Health Canada Announces Changes to Medical Device Trial Approval Process

Health Canada has released a new guidance document for research teams conducting device trials. The document titled “Applications for Medical Device Investigational Testing Authorizations (ITA)” is similar to the guidance document already available for investigational new drug applications.

Of note is that Health Canada has changed their requirements regarding the timing of Research Ethics Board (REB) approval. In the past, an ITA could not be submitted to Health Canada until REB certifications/approvals were in place. As of October 1, 2018, an ITA can be submitted before REB approval has been received.

Health Canada still requires to be notified about REB certification/approval prior to the start of a device trial. This is now done by completing the “Application for Revised Investigational Testing Authorization Form” and sending it to: hc.devicelicensing-homologationinstruments.sc@canada.ca.

For more information, please refer to the Health Canada email below or reach out to linda.longpre@ucalgary.ca.

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Notice: Applications for Medical Device Investigational Testing Authorizations – Changes to the Timing of Research Ethics Board (REB) Approval


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Notice: Applications for Medical Device Investigational Testing Authorizations – Changes to Information Requirements


Applications for Medical Device Investigational Testing Authorizations Guidance Document - Summary

Applications for Medical Device Investigational Testing Authorizations Guidance Document

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