



Note to File

Date:	2018NOV02
Re:	CAN/CGSB 191.1-2013 Research Ethics Oversight of Biomedical Clinical Trials
Title:	Withdrawal of Standard CAN/CGSB-191.1-2013 Research ethics oversight of biomedical clinical trials.

On September 11, 2018 the following email was circulated from Jennifer Jimenez, Team Leader Standards Division, Canadian General Standards Board to the Research Ethics Board distribution list:

From: jennifer.jimenez@tpsgc-pwgsc.gc.ca [<mailto:jennifer.jimenez@tpsgc-pwgsc.gc.ca>]

Sent: September-11-18 14:47

To: Distribution@ssf.scc.ca

Subject: Withdrawal of Standard CAN/CGSB-191.1-2013 Research ethics oversight of biomedical clinical trials

<https://ssf.scc.ca/forums/cgsb-ongc/dispatch.cgi/f.researcheth/showFolder/100430>

Forum: Research Ethics Board

Entry: 19. Withdrawal of Standard CAN/CGSB-191.1-2013 Research ethics oversight of biomedical clinical trials.

From: Jennifer Jimenez

Date: Tuesday September 11, 2018 02:45 PM EDTDear Members,

This notice is to advise you that, effective July 2018, CGSB has withdrawn the Standard CAN/CGSB-191.1-2013 Research ethics oversight of biomedical clinical trials.

As an accredited Standards Development Organization, CGSB must follow the procedures set out by the Standards Council of Canada (SCC) for the development and maintenance of National Standards. The SCC requires that regular maintenance is conducted to determine whether a Standard should be reaffirmed, revised or withdrawn. The review cycle is normally five years from the publication date of the latest edition of the Standard.

Additionally, CGSB operates on a revenue dependent cost-recovery basis to maintain its Standards collection. Various sponsors such as Federal, Provincial, Municipal and the private sector / industry may contribute financially towards a project. For the work on CAN/CGSB-191.1, Health Canada was the single sponsor to support the initial development of this Standard back in 2013. At this time, however, Health Canada has indicated to CGSB that they no longer wish to financially support this Standard going forward and that there may be other documents available for use in this subject area.

CGSB is fully aware of the time and effort it took to develop the first edition of this Standard and it is unfortunate that the withdrawal of this Standard has been the outcome. CGSB remains open to discussing future editions and possible solutions going forward should Health Canada or the industry

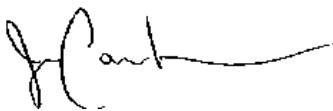
wish to do so.

If you have any questions, please feel free to contact.

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As a result of the withdrawal of the Standard CAN/CGSB-191.1-2013 Research ethics oversight of biomedical clinical trials, the policies and standard operating procedures (SOPs) for the Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board (HSREB) are not currently reflective of the withdrawal of these regulations.

The HSREB SOPs will be updated in 2019 to reflect the withdrawal of this regulation. Until all references to these regulations have been removed from the HSREB policies and procedures, please disregard all references to the Standard CAN/CGSB-191.1-2013 Research ethics oversight of biomedical clinical trials. This regulations will no longer be enforced by the HSREB.

Name:	Jennifer Couture
Role:	Ethics Compliance Advisor
Signature:	
Date:	2018NOV02