

Guidance for Enrolling Non-English Speaking Subjects and Obtaining Translated Study Documents

If a site plans to enroll a non-English speaking subject, the Schulman-approved site-specific informed consent document ("ICD"), applicable attachments (e.g., California Bill of Rights, HIV Consent, additional consents), any study related materials (e.g., Subject Diaries, Questionnaires, Subject Information Sheets) and any recruitment material used for the recruitment of non-English speaking subjects must be translated into a language that the subject can read and understand. During a study, the non-English speaking subjects must receive in their language the same information as English speaking subjects receive. If during a study a Schulman-approved study document is revised, the non-English version likewise will require revision.

Additionally, any site planning to enroll non-English speaking subjects must provide someone (i.e., employee, member of the study staff, professional [impartial] translator) fluent in the language of the non-English speaking subject who is capable of explaining the study and answering questions in the language of the non-English speaking subject. This person cannot be a family member or friend of the subject and must be available throughout the subject's participation in the study including study visits, after-hours telephone contacts and/or emergency situations.

Translated study documents may be obtained either by requesting that Schulman use its translation vendor or by the Sponsor, CRO or Site providing the Schulman-approved English study documents to their own translation vendor. Please see below for details on both options.

Schulman obtains translated study documents

- The Sponsor or CRO must authorize any request for a translation.
- The Sponsor or CRO must provide the name and contact information of the party to be billed for the translation.
- Turnaround time for the translation of study documents is an approximation and pertains to Spanish translations only (see below). Schulman uses an independent translation service and cannot guarantee turnaround time.
 - Translated Initial ICD and applicable attachments -Within 5-7 business days.
 - Translated Revised Main ICD – Within 3-5 business days.
 - Translated Initial and Revised Study related material- Within 2 to 4 business days.
 - Translated Initial and Revised Recruitment material- Within 2 to 4 business days.

Please Note: It is not standard process for Schulman to provide translation of the template ICD or to request back translations of any translated documents. If the Sponsor or CRO requires translation of the template ICD or back translation of any document(s), it is the Sponsor or CRO's responsibility to request these by notifying Schulman in writing. Additionally, the processing of back translations and translations of languages other than Spanish may increase the above stated turnaround time(s).

Sponsor/CRO/Site obtains translated study documents

- The Sponsor/CRO/Site must provide the Schulman approved site specific ICD and all other Schulman-approved study documents to their translation vendor.
- The Sponsor/CRO/Site must provide the translated ICD and study documents to Schulman accompanied by the certificate of translation (see certification requirements below).
- If obtaining a translation for multiple sites on the same protocol, you must use the same translation service for all sites in order to maintain consistency in the translation.

Canadian Sites: Schulman Associates IRB does not consider French speaking subjects to be vulnerable.

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Certification Requirements

The translation service must provide a certification that contains the following information:

- (1) A statement that the translation is a true and accurate translation of the Schulman-approved English version; and
- (2) The Schulman site-specific approval date (found in the top right box) on which the translation was based.

Schulman must receive the translated ICD, applicable attachments, study related material and/or recruitment material and a letter from the professional translation service certifying the translation before Schulman will issue 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.

Translated Document Requirements

The translated ICD must contain:

- (1) Date of the latest Schulman approved English version on which the translation was based and the Schulman reference number in the upper right hand corner of each page;
- (2) Investigator's name, phone number and compensation information;
- (3) "History lines" on the last page (Schulman's notations for internal tracking purposes)--this text should remain in English as it is strictly for internal purposes; and
- (4) Version Date of the ICD in the bottom left corner of each page.

Schulman cannot process translated template ICDs that do not include site-specific information. Site specific information cannot be handwritten on template ICDs.

Please note that California sites must have a translated Experimental Subjects' Bill of Rights included with the ICD. The English and Spanish versions are available from our forms page at sairb.com/forms.

Professional Translation Services

While Schulman cannot recommend a particular translation service, we have listed several companies that you may contact for translations:

Cincilingua, Inc.

World Language Building
322 East Fourth St.
Cincinnati, OH 45202
Phone: (513) 721-8782
e-mail: translate@cincilingua.com

Conversa Language Center

817 Main St., Sixth Floor
Cincinnati, OH 45202
Phone: (513) 651-5679
e-mail: conversatranslations@gmail.com
e-mail: conversa@iac.net

Transperfect Translations

601 Thirteenth St., NW, Suite 320 North
Washington, DC 20005
Phone: (202) 347-2300
e-mail: info@transperfect.com

Global Language Solutions

25 Enterprise, Suite 500
Aliso Viejo, CA 92656
Phone: (949) 798-1400 Main Office
Phone: (513) 683-8711 Midwest Regional Office
e-mail: info@globallanguages.com

If you have any questions, please contact Schulman Associates IRB at (513) 761-4100.