Information on Health Canada's Interim Order Respecting Clinical Trials for Medical Devices and Drugs Relating to COVID-19

On May 23 2020, Health Canada issued an Interim Order to facilitate the conduct of COVID-19 clinical trials while maintaining the participant safety and study data integrity.

Notable highlights found within the Interim Order are:

1) Expanded definition of a Qualified Investigator:
    a. Including other health care practitioners, such as nurse practitioners, pharmacists and midwives.

2) Acceptable alternate forms of informed consent:
    a. Remote written consent of participant
    b. Non-written informed consent through the reading of the informed consent form to participant with a witness present

3) Good Clinical Practice (GCP) still applies to the conduct of COVID-19 clinical trials

To access the Interim Order and its associated guidance document, please follow the links provide:

1) Interim Order Respecting Clinical Trials for Medical Devices and Drugs Relating to COVID-19: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/interim-order-respecting-clinical-trials-medical-devices-drugs.html

2) Applications for drug clinical trials under the Interim Order: Guidance document: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/interim-order-respecting-clinical-trials-medical-devices-drugs/drug-guidance.html#a101

Note: A copy of this guidance document should be placed into the Investigative Study File.

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