INITIAL IRB APPLICATION FORM CHECKLIST

This document serves to facilitate the study team in preparing the Application Form and Research Office Checker in checking new application on ECOS.

1. Minimum Training Requirements

a. All investigators conducting Human Biomedical Research and other research are required to complete:
   i. CITI Program (Biomedical Research Investigators and Key Personnel Module); and
   ii. SingHealth eHBRA training or equivalent.

b. All investigators conducting Clinical Trials regulated under Health Products Act or Medicine Act are required to complete:
   i. CITI Program (Biomedical Research Investigators and Key Personnel Module); and
   ii. ICH GCP Course.

c. Please refer to the RICE website for more information.

d. Please ensure the required training documents are uploaded in the "Profile and Minimum Training Information" on ECOS.

2. Application Form

Below are important points to take note when filling up the Application Form on ECOS.

Sections	Notes
C1 – Information on Study Funding	Please note that if the grant is yet to be approved and study initiation is dependent on grant, the IRB may only start reviewing the study when the preliminary result for the grant application is available.
D1 – Form Type	Please select "Application Form" if the study is a Human Biomedical Research and/ or restricted Human Biomedical Research regulated under the Human Biomedical Research Act (HBRA). "Exemption Application Form" shall not be used for studies regulated under HBRA.
D2 – Study Classification	• For studies involving the testing and/ or study of medical devices and not requiring Clinical Trial Certificate (CTC), Clinical Trail Authorisation (CTA) or Clinical Trial Notification (CTN), please ensure "(b) Human Biomedical Research - Regulated by Human Biomedical Research Act (MOH)" is selected in D2. • If "Clinical Trial – Regulated by Health Products Act/ Medicines Act (HSA)" is selected, please ensure "Interventions/ Invasive Procedures" is selected in D3.

D3 – Study Procedures involved	If the study involves any of the items listed in D3, they should be selected. More than one items can be selected.
D5 or F3 – Type(s) of Consent	Please select those that apply in D5 or F3.
E3 or G7 – Experimental Designs and Procedures	• Please attach study related materials (Data Collection Form, Questionnaires, Surveys, Focus Group Discussion script etc.) that will be used for the research participants in E3 or G7. • For Data Collection Form: a. If the data collection form is to be used as a case report form, it should not contain any research participant identifiers (e.g., Name, NRIC, Date of Birth.) or allow sticker labels containing research participant identifiers to be pasted on it. This is to ensure data confidentiality. b. If the data collection form is to be used as a source document, it is crucial for research participant identifiers to be included for traceability purposes (information should be recorded, handled, and stored in such a way that allows its accurate reporting, interpretation, and verification). Note that the data collection form should be filed with secure access to protect the privacy of the research participants and confidentiality of data, as how other types of source documentation (e.g., patient's medical records) are maintained.
E7 or G16 – Potential Risks	Please select the applicable potential risks listed and explain in the textbox provided.
E10 or G19 – Study Protocol	Please check the following: • The version number and date should tally throughout the document. • Study Title must tally with that stated in A1 of the Application Form.
I1 – Medical Device	Please add one medical device at a time if more than one medical device will be tested and/or studied.
J13 – Informed Consent Document(s)	Please use the CIRB latest consent template. The template can be downloaded from the CIRB website.
V – Research Data – Use of Software or mobile applications	If software and/or mobile application will be used in this study, please upload the product brochure/ diagram/ user manual in V1.

W1 – Human Biological Materials	Please add one Human Biological Material (existing or prospective) at a time if more than one type of material will be collected.
All Sections	• "NA/ Not applicable/ Nil/ None/ Not required/ Not necessary/ As above/ Refer to earlier Section" or similar is not acceptable. • Attachments must be readable and can be opened using common applications, e.g., pdf, word, excel. • Information in the study documents should tally with the information provided in the Application Form. • Do not submit blank or draft documents for review. • All study documents must be given an appropriate document title (to reflect content of the document), pagination (If the study documents have more than one page), version number and version date (Good Documentation Practice) should be included. • Upload attachments to the correct location (e.g., Participant Information Sheet and Consent Form should be attached under Section J13 and not under 'Other Attachments' section). • The same document should not be uploaded twice (e.g., Participant Information Sheet and Consent Form should be attached at Section J13 only and not in both the Section J13 and 'Other Attachments' section). • Do not include table(s) and image(s) in the Application Form. Please submit the table and image as an attachment. • Please ensure the latest document templates (e.g., Participant Information Sheet and Consent Form, Assent Form etc.) are used. Please refer to CIRB website for the latest templates.

3. Endorsement

For single site studies, the application will reach the IRB after the Research Office checked (if applicable), Department Representative endorsed and Institution Representative endorsed. For multi-site studies, it is similar to the single site studies, the application will reach the IRB after all the Institution Representatives have completed endorsement.