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Good Clinical Practice Q&A: Focus on Translations

Is it mandatory to confirm the validation of translated documents by back translations into English? Or will a certificate of the translation done and the CV of translator be acceptable?

FDA's regulations require that the IRB must review and approve all English and non-English language versions of any consent documents (long form or short form with written summary) that are to be used by investigators to document the informed consent of subjects (21 CFR 50.27(a) and 21 CFR 56.111 (a)(4) and(5)). When reviewing proposed informed consent procedures involving translation of written and oral information that is to be presented to subjects, FDA recommends that the IRB review, and if appropriate, approve procedures to ensure that a qualified individual or entity will prepare the translations. The determination of what party is appropriately qualified to translate the informed consent document and the actual process to review and obtain the translated version is left to the individual IRB to determine. It is recommended that a sponsor not only have appropriate procedures in place for doing so but also maintain sufficient records of the actual process.

Source

"Good Clinical Practice: A Question & Answer Reference Guide", Barnett International. The Guide is available at http://www.barnettinternational.com in electronic and paper form.

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