23OpenForum_NonEnglish.pdf.