

- See 32.5 Decisionally impaired subjects for more information on IRB review of their participation in research.

28.12 Obtaining consent from non-English speaking subjects

Researchers should take great care when they obtain informed consent from individuals who do not speak English or whose understanding of the language is limited. Researchers should be fluent in the subject's language or an interpreter should be available during the consent process and throughout the subject's participation as needed. Consent forms should be prepared in the language understandable to potential subjects. For more information, see 28.13 below.

When performing research using non-English speaking subjects, the use of short form consent documents should **only** be used when unexpected circumstances arise and there is not sufficient time to prepare a full consent form translation. The short form should not be used as a convenient way to circumvent translation of the full consent form. See 28.6 for more information.

While the use of non-English speaking subjects presents a unique set of challenges for the researcher, care must be taken not to exclude non-English speaking subjects from research that may have potential benefits.

28.13 Translation and informed consent

Attention should be paid to both oral interpretation and written translation in the informed consent process.

28.13.1 Oral interpretation

Oral interpretation should be performed by a qualified individual who is not a family member of the prospective subject. The individual performing the interpretation should be available for ongoing communication between subjects and investigators.

28.13.2 Written translation

Written translation of informed consent documents should be performed by a qualified individual. Though there is no standard definition of what constitutes a "qualified individual," the investigator should demonstrate due diligence in obtaining an adequate translation of the informed consent documents from an individual whose qualifications would appear adequate to a reasonable person. Back translations to English may be one method for validating the accuracy of the translation; however, back translations are not always sensitive to dialect and idiom.

28.14 Consent for use of stored samples and genetic testing

In general, all anticipated uses of collected samples of human tissues, body fluids, or biological products should be carefully delineated in the *Procedures* section of the consent form.