



Office of Research Ethics

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MEMORANDUM

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| FROM: | Toni Fletcher, Manager |
| | September 18, 2009 This memo will not be updated on an annual basis but will remain on the UWO Office of Research Ethics website as long as it is valid. |
| RE: | Health Canada REB Attestation Form Guidance for Clinical Trial Sponsors: Clinical Trial Applications Guidance Document dated 2002/06/25 Health Products and Food Branch Health Canada |

With regard to Sponsor's requests for the UWO HSREB to complete the Health Canada Attestation Form we would refer you to Section 14b) of the above referenced Guidance document. "Research Ethics Board(s) may wish to use the Research Ethics Board Attestation(s) or develop similar documentation that meets the requirements of Part C, Division 5 of the Food and Drug Regulations." Please note that REB Attestation forms are not sent to Health Canada, they are to be kept on file by the Sponsor.

The UWO HSREB does not sign the Health Canada REB Attestation Form. The UWO HSREB currently uses an Ethics Approval notice that contains the required attestation as per Health Canada regulations and this should be used by the Sponsor in lieu of the Health Canada REB Attestation form. We do not issue duplicate originals, it is the responsibility of the local Investigator to retain this approval notice and provide a copy of this form to the Sponsor if requested.

If Sponsors require annual Updated Approval Notices it is the responsibility of the local investigator to submit a Request for Updated Approval to the UWO HSREB within the appropriate time frame.