CIRB Updates

1 March 2023

The CIRB Updates cover the following:

1. Participant Information Sheet and Consent Form Template Update
2. Revised Guidance on Requirements For Informed Consent Documents

Note: All the documents and templates mentioned in this updates can be downloaded from RICE website, click here.

1. Participant Information Sheet and Consent Form Template Update

The template has been updated to include the following:

a) Single Informed Consent Document (ICD) for multiple SingHealth sites study – The use of Single ICD is mandatory for Investigator Initiated Studies. Industry Sponsored Studies are welcomed to adopt the single ICD approach as well.

b) The guidance notes and examples of consent language have been added/revised for the following:

- Videography/photography
- Linkages of research data with other sources
- Deposition of research data into databases
- Destruction of samples following withdrawal from research
- Liability exclusion on data breach
- Information and Consent Form future research

Please refer to Page 1 – 2 of the template for details. Annex A listed some questions to help researchers on the use of Single ICD for multiple SingHealth sites study.

2. Revised Guidance on Requirements For Informed Consent Documents

The guidance has also been updated to include the changes of the Participant Information Sheet and Consent Form Template.

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

For previous CIRB Updates, please click here.

Annex A

Frequently Asked Questions

The use of Single Informed Consent Document (ICD) for multiple SingHealth sites study

1. **What should I do when there is a change of Principal Investigator (PI) or site-PI in any of the study sites.**

   The single ICD will need to be updated to reflect the change. Upon CIRB's approval of the amended ICD, all study sites to use the latest CIRB-approved ICD.

2. **Is there a need to re-consent participants recruited at the study sites where there is a change of PI or site-PI information?**

   According to FDA guidance for informed consent (contact), the update of new contact information must be provided to participant and can be done through various ways. There is no mandatory requirement to re-consent. Please click on the link for more information.

3. **Participant A is transferred from site A to site B. Should the Participant A be re-consented by site B.**

   Yes, re-consent should be obtained from Participant A for the participation at site B.

4. **Am I allowed to use separate ICD for each SingHealth study site where there are differences in the study procedures?**

   The recommendation is to use a single ICD. CIRB will assess on case-by-case basis on the request for use of separate ICD for each SingHealth study site. Justification should be included in the CIRB application.

5. **Can the ICD be printed with the study site checked instead of having the consent taker manually checked the box?**

   Pre-checked of the study sites before printing is acceptable.

6. **I have an existing approved multiple SingHealth sites study. Can I implement the single ICD for my study?**

   There is no mandatory requirement to update existing approved study (i.e. study approved prior to 1 Mar 2023) to use single ICD. You may implement single ICD if preferred.

7. **Should multi SingHealth sites study sponsored by industry adopt the Single ICD?**

   We understand that industry sponsored studies may need to align with the global approach for the same study and may not be able to follow the single ICD's requirement. Hence, the single ICD is not a mandatory requirement for industry sponsor studies. However, we encourage industry sponsored studies to use single ICD where possible.