

Summary of Changes

Clinical Trial Protocol Template (Version 6 to 7)	
Page 1	Updated information to guide investigators who are conducting clinical trial of medical devices (that are not regulated by HSA) to use the Research Study Protocol template.
Page 4	Added fields for multi-study site(s).
Section 7.1	Updated definitions of Adverse Events.
Section 7.2	Adjusted the language on reporting requirements to CIRB.
Section 7.3	Adjusted the language on reporting requirements to HSA.
Section 7.6	Added HSA reporting requirements for clinical trial which is also a trial on medical device.