The Guidance Document: Part C, Division 5 of the Food and Drug Regulations “Drugs for Clinical Trials Involving Human Subjects” (GUI-0100) was published online today, August 20, 2019 and can be found on the Health Canada website at: https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-clinical-practices/guidance-documents/guidance-drugs-clinical-trials-human-subjects-gui-0100.html

This guidance document will help those involved in the conduct of clinical trials of drugs in human subjects in Canada to comply with Part C, Division 5 of the Food and Drug Regulations (the Regulations) and to understand the International Council for Harmonisation (ICH) Guidance Document: Good Clinical Practice: Integrated Addendum to E6(R1) ICH Topic E6(R2) in the Canadian context.

The content of GUI-0100 has taken into consideration:

- Comments received from the public consultation on the draft of GUI-0100 held between December 15, 2017 and April 15, 2018.
- Recommendations from the Initiative to Streamline Clinical Trials (ISCT) – Guidance for Investigator-Sponsors (February, 2014), which address issues raised by the academic/non-commercial research community.
- The content of Guidance for Records Related to Clinical Trials (GUI-0068, May 2006) published by Health Canada, which is replaced by GUI-0100.
- Frequently asked questions posed by stakeholders to Health Canada’s Clinical Trial Compliance Program over the years, seeking clarification on regulatory interpretation.
Should you have any further questions, please do not hesitate to contact us at GCP_BPC@hc-sc.gc.ca.