1. Investigator provides a written translation of the IRB-approved English version consent (including recruitment materials).
2. Investigator provides a qualified interpreter to facilitate the consent discussion.
3. By answering and asking questions, the investigator determines whether the subject comprehends the consent information to ensure the informed consent is valid.

Signatures required:

1. Subject or legally authorized representative (when approved)
2. Interpreter
3. Person obtaining consent

A signed copy is given to the subject.