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BC Cancer Research Ethics Board's Guidance on the Use of Interpreters and Translated Documents

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Introduction

The use of interpreters and translated documents for the consent of persons for research studies is guided by the principles of non-discrimination and fairness. It is important to not discriminate in the enrolment of persons in research studies based on their language or reading ability. As well, the informed consent form is a critical document for the participant to have in their possession and be able to read in their language and refer to at their discretion, particularly for information relating to risks and/or side effects.

In Summary

Baseline expectation is that all documents for all research studies (regardless of FDA-affiliation, sponsored by CCTG, etc.) be presented in a language understandable to the participant.

1. If anticipated that non-English speakers will be recruited the consent form should be translated in advance of recruitment
2. If a non-English speaker presents unexpectedly during recruitment:
    a. Contact the REB as soon as possible with consenting plan (via phone or email and with Request for Acknowledgement in RISe)
    b. Use PHSA Provincial Language Services in the consent discussion to expedite enrolment, if necessary
    c. Have consent form translated as soon as possible
3. Call the BC Cancer Research Ethics office for guidance

    Research Ethics Officers:
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References and Resources

The BC Cancer Research Ethics Board (REB) references the following resources in relation to the use of interpreters and translated documents when conducting research at BC Cancer:

Provincial Language Services: http://www.phsa.ca/our-services/programs-services/provincial-language-service

PHSA Language Access Policy: http://shop.healthcarebc.ca/phsa/PHSAPOD/Provincial%20Language%20Service/C-99-11-20450.pdf

PHSA Accessing Interpreting and Translation Services in PHSA: http://shop.healthcarebc.ca/phsa/PHSAPOD/Provincial%20Language%20Service/C-99-13-20450.pdf

UBC REB Policy Statement: The exclusion of research participants based on language: https://ethics.research.ubc.ca/sites/ore.ubc.ca/files/documents/Exclusion_of_research_participants_based_on_language.pdf.

UBC Clinical Research Ethics General Guidance Notes Article 13.2.1: Translated Consent Documents https://ethics.research.ubc.ca/ore/ubc-clinical-research-ethics-general-guidance-notes - scroll down.

FDA – CFR 21 – Subpart B – Informed Consent of Human subjects: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50&showFR=1&subpartNode=21:1.0.1.1.20.2

FDA Information Sheet Guidance, Guide to Informed Consent: www.fda.gov/RegulatoryInformation/Guidances/ucm126431.htm

FDA's Information Sheets Guidance, FAQs: www.fda.gov/RegulatoryInformation/Guidances/ucm126420.htm

Note: Clinical trials researchers and staff must also ensure they refer to and abide by BC Cancer Clinical Trials Standard Operating Procedures

Key Definitions (see above - Accessing Interpreting and Translation Services in PHSA)

Interpreting is the oral or signed rendering of one language into another and vice versa to facilitate the exchange of communication between two or more persons speaking different languages.

Translation is the written rendering of one language into another written language ensuring equivalency in meaning.

Sight Translation is oral rendering of written text from one language into another and usually done in the moment.

Frequently Asked Questions

NOTE: All consent methods and documents should be approved by the REB *before a potential participant is consented* to take part in the research project. If a non-English speaking potential participant is identified, please contact the REB for advice prior to taking any further steps.

While the BC Cancer REB references and adopts the above policies, in order to provide further guidance to researchers, the following questions and answers are set out below:

FDA regulated studies

Q. My study is regulated by the FDA – what steps do I need to take in relation to non-English speaking participants?

A. While an independent qualified interpreter can be used during the informed consent process and any ongoing interactions with the participants, in **all FDA regulated trials**, in order to meet the requirements of 21 CFR 50.20, a non-English speaking participant **MUST** be provided with a copy of the informed consent document (in its entirety) in the language understandable to them. Both forward and backward translations must be done for the informed consent document, and a translation certificate is required.

The REB would expect that the consent form is translated by an independent qualified translator into the language understandable to the potential participant prior to consent being obtained from the participant.

If there is urgency in relation to enrolling the participant, or if pre-screening is required and there is an informed consent document specific to screening, the BC Cancer REB will consider sight translation of the informed consent document to be sufficient for enrolment and pre-screening purposes (note: this requires the use of an independent qualified interpreter who would sight translate the English consent form to the non-English speaking participant). However, in order to meet the requirements of 21 CFR 50.20, the English consent documents must then be translated by an independent qualified translator into the language understandable to the enrolling participant. The REB would expect that the translated documents be provided to the participant as soon as practicable, but no later than six (6) weeks from the initial consent discussion.

Specific 'groups' of non-English speaking participants

If the study is going to be conducted at sites where 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.

Q. Can the informed consent form be translated into a 'short form' consent instead of getting the entire document translated?

A. The use of short form consents relate to US FDA regulated studies only, and are permitted to be used when non-English speaking participants are 'unexpectedly encountered', and/or in 'emergent' situations. Given the diverse, multi-cultural, and multi-lingual population that BC Cancer operates in, the BC Cancer REB's position is that it is highly unlikely that non-English speaking participants could be said to be unexpectedly encountered. The majority of research being undertaken would also not be viewed as arising suddenly so would likely not be considered emergent. Therefore, the BC Cancer REB will not approve the use of short form consents except in extraordinary circumstances, and would also require that, as soon as practicable, the informed consent document be subsequently translated in its entirety and provided to the participant in order to satisfy FDA requirements.

Non-FDA regulated studies (clinical and/or behavioural studies):

Q. Can I exclude non-English speaking participants from my study because it is inconvenient, too expensive, and/or time consuming to access interpreters and/or obtain translated documents?

A. The selection of research participants must be fair and equitable and based on the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2 2018) Principles of Fairness and Equity in Research Participation: (http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter4-chapitre4/). In addition, while language is not a prohibited ground of discrimination in our various human rights codes, language can be related to protected grounds such as ancestry, ethnic origin, and race. Our processes and policies must not allow discrimination due to the relatedness of language to these protected grounds. Provincial Language Services is also available for both clinical and research use at PHSA/BC Cancer, so it is expected that researchers use this resource.

Therefore, the exclusion of non-English speaking individuals from research is generally unacceptable unless there is 'sufficient justification' for the exclusion. Inconvenience, costs, and/or time delays will not automatically be deemed as sufficient justification for the exclusion. Of course, there may be circumstances where costs, time delays, or resource constraints associated with interpreters and/or translation may have significant ramifications for the study (for example, an investigator-initiated study with limited funding and study personnel), but these will need to be assessed by the REB on a case by case basis.

If costs, time, or resource constraints are cited as reasons for seeking to exclude non-English speaking, the REB will likely 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). In relation to industry sponsored trials, the REB strongly encourages investigators to consider the high probability of encountering non-English speaking participants given BC Cancer's diverse, multi-cultural, and multi-lingual participant population, and ensure that costs for translators/interpreters are factored into budget and contract negotiations.

Q. Do I have to get informed consent forms and/or other study-related documents translated for every study?

A. The BC Cancer REB **does not** expect informed consent forms and/or other study-related documents to be translated in every study as a matter of course (with the exception of FDA regulated studies – see above). All applications submitted for review should include a plan on how the study team will manage the use of interpreters and translated documents. The REB will review the plan with consideration of factors such as risk level of project, target participant population, sponsorship, use of validated questionnaires, expected enrollment numbers, etc. If you are unsure of how to develop your plan please contact the research ethics office before submitting.

Q. Can't I just ask an interpreter to do 'sight translation' (see Key Definitions above) during the informed consent discussion?

A. It depends. The BC Cancer REB's position is that when participants do not speak English, the informed consent form should be translated into the participant's preferred language, and an independent qualified interpreter should be used during the consent discussion (as well as throughout the project life, as necessary). The use of sight translation only especially for high risk and/or complex projects is not ideal as the threshold of 'informed' consent may not be able to be met as the level of comprehension obtained using only verbal translation of lengthy and complex document may be subject to question. However, in order to avoid enrolment delays, the BC Cancer REB may consider sight translation of the informed consent document to be sufficient for enrolment purposes, but this should then be followed up by obtaining a translated consent form and providing same to the participant as soon as practicable, but no later than six (6) weeks from the initial consent discussion.

Q. Who can act as an interpreter and/or translate documentation for use in the study?

A. It is not acceptable for family, friends, study or staff members to act as interpreters or translators. The BC Cancer REB requires that an independent third party provide interpretation and/or translation services. Provincial Language Services provides qualified interpreters and translation services.

Q. What is the process for submitting translated documents to the BC Cancer REB?

A. After the BC Cancer REB has approved the English version, an amendment may be sought for approval of translated informed consent documents/ (and/or other study-related documents). The English version of the document/s, and copy/ies of the translated document/s must be submitted with the amendment. In addition, documentation must be provided by the translator confirming their qualifications, the name and version date of the translated document, and that the translation is accurate.

See also: UBC Clinical Research Ethics General Guidance Notes Article 13.2.1: Translated Consent Documents https://ethics.research.ubc.ca/ore/ubc-clinical-research-ethics-general-guidance-notes - scroll down.

Q. What if we didn't seek prior approval from the BC Cancer REB prior to the use of an interpreter and/or translated documents?
A. Please submit a Request for Acknowledgement.

Q. When interpreters and/or translated documents are involved, who signs what?
A. The interpreters should be guiding involves persons appropriately and, importantly, the entire consenting discussion must be documented appropriately in the study records (this is key). Generally, the participant and the interpreter sign the translated informed consent document, and the BC Cancer person conducting the consenting discussion signs the English version of the informed consent document. The two forms should then be filed together (for clinical trials – refer to SOP Number: PRO-CTC-0006).

It is also important to remember that consent is an ongoing discussion that should be revised with the participant throughout the duration of their study participation – it does not end with the signing of a form. See: https://ethics.research.ubc.ca/sites/ore.ubc.ca/files/documents/SOP%20701%20INFORMED%20CONSENT%20FORM%20REQUIREMENTS%20AND%20DOCUMENTATION.pdf (S 4.2.2.the research participant will sign the translated version of the informed consent form document").