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EFFECTIVE: September 1, 2005	Requirements for Clinical Trial Registration and Dissemination of Trial Results		

Dissemination of Research Results

In the interests of the public good and scientific advancement, and, in keeping with requirements for clinical trial registration, and the International Journal Editors statement on Clinical Trial Registration, the HSREB expects that there will be timely dissemination of clinical trial results for Phase II studies in serious or life threatening diseases and all Phase III and Phase IV clinical research. Dissemination of results may be by means of journal publication, clinical trial registration, or other appropriate means, preferably within six months but not more than one year after final data analysis.

If there is no intention to make the results public, researchers must make a compelling case as to why dissemination is not possible or desirable. Researchers may also be required to put the following statement in the Informed Consent documentation.

“There are no intentions to make the results of this study publicly available. When research sponsors or investigators conceal the presence or outcomes of selected trials, these studies cannot influence the thinking of patients, clinicians, other researchers and experts who write practice guidelines or decide on insurance-coverage policy.”

Registration of Clinical Trials

The HSREB strongly endorses the recommendations of the ICMJE regarding the requirement for registration of all clinical trials on a publicly accessible and recognized registry. To that end the HSREB will require a declaration and evidence from researchers regarding their, or the sponsor’s intention to register the clinical trial. It is highly unlikely that a clinical trial protocol submitted to the UWO HSREB will receive ethics approval if the trial will not be registered in an approved registry.

If the trial is not to be registered, researchers will be required to make a compelling case as to why registration is not possible and/or desirable. Researchers may also be required to put the following statement in the Informed Consent documentation.

“This study will not be registered with a recognized, publicly-accessible clinical trial registry and therefore it is unlikely the study results will be published by established medical journals.”

References:

- NEJM 352;23 June 9, 2005 Editorial : Is This Clinical Trial Fully Registered? – A Statement from the International Committee of Medical Journal Editors.
- ICMJE Oct 2004 Update on Clinical Trials Registration
- ICMJE Sept 2004 editorial Trials Registration
- Health Canada – Ottawa Statement