

Informed Consent Translation Checklist — LATAM

Six-Gate QC · Applies to ANVISA, COFEPRIS, INVIMA, ANMAT, ISP, DIGEMID, ARCSA, MINSA (Panama).

1. Source-document readiness

- Latest IRB/EC-approved ICF version confirmed with sponsor.
- Version number, protocol code, and effective date visible on every page.
- Track-changes accepted; no residual comments or hidden text.
- Any local site-specific insert (e.g., site name, PI, phone) marked as [placeholder].

2. Regulatory scope per country

Brazil (ANVISA / CONEP)

- TCLE prepared in Brazilian Portuguese (pt-BR).
- Reading level appropriate for the target population; no European Portuguese vocabulary.
- Data-protection language aligned with LGPD (Lei 13.709/2018).
- Compensation, insurance, and contact points explicit.

Mexico (COFEPRIS / CONBIOÉTICA)

- Spanish (es-MX); use 'usted' register throughout.
- COFEPRIS-approved sponsor and site information present.
- NOM-012-SSA3-2012 elements addressed.

Colombia (INVIMA)

- Spanish (es-CO); certified translation if source is non-Spanish.
- Resolución 8430/1993 informed-consent elements addressed.

Argentina (ANMAT)

- Spanish (es-AR) — rioplatense register acceptable; avoid Mexican colloquialisms.
- Disposición 6677/10 required elements present.
- Translation by traductor público matriculado (CTPCBA or provincial college).

3. Linguistic quality gates

- Bilingual medical reviewer sign-off on terminology.
- Back-translation performed on risks, procedures, and rights sections.
- Reconciliation report attached; discrepancies resolved and logged.
- Reading-grade level $\leq$ 8th grade (or country equivalent) verified.

4. Formatting and layout

- Same section order and numbering as the source ICF.
- Signature block matches local requirement (participant, witness, investigator).
- Page numbering: 'Page X of Y'; version + date in footer of every page.
- Font size ≥ 11 pt; no scanned images of text.

5. Certification, apostille, notarization

- Translator declaration with name, credential, date, contact.
- Sworn/public translator seal where required (BR, AR, CO — see country rules).
- Apostille (Hague) attached where the receiving authority requires it.
- Certificate of Accuracy included with sponsor letterhead.

6. Delivery package

- Clean PDF (searchable) + editable DOCX per language.
- Version-controlled filename: [Protocol]_ICF_[country]_v[X.Y]_[YYYY-MM-DD].
- Change log vs. previous version (added / removed / clarified).
- QC certificate referencing the Six-Gate workflow.