

to submit the translated documents in addition to the Certificate of Translation for full approval can be granted. It is the PI's responsibility to locate a translation company and ensure that it is reputable.

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Waiver or Alteration of Informed Consent and Documentation of Consent

According to [45 CFR 46.117\(c\)\(1\)](#), PI's may request a waiver or alteration of informed consent and/or from obtaining documentation of written informed consent if the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained. In this case, PI's must submit a short form written informed consent document stating all the required elements of informed consent as well as a written summary statement that will be presented orally to participants or their legally authorized representatives. In this case, the consent process must be witnessed, and the witness must sign both the short form consent document and the summary indicating that all elements were addressed with the subject. If appropriate, the participant or legally authorized representative could be asked to sign the short form document. A copy of both documents must be provided to participants or their legally authorized representatives.