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CIRB Updates

30 August 2022

The CIRB Updates cover the following:

1. Assent Requirements and Template Update
2. Informed Consent Document (ICD) Template Update
3. Revised Guidance on Requirements For Informed Consent Documents
4. New Consent Elements Checklist for Clinical Trials
5. CIRB Application/ Amendment Form Update
6. Change of CIRB Hotline Number

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

1. Assent Requirements and Template Update

(a) The Assent Form template has been revised to include:

- More examples of language that researchers can incorporate into the study documents, as needed, to suit their specific research study.
- Provision for documentation of impartial witness, where applicable, if the child/ participant is unable to read, and/or write his/her name and/or date on the assent form.

(b) The guidelines for assent requirements have been updated as follows:

- All new IRB applications submitted on and after 1 October 2022, are required to implement the changes (revised guidelines), outlined in **Table 1**.
  Note: *The term "submitted" refers to the date when the IRB application reaches CIRB via iSHaRe, upon completion of the institution endorsement process.*

Table 1: Revised guidelines for assent requirements and documentation

(Applicable to new IRB applications submitted on and after 1 October 2022)

	Child has sufficient understanding and intelligence	**Child does not have sufficient understanding and intelligence**
0 to 5 years	Written agreement of the child is not required	Written agreement of the child is not required

6 to 11 years	Assent Form	Assent Form *(unless waived by the IRB)*
12 to 20 years	Consent Form	Assent Form *(unless waived by the IRB)*

- Studies submitted and/or approved before 1 October 2022 may continue with the "existing" assent requirements and documentation, as outlined in Table 2 till study completion, unless the researchers make the voluntary determination to implement the changes.

Table 2: "Existing" guidelines for assent requirements and documentation

(Applicable to studies submitted and/or approved before 1 October 2022)

	Child has sufficient understanding and intelligence
0 to 5 years	Written agreement of the child is not required
6 to 12 years	Assent Form
13 to 20 years	Consent Form

2. Informed Consent Document (ICD)Template Update

The ICD template has been revised to include:

- Change in Security Marking label.
- Change of CIRB hotline number.
- More examples of language that researchers can incorporate into the study documents, where applicable, to suit their specific research study.

3. Revised Guidance on Requirements For Informed Consent Documents

The guidance document has been expanded to include additional consent requirements for research involving genetic/genomic testing.

4. New Consent Elements Checklist for Clinical Trials

Please be reminded for new clinical trials regulated under the Health Products Act (HPA) and Medicine Act (MA) that are submitted to H.S.A after 1 August 2021, additional consent elements are required when the trials involve storing of tissue.

For trials involving the collection, storage, supply or use of additional human tissue/ leftover human tissue for purposes outside of the regulated clinical trial, the consent elements should comply with the requirements of the Human Biomedical Research Act (HBRA) Section 12(2).

Please use the new "Consent Checklist for Clinical Trials regulated under HPA/MA" as a guidance to ensure the consent elements are included in the Informed Consent Documents.

5. CIRB Application/ Amendment Form Update

The following sections are updated:

Section	Description
D1	➢ Amended “Device” to “Medical Device”. ➢ Additional information on study involves investigating of medical device(s).
M5	➢ Guidance notes for assent requirements and documentation have been updated. Description for the options with regards to documentation of assent has also been rephrased.

6. Change of CIRB Hotline Number

With effect from 1 October 2022, the CIRB hotline number will be changed to 8126 3660. The current number 6323 7515 will be discontinued. When callers dial in to 6323 7515, there will be a call announcement to inform them of the new number.

The new CIRB hotline number has been updated in the latest version of the CIRB Informed Consent Document (ICD) template. Researchers should update their ICD with the new CIRB hotline number the soonest possible or latest before 1 October 2023.

The following are some guidelines for your information:

<u>Implementation for the change of CIRB hotline number</u>

	What action is required from the Researchers
New research studies	**IRB application (In draft)** ➢ Use the latest version of the ICD template with the new CIRB hotline number.

	IRB application (Pending IRB review) ➢ Update the ICD with the new CIRB hotline number.
Ongoing research studies	**Amendment (change of CIRB hotline number <u>only</u>)** ➢ Revise the ICD with the new CIRB hotline number. ➢ Include a note-to-file in Investigator Site File, to document the revision of ICD with the new CIRB hotline number and implementation date. Change of version number of the ICD is not required if this is the only revision. ➢ Submit the revised ICD in the next study amendment, for IRB review and approval. *(Note: Immediate submission for IRB review will not be required.)* **Amendment (change of CIRB hotline number + other amendments)** ➢ Revise the ICD with the new CIRB hotline number. ➢ Submit the revised ICD together with other amendments, for IRB review and approval.

<u>Communication to Participants on the change of CIRB hotline number</u>

	What should the Researchers do?
Participants who have ongoing follow-up procedures/ visits	➢ Inform participants of the change in CIRB hotline number. Document the communication on study file. ➢ Re-consent from the participants is not required.
Participants who have completed all study procedures; with no further follow-up visits	➢ No need to inform participants on the change in CIRB hotline number. ➢ Re-consent from the participants is not required.

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