UBC Research Ethics Boards

Policy Statement: The exclusion of research participants based on language

Article 1: Background and Purpose

The Tri-Council Policy Statement (TCPS2(2014)) states that "researchers shall not exclude individuals from the opportunity to participate in research on the basis of attributes such as culture, language, religion, race, disability, sexual orientation, ethnicity, linguistic proficiency, gender or age, unless there is valid reason for the exclusion."[i] Equitable selection of participants is a primary ethical principle for all research conducted under the auspices of UBC. [ii]

The exclusion of a person based on language is considered unethical unless there is a directly relevant reason based on the research questions. For example, in a study being conducted by a linguistic researcher related to how native speakers of a certain language learn to communicate with speakers of another language, exclusion of individuals who do not speak the language being studied is justifiable and necessary for the study. In British Columbia, the mother tongue of forty percent of the population is a language other than English or French. Therefore, it is particularly important in cases where research is of therapeutic intent or is designed to investigate areas that would necessarily require certain populations who may not speak English, that researchers make efforts to recruit and include non-English speaking participants. See the UBC Clinical Research Ethics Board Guidance Notes, Article 9.3. Fundamentally, participant selection criteria for study inclusion must be germane to the research question being asked. Otherwise, the exclusion of non-English speakers or their data or biological material from a research study may result in that group not receiving fair benefits of the research.[iii]

Article 2: Statement of Principle

UBC's REBs prohibit the exclusion of non-English speaking individuals from research unless there is sufficient justification for the exclusion. Selection of research participants must be fair and equitable and based on the Tri-Council Policy Statement's Principle of Justice.

Article 3: Process for Researchers

Studies not subject to the US regulations

Most studies conducted under the auspices of UBC by UBC researchers are not US regulated. The TCPS2 2014 gives considerable latitude to the REB to determine how to deal with translation and interpretation issues. The TCPS2 does not specify when investigators should translate a complete consent form, or address questions related to translating or interpreting other documents read by participants, other than to stipulate that "When language barriers necessitate the assistance of an intermediary for communication between the research team and participants, the researcher should select an intermediary who has the necessary language skills to ensure effective communication." [iv]

The TCPS2 further provides in Article 4.1 under the heading of Appropriate Inclusion, that: "When a language barrier exists between the researcher and the prospective participant, various measures may be used to ensure effective communication in recruitment and consent discussions. For example, an intermediary who may not be part of the research project or team, but who is competent in the language used by the researchers, as well as that preferred by the participant, may assist with communication between prospective participants and researchers. The selection of an intermediary and their activities will depend on the nature, context and risks of the research." [v]

Researchers need to plan for the inclusion of non-English speaking participants throughout all stages of the research study. Justifications for excluding non-English speaking participants may be appropriate in limited circumstances, such as when there are methodological limitations based on the lack of appropriate validated instruments, surveys or assessment. In some situations, use of another language may confound the research results or not permit appropriate analysis of the data especially when protocols are designed with a small sample size. Inconvenience and lack of resources is not an adequate justification in most cases, particularly for studies with a potential for therapeutic benefit. *

When participants do not speak English, use of a translated consent is preferred. In addition to a translated consent and other study documents, an interpreter is usually required during the informed consent process and ongoing interactions with the participants. UBC's Clinical Research Ethics Board guidance notes provide direction to researchers at Guidance Note 13.2.1.

US Regulated Studies

US regulated studies are generally studies that are funded by the US Government (including Department of Health and Human Services Agencies) as well as those that are subject to the US FDA requirements.

The requirements can be found here and below:

1. **When Non-English Speaking Subjects are expected or likely to be participants**

To meet the requirements of 21 CFR 50.20, the informed consent document should be in language understandable to the subject (or authorized representative). When the consent interview is conducted in English, the consent document should be in English. When the study subject population includes non-English speaking people or the clinical investigator or the IRB anticipates that the consent interviews will be conducted in a language other than English, the IRB should require a translated consent document to be prepared and assure that the translation is accurate. As required by 21 CFR 50.27, a copy of the consent document must be given to each subject. In the case of non-English speaking subjects, this would be the translated document. While a translator may be helpful in facilitating conversation with a non-English speaking subject, routine ad hoc translation of the consent document should not be substituted for a written translation.

2. **When a non-English speaking subject is unexpectedly encountered**

investigators will not have a written translation of the consent document and must rely on oral translation. Investigators should carefully consider the ethical/legal ramifications of enrolling subjects when a language barrier exists. If the subject does not clearly understand the information presented,

the subject's consent will not truly be informed and may not be legally effective. If investigators enroll subjects without an IRB approved written translation, a "short form" written consent document, in a language the subject understands, should be used to document that the elements of informed consent required by 21 CFR 50.25 were presented orally. The required signatures on a short form are stated in 21 CFR 50.27(b)(2).

Note: *While the US regulations provide for a short form written consent document in situations where a non-English speaking participant is* ***unexpectedly*** *encountered, UBC's REBs do not encourage this practice which would ONLY be available for US regulated studies. It is important to note that for US regulated studies, consent* ***must*** *be obtained through one of the two methods outlined above.*

Article 4: Resources

The BC Provincial Language Service provides interpreting and translation services to BC health authorities. Their web-site is located at this link.

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

The Society of Translators and Interpreters of British Columbia has publicly available member directories of both translators and interpreters. Their web-site is located at this link:

http://www.stibc.org/

[i] TCPS2 2014, p. 50.

[ii] UBC Policy 89 Articles 2.1 and 7.2.3

[iii] TCPS2 2014, p. 9.

[iv] TCPS2 2014, p. 30

[v] TCPS2 2014, p. 50