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BC Cancer Research Ethics Board's Hints & Tips on the Use of Interpreters and Translated Documents

FDA regulated research – it is a regulatory requirement that ICFs MUST be provided in a language understandable to the participant

- For studies with ethics approval pre-Jan 1, 2020 – check application/protocol/budget (if it's been stated that translated documents will be acquired and this was approved, then this should occur). If not, request sponsor to pay; if sponsor refuses to pay – contact REB with reasons, etc. – REB will review and make determination
- For new studies submitted for review post-Jan 1, 2020 – contracts should be negotiated up front; consider whether ICFs/any other study related documents translated 'up front'; or, as non-English speaking encountered. If there is a reasonable expectation that specific ethnic groups who may be non-English speaking may present for potential enrolment in research, the investigator/sponsor should discuss with the REB how to proactively prepare for this. In these cases, as per FDA guidance, the BC Cancer REB will generally require that the consent form is translated into the specific language(s) upfront. Plan should be provided in ethics application – REB will review and make determination
- If there is urgency in consenting the participant, and a translated ICF is not immediately available, the participant can be consented using the approved English ICF and having a qualified and independent third party interpreter present during the consenting discussion. Arrangements should be made to have the ICF translated within 6-8 weeks.
- The necessity to translate all other study-related documents (eg questionnaires, etc) will be assessed based on contextual specifics of each study (there is no one size fits all approach)

Non-FDA research (clinical or behavioural) - every attempt should be made to ensure translation of ICFs (at minimum), as well as study-related documents

- For studies with ethics approval pre-Jan 1, 2020 – check application (if it's been stated that translated documents will be acquired and this was approved, then this should occur). If not, contact REB to discuss options, etc. – REB will review and make determination
- For new studies submitted for review post-Jan 1, 2020 - Preference is that the ICF (at minimum), as well as study related documents are translated. All applications submitted for review should include a plan on how the study team will manage the use of interpreters and translated documents.
- If there is urgency in consenting the participant, and a translated ICF is not immediately available, the participant can be consented using the approved English ICF and having a qualified and independent third party interpreter present during the consenting discussion. Arrangements should be made to have the ICF translated within 6-8 weeks.
- The necessity to translate all other study-related documents (eg questionnaires, etc) will be assessed based on contextual specifics of each study (there is no one size fits all approach)

The following are some of the things that should be considered when developing a plan (note: this is not an exhaustive list – the contextual specifics of individual projects need to be taken into account):

- Risk level of the project. Just because the project is minimal risk, does not mean that ICFs/study-related documents do not need to be translated or interpreters used. The REB will assess all relevant factors, including risk level, in making a decision. However, the greater the risk to participants (particularly if there are safety implications) = the greater probability that translated consents/study-related documents will be required;
- Clinical research (e.g. intervention, treatment, drug trial, etc.) v behavioural research (e.g. questionnaire, interview, focus group, etc.). Clinical research = greater probability that translated consents/study-related documents will be required;
- Participant sample. If the research is being conducted at a site known to regularly encounter participants who primarily speak another language (e.g. Farsi, Punjabi, Mandarin, etc.), or the research is clearly targeting non-English speaking participants, the BC Cancer REB will likely request that the study documentation be translated.
- Validated questionnaires/instruments. It may not be acceptable to translate validated questionnaires or instruments as this may impact analysis of the data, the reporting of results, etc. Discuss with the REB.
- Costs, time lines, resource constraints, etc. If costs, time, or resource constraints are cited as reasons for seeking to exclude non-English speaking, the REB will request that details be provided (e.g. estimated translation costs, turnaround times, or resource limitations) so an informed decision can be made about the course of action to be taken. Quotes can be sought by contacting Provincial Language Services (or, if an industry sponsor is involved, the service provider they wish to utilize).