BUMC IRB Process for Translated Consent Forms and Other Documents

The IRB is no longer requiring that an exact, word for word “back translation” be obtained for foreign language consent forms. Instead the IRB has approved the use of a Verifier who will verify the accuracy of the translated consent forms.

To Obtain Approval for Foreign Language consent forms the investigator will now:

1. Obtain Approval for the English version of the consent form in section Q
   a. complete the attestation form with the protocol number, type of consent form (i.e. assent, adult consent, etc), and the valid date
   b. indicate on the attestation form which foreign language the document will be translated to

2. Have the English version translated to that foreign language
   a. provide the printed name of the person who translated the form from English to the foreign language
   b. provide the qualifications of the person doing the translation

3. Have the translated version reviewed by a second person (the verifier)
   a. the Verifier does NOT have to provide a word for word back translation of the foreign language consent
   b. instead the Verifier verifies the accuracy of the back translation
   c. For consent forms: the second person verifies that the translated consent contains all of the required elements of informed consent
   d. Note: if the IRB has waived certain requirements then be sure to indicate that on the form prior to giving the form to the Verifier to complete

4. Complete the attestation form with information about the Verifier
   a. provide the verifier’s printed name
   b. provide the verifier’s qualifications
   c. NOTE: the Verifier can NOT be the same person who provided the translation from English to the foreign language

5. The Verifier must then sign and date the verification form.

6. The attestation form and the foreign language consent form are then attached to the protocol in INSPIR and submitted to the IRB. Please attach the foreign language consent form in the ‘Informed Consent’ section, and the Attestation form in the ‘Other Study Documents’ section.

7. The IRB will then review and approve the documents. The IRB will stamp the foreign language consent form with the valid approval date.

The IRB also requires the submission of translated recruitment materials and/or study tools other than the consent forms. Only the translated consent form requires an accompanying Attestation form, however.