

<b>UWO – HSREB &amp; NMREB</b>	<b>GUIDELINE</b>	<b>1-G-001</b>	<b>Page 1 of 1</b>
Effective date: January 1, 2001	Revisions and changes to approved protocols		

**All changes and revisions must be submitted for REB approval prior to being implemented.**

There are three levels of Review/Approval for Revisions. In general, changes to protocols that initially received Expedited approval will continue to receive Expedited or Administrative review. For studies that were initially reviewed and approved by the Full Board, administrative changes or changes that are of minimal risk to participants will receive Expedited or Administrative review and approval at the discretion of the Chair of the REB. Administrative and Expedited approvals are reported to the REB at the regular REB meetings and are documented in the REB minutes.

- Administrative review is for administrative changes only and these are reviewed and approved on behalf of the REB by one of the following: Ethics Officer, Monitoring Officer, Director of the Office of Research Ethics or the Chair of the REB or his/her designate. (1 copy of materials required)
- Expedited review is for minimal and low risk protocol changes; these are reviewed and approved on behalf of the REB by the Chair of the REB. (1 copy of materials required)
- Full Board review is for changes that are not acceptable for Expedited or Administrative review and/or must have the Full Board review for reporting to regulatory agencies. It is important to realize that the REB members do not have ready access to previously approved protocols and documents and it is the Investigator's responsibility to ensure the package prepared for REB review has sufficient information to allow the reviewers to make an informed decision about requested changes. (# copies required - [HSREB 16] or [NMREB 11])

In the case of research that has been underway for a year or more, the reviewers may take the opportunity to review the entire file and request changes to ensure the protocol and/or any documents (e.g. Letter of Information) are in line with current ethical standards.

Investigators are required to:

- Submit the REB-appropriate revision request form (see below)
- provide a detailed description of all changes requiring REB approval;
- relate them to the protocol/procedures/forms already approved by the REB and provide revised versions of the relevant documents;
- discuss the implication of the change (e.g. why more subjects are required).

*FORMS & INSTRUCTIONS:*

HSREB

- REQUEST FOR APPROVAL OF REVISIONS, AMENDMENTS, REVISED BROCHURES TO AN APPROVED PROTOCOL - Instructions
- NOTIFICATION OF REVISIONS, AMENDMENTS, REVISED BROCHURES TO AN APPROVED PROTOCOL Form

NMREB

- **NOTIFICATION OF REVISIONS, AMENDMENTS, REVISED BROCHURES TO AN APPROVED PROTOCOL Form**