

June 27, 2019

**RE: HSREB's Requirement to have a Protocol/Research Plan.**

Dear Colleagues,

A protocol/research plan is critical for almost all types of research. Western's Health Sciences Research Ethics Board (HSREB) strongly believes research cannot be conducted in a predictable, organized fashion without a protocol because it establishes a blueprint that specifies all aspects of a study's conduct. This includes pre-specifying research questions, hypotheses, outcomes, analysis plans and the duration of follow-up.

With the inclusion of a protocol/research plan, it has been noted that the completion of the WREM application has been more consistent and comprehensive. Including a protocol/research plan also facilitates the submission of amendments in an organized and tracked fashion because having a stand-alone protocol/research plan allows you to easily track when, and what changes, have occurred to your study. Equally, having a stand-alone document allows the Ethics Officers to more efficiently review your amendments as changes to your study can be easily tracked from one iteration to the next.

While our online application platform – WREM – asks specific questions that assess regulatory and ethical considerations, a protocol provides explicit details and context related to the study's conduct. WREM is insufficient to replace a stand-alone protocol/research plan document.

The HSREB understands different disciplines will have unique approaches to writing protocols/research plans; however, the fundamentals of explaining the “who”, “what”, “when”, “where” and “how” of a study will still apply. A protocol/research plan should include sufficient detail for reproducibility and allow for future changes to be made through amendments.

**As of January 1, 2020, all initial HSREB applications (delegated level 1 & 2 and full board) must include a protocol/research plan. NOTE: this policy is not applicable to applications submitted to the Non-Medical (NM) REB.**

The Office of Human Research Ethics has a guidance document and protocol/research plan templates to help researchers develop this document. If you have any questions, please contact a member of the [Office of Human Research Ethics](#).

Sincerely,

Ms. Erika Basile, Director, Office of Research Ethics, Western University

On behalf of

Dr. Joseph Gilbert, HSREB Chair, Western University

Dr. Philip Jones, HSREB Vice-Chair, Western University

Dr. Doreen Matsui, HSREB Vice-Chair, Western University