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”).