CIRB Updates

6 Sep 2024

CIRB Participant Information Sheet and Consent Form Template

The CIRB Participant Information Sheet and Consent Form Template has been updated from version 13 to 14. Major change has been made to this template to provide guidance and examples of consent language to fulfil consent element specified under section 12(2)(c) of the HBRA.

Please refer to Table 1 of the CIRB Participant Information Sheet and Consent Form Template for the Management & Implementation Plan for The "Affected Studies". For "Affected Studies", the ICD must be updated by 31 Dec 2024.

Affected Studies	• Ongoing, approved HBR study involving removal of human tissue • Ongoing, approved CT study involving collection, storage, supply or use of leftover human tissue for purposes outside of the regulated clinical trial (e.g. for biobanking or future research) – Such activities should comply with the relevant requirements of the Human Tissue Framework under the Human Biomedical Research Act (HBRA)

For ongoing research studies, where the Informed Consent Documents are already in compliance with the applicable consent requirements as stipulated in the Human Biomedical Research Act (HBRA), Health Product Act (HPA), and Medicine Act (MA), the researchers can continue to use the current approved ICDs without further modification.

Other minor changes are described in a separate document - Summary of Changes: Participant Information Sheet & Consent Form (version 13 to 14).

If you have any questions, please contact CIRB at irb@singhealth.com.sg.