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OHRI Standard Operating Procedure Addendum

Rationale: The OHSN-REB is a member of the Network of Networks (N2) and the Canadian Association of Research Ethics Boards (CAREB), and as approved by the Operations Committee, has converted to N2 - CAREB SOPs. In order to reflect specific OHSN-REB requirements, this addendum complements the N2- CAREB SOP noted below.

N2/CAREB SOP: # 701 – Informed Consent Form Requirements and Documentation

N2-CAREB SOP Guidelines	OHSN-REB Standard Operating Procedure Addendum
5.2.4 The REB requires that the translated informed consent materials be submitted for review and approval prior to use in enrolling non-English-speaking participants. The REB may require that the Researcher include a certificate or statement signed by the translator indicating that the translated materials are a true and accurate translation of the REB approved English materials;	• The investigator can submit the English documents for review and may receive a two- month conditional approval for the recruitment of English speaking subjects while the French documents are being translated. • If French documents are not submitted within the two-month period, the **conditional approval will be revoked**. • If the French translation of research documents is performed by a third party (e.g. sponsor, translation company), a certificate of translation is required or the translation must be verified by the REB official translator (or Translation Services for the University of Ottawa Heart Institute). • On investigator-initiated studies, investigators or consent form authors whose primary language is French may request that instead of having their English version translated into French, as an alternative they may have their French version translated into English (the investigator's second language). • On investigator-initiated studies, if any investigator considers themselves or their consent form author to be **completely bilingual** (regardless of their primary language, English or French), then the investigator may request an exemption from using the OHSN-REB official translator (or UOHI Translation Services). In this circumstance, the investigator **must** agree to assume responsibility, in writing, for the accuracy of the translation. The REB retains the right to have the French and/or English consent forms reviewed by an official translator at any time should concerns regarding the concordance of the content arise.

	In addition, as part of its quality management system, the REB will perform an annual audit of a sample of consent forms approved under this exemption. • Patients must be provided the opportunity to read a consent form in the language of their choice (English/French). Note: an individual may be capable to converse in English (for recruitment by English speaking personnel), but they must still be given the opportunity to read the consent in French. When a small part of a trial, such as a Quality of Life (QoL) questionnaire is not available in French as a validated survey, participants must still be offered the main consent form in French when that is their preference. Obviously, there would be no data collection for the QoL questionnaire, since it has not been validated in French for this trial. The lack of a validated questionnaire in French is NOT justification for the whole trial to seek a French exemption. • When a study is exclusively a QoL questionnaire and not validated in French, the study would qualify for the French language exemption. **Exemptions** may be granted in one or more of the following circumstances: • Anticipated recruitment period **of less than 2 months.** • Studies exclusively using questionnaires, data collection tools, cognitive and/or psychological tests that have been validated only in one language • Issues related to idiosyncrasies of the subject population (i.e. where French translation may be irrelevant for a study being done in a specific population). • Studies where there is no anticipated benefit to the study population. • Exemptions will **not** be granted because research staff is unilingual or due to funding constraints. • If the request for an exemption is denied by the Chair/Vice-Chair/Delegate, the investigator must provide the translated documents.

This N2-CAREB SOP Addendum has been reviewed and approved by the OHSN-REB Administrative Group on March 1, 2016.