From: clinical-coordinators-l-bounces@mailman.ucalgary.ca on behalf of CCCR
To: clinical-researcher-L@mailman.ucalgary.ca; clinical-coordinators-l@mailman.ucalgary.ca
Subject: [Clinical-coordinators-l] CCCR News: Health Canada Announces Changes to Medical Device Trial Approval Process
Date: October 11, 2018 1:37:47 PM

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.

Calgary Centre for Clinical Research
Health Sciences Centre, Suite G351

From: Policy Bureau Enquiries (HC/SC) <hc.policy.bureau.enquiries.sc@canada.ca>
Sent: Tuesday, October 2, 2018 8:29 AM
To: Policy Bureau Enquiries (HC/SC)
Subject: Notice: Applications for Medical Device ITA – Change to the Timing of REB Approval/Avis : Demandes d'AEE pour les instruments médicaux – Modification au moment de l'approbation du CER

Dear stakeholders/Aux parties intéressées,

Please be advised of the following posting on Health Canada's website concerning changes to certain information requirements with respect to investigational testing, namely, the timing of REB approval.

Veuillez prendre note d' une publication au sujet de certaines modifications aux renseignements requis pour les essais expérimentaux, c`est-à-dire le moment de l`approbation du CER.

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Notice: Applications for Medical Device Investigational Testing Authorizations – Changes to the Timing of Research Ethics Board (REB) Approval
https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/activities/announcements/changes-information-requirements.html

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

www.canada.ca

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

https://www.canada.ca/fr/sante-canada/services/medicaments-produits-sante/instruments-medicaux/activites/annonces/modification-exigences-matirre-renseignements.html

Applications for Medical Device Investigational Testing Authorizations Guidance Document - Summary
https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/investigational-testing-authorizations-guidance.html
https://www.canada.ca/fr/sante-canada/services/medicaments-produits-sante/instruments-medicaux/information-demandes/lignes-directrices/autorisation-essai-experimental-ligne-directrice.html

Applications for Medical Device Investigational Testing Authorizations Guidance Document
https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/investigational-testing-authorizations-guidance/guidance-document.html
https://www.canada.ca/fr/sante-canada/services/medicaments-produits-sante/instruments-medicaux/information-demandes/lignes-directrices/autorisation-essai-experimental-ligne-directrice/document-reference.html

Bureau of Policy, Science and International Programs