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Columbia University Institutional Review Board

Guidance on AI-Assisted Translation of Study Materials and Informed Consent

Regulatory Context

Columbia University's Institutional Review Board (IRB) Policy on the [Enrollment of Non-English-Speaking Subjects](#) in Research sets forth the institutional requirements for recruitment, informed consent, and ongoing communication with human subjects who are not fluent in English.

With the increasing availability of technological tools, principal investigators and research personnel may consider utilizing artificial intelligence (AI) and machine translation software to draft research materials. This guideline establishes the IRB's position on using AI in translation of study related materials.

I. Standard Requirements for using AI in drafting translations

Regardless of whether AI was used to generate the initial draft, all materials must follow the standard IRB translation workflow prior to submission:

1. **Human Verification & Post-Editing:** All translated study documents must be reviewed, post-edited, and formally certified by a qualified human **Acceptable Translator** as defined by the [Enrollment of Non-English Speaker's Policy](#).
2. **Back-Translation Standards:** For greater-than-minimal-risk studies (or where required by the IRB), back-translations must be conducted **manually** and **independently** by a separate human translator. **AI tools are strictly prohibited from performing or assisting with back-translations.**
 - a. when a back translation is required, documentation of certification must be provided from each translator
3. **Attestation & Certification:** Investigators must submit standard written certification from the **Acceptable Translator** confirming that the final text is consistent in content, style, and readability with the IRB-approved English version. Non-commercial translators must also include an explanation of their language qualifications.