

SPONSOR DOCUMENTS

A. New Protocol Submissions

The UWO REBs do not review nor approve the Sponsor's documents. The REBs will approve only UWO new protocol submission forms, letters of information, consent forms and documents such as questionnaires, forms, diaries etc used in the study. It is the responsibility of the investigator to transfer all relevant information from the Sponsor documents to UWO forms. Sponsor documents will be accepted for information only and a copy will be retained in the Office of Research Ethics files. The Office of Research Ethics will attach any reference number requested to the Approval notice to assist the investigator in tracking the approvals but inclusion of this reference does not infer review and/or approval of Sponsor documentation with the same reference.

B. Changes to Approved Protocols & Requests for Updated Approvals

The REB's will accept Sponsor documents for filing and reference, but as with initial submissions, will not review nor approve them specifically. Investigators are required to provide a detailed description of all changes requiring REB approval; relate them to the protocol/procedures/forms already approved by the REB; and discuss the implication of the change (e.g. why the upper age limit was increased from 60 to 70 years of age).

The Office of Research Ethics will attach any reference number requested to the revised or updated Approval notices to assist the investigator in tracking the revisions but inclusion of this reference does not infer review and/or approval of Sponsor documentation with the same reference.