

Ottawa Health Science Network Research Ethics Board/ Conseil d'éthique de la recherche du réseau de science de la santé d'Ottawa

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ANNOUNCEMENT

Major Protocol Amendments and Continuing Reviews (Annual Renewals) May Require Review at a Full Board REB Meeting

Occasionally your major amendment may require review and approval by the Full Board.

The regulations and guidance documents mandate that if an application was **reviewed at a convened Full Board REB meeting**, and the proposed change **represents more than minimal risk**, it requires review by **the Full Board** at the next available convened meeting.

Changes that represent more than minimal risk are changes that affect the rights, safety, or well being of the research participants or the integrity of the study. (*TCPS 2 (2014) 6.16; HC FDR C.05.012 (g)*)

Examples of amendments that could represent more than minimal risk could include (but not limited to): increases in drug dosing/duration of exposure; new or additional genetic testing; changes to safety monitoring; or increased risk to participant privacy/confidentiality.

For **Continuing Review (annual renewal) Reports**, if any of the changes above took place since the last renewal then the continuing review report may also require review by the Full Board.

If your amendment/renewal requires review at a full Board meeting, your protocol officer will inform you which meeting it has been assigned to, and request that you send a copy of the documents electronically.

Thank you.

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