

NOT EVERYONE SPEAKS ENGLISH

Being in research is a privilege. Not every potential subject must be enrolled. On the other hand, discrimination against a person or a group may be quite inappropriate.

Solution 1: exclude people who don't:

"Eligibility Exclusion: • all patients unable to read or write in English."

All other solutions need care, concern and work. Things to consider include:

Is there a translated consent form? Perhaps there is one at another site?

Is there a translator available? Family, friend, bilingual staff, or trained translator?

Are supporting forms (diaries, quality of life questions) translated?

Is there a need for 24 hour emergency coverage in that language?

Are cultural concerns and differences accounted for? (different holy days, dietary?)

Verbal translation

Bilingual staff and trained translators are far preferred to family and friends. The latter may bias the translation to soften a concept or may miss a nuance.

Written translation

Just as English is different in England, India, South Africa, and the United States, so are many other languages. Care should be taken to be generic and to address the local idiom. A certified professional translator may do a lovely job for the wrong part of the country.

IRC has *no preference* about who translates from English to the second language. However, we ask that the second language be back-translated by a separate, bilingual person representative of or knowledgeable of the potential subject. This person might be, for instance, a nurse or a local teacher. This person should be given the translated form and asked to back translate without first having knowledge of the English consent form or the protocol. Both the translation and the back translation should be submitted.

A general written acknowledgement that validates the translation, issued and signed by the translator should accompany the translated document. This applies to both the original translation and the back-translation.

Translation needed on a Single occasion

Many languages are not heard often and it is a waste of time and resources to prepare for an eventuality that is not likely to occur. It may be best to forego inclusion of this single person. If, however, it is a clinical trial with a potential for benefit, inclusion might be desirable. Verbal translation may be used. The translator (preferably not family or friend) should sign the consent form.

After the first encounter with this language group (if the interaction is positive), more patients from that community might appear. Serious consideration should be given to the possible need for translation.

Translation for Multiple occasions

Preparation is the key. In addition to having written documents (consent forms, authorizations, diaries, quality of life instruments, etc.) ready, the verbal translators should be educated about the protocol. This person should be listed on the consent form as the person to call if there is any later questions, side effects or problems.

