

HSREB Guidance Document	Approval of Sponsor Documents
Effective Review	Delegated & Full Board
Version Date	September 2003

In addition to the required UWO HSREB protocol submission form and information and consent documentation; and, in accordance with the Health Canada/ICH Good Clinical Practice: Consolidated Guideline Section 3.1.2, the UWO HSREB will accept and review sponsor documents (e.g. Study Protocol, Investigator Brochures) as part of their deliberations. However, the UWO HSREB will not approve sponsor’s documents per se or in isolation.

Please note that not all members of the HSREB review the sponsor documents. This task is delegated to a subset of members with relevant and specific clinical trial or pharmacological expertise.

Even though the HSREB will review sponsor documents it does not absolve the local investigator from transferring all relevant information from the sponsor documents to UWO forms. Failure to transfer all the relevant information to the HSREB forms and fully disclose all procedures, risks and benefits may result in refusal or withdrawal of ethics approval.

The UWO HSREB Approval Notice will list all the documents reviewed by the HSREB and give ethics approval for the research described therein. The Approval Notice will contain the reference(s) (e.g. Amendment 3, March 22, 2002) shown on the sponsor documents reviewed by the HSREB to assist the investigator in tracking the approvals and revisions. However, inclusion of this reference does not infer approval of the actual and entire Sponsor document with the same reference