Guidance on Using and Obtaining Translated Materials

If your site enrolls non-English speaking subjects, you must use Schulman approved translated informed consents (ICs). All study-related materials and relevant recruitment materials must also be translated. If a reviewed document is revised, the translated version must also be revised. It is your responsibility to request or provide updated translations after such changes.

In addition to the translated documents, your site must provide someone who is capable of answering questions about the research in the language of the non-English speaking subject. The Board requires that an employee, study staff member, and/or impartial translator who is fluent in the subject’s language and capable of explaining the study be present during the consenting process and be available throughout the study to answer the subject’s questions or translate the investigator’s answers. A family member or friend of the subject may not serve as an interpreter or translator.

Translations may be obtained either by Schulman or the Sponsor, CRO, or Site at the discretion of the Sponsor. Your site may inform Schulman that you will be using translated materials either on your initial submission form or via email to translation@sairb.com.

Guidelines for Submitting Translated Documents

For a Sponsor, CRO, or Site obtaining a translation, we recommend providing the Formatting Guidelines to your translation vendor. Documents that do not adhere to these guides may be returned for revisions, which may delay processing and approval.

Provide your vendor with the current Schulman approved site specific IC and/or study documents. Request a Certificate of Translation (COT) from the vendor along with the translation. For additional details, please consult the Formatting Guidelines.

When you submit recruitment or study-related material translations, please provide the Recruitment and Study Related Materials Submission Form. All translated materials must first be reviewed and approved in English. Failure to provide the identifying MA number for the approved English document may delay processing and approval of the translation.

Please note that California sites must include a translated Experimental Subjects’ Bill of Rights with the IC. English and Spanish versions are available from our forms page. Other languages may be available on request.

Schulman must receive both the translated document and accompanying COT before issuing an approval letter. The Board reserves the right to have the certified translation verified. If the Board decides the certified translation must be verified, the party responsible for translation costs will be billed.

Turnaround Estimates for Schulman Translations

The Sponsor or CRO must authorize all requests for translations. The estimates provided here apply only to Spanish translations. Schulman cannot guarantee turnaround time for any translation.

- First-time translation of IC and attachments: 5-7 business days
- Additional sites’ IC and attachments: 3-5 business days
- Revised IC: 3-5 business days
- Study-related and Recruitment material: 2-5 business days

Please Note: Schulman will not obtain translation of the template IC or back translation of any translated document unless specifically requested. Obtaining back translation will increase the overall turnaround time.