

<b>HSREB Guidance Document</b>	Approval of Sponsor Documents
<b>Effective Review</b>	Delegated & Full Board
<b>Version Date</b>	March 11, 2022

The Western University Health Sciences Research Ethics Board (HSREB) requires that all information, sponsor documents, and local documentation be submitted through our online application system called Western Research Ethics Manager (WREM). This includes the review and approval of any initial, amendment, reportable event, annual review, or study closure application. Ultimately, we approve the contents of the WREM application. This is in recognition that there may be local information or activity that differs from, or provides additional detail, compared to sponsor documents. The WREM application will reflect compliance with institutional policy where sponsor documents may not.

In addition to the WREM application, the HSREB will approve local Letters of Information and Consent. In accordance with the Health Canada/ICH Good Clinical Practice: Consolidated Guideline Section 3.1.2, the HSREB will accept and review sponsor documents (e.g. Study Protocol, Investigator Brochures etc.) as part of their deliberations. The HSREB will approve and/or acknowledge the sponsor’s documents as appropriate but the approval notice may note limitations on this approval (for example, that a sub-study is not occurring locally, that a third party service is not being used locally etc.).

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 WREM forms. One of the purposes of the WREM application is for the local investigator to summarize and show an understanding of the sponsor documentation. Failure to transfer all the relevant information to the WREM forms and fully disclose all procedures, risks and benefits may result in refusal or withdrawal of ethics approval.

The 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 version and/or version dates (e.g. Amendment 3, March 22, 2021) shown on the sponsor documents, as entered into the WREM application, to assist the investigator and HSREB 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.