

Flowchart of the Review Process for Translated Materials

IRB APPLICATION & PROTOCOL NARRATIVE

- Describes consent process for non-English speakers
- Identifies languages likely to be encountered
- Includes consent materials:
 - English version only
 - Written at 8th grade level or lower
 - Submitted with the application



IRB REVIEW

- If needed, the IRB requests changes to the English version consent materials.
- Researcher revises English version and resubmits with response.

IRB-APPROVAL

- Approval letter identifies IRB-approved consent requirements and indicates if short form consent is approved.



TRANSLATIONS

- Researcher obtains accurate written translations of the IRB-approved English version consent and any recruitment materials.
- Researcher submits translated consent materials (including any recruitment materials) to the IRB for approval **before** enrolling subjects using the translated consent form and recruitment materials (as described in the “preferred method”).