

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH	Human Research Protection Program Policies & Procedures	
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Title: Informed Consent process	Date Effective 9-16-04	Supercedes P&P dated

Consent Obtained in a Language Other than English

Federal regulations require that consent be obtained in a language understandable to the subject. If non-English speaking subjects will be included, the English version of the consent document(s) must be submitted with the research application for review and approval by CHR. When the project is approved, the approved English version of the consent will be given to the investigator for translation and for review by the local IRB (if there is one). A memo outlining any changes in the consent document required by the local IRB along with a revised English version and local language translation of the consent must then be submitted to CHR for review and final approval.

To ensure that the consent has been translated accurately, a [Certificate of Translation, \(CHR Form F\)](#) must be provided to CHR, along with a copy of the local language consent document(s). The investigator(s) conducting the research may not certify the translation. For international research, the local IRB can certify the translation. Alternatively, a translator fluent in English and the local language may certify the translation.

Contact with subjects may not be initiated until CHR has formally approved both the English and local language versions of the consent, and has received the Certificate of Translation.

Unless waived by CHR, consent should be a *written document* that contains all of the basic elements of informed consent and appropriate additional elements. Alternatively, with CHR approval, oral presentation of consent information may be used together with the *short form written consent*. In this case the oral presentation and short form document must be in a language understandable to the subject. The English language consent approved by CHR may, however, serve as the summary and the witness must be fluent in both English and the language of the subject. If the person obtaining consent is assisted by a translator, the translator may serve as the witness. A copy of the local consent document must be given to each research subject when their consent is obtained.