CIRB Initial Application Checklist

This checklist serves to facilitate the study team (Principal Investigator, Co-Investigator and Study Team Member) in preparing the application as well as the Research Development Office (RDO) in checking new submissions on iSHaRe via e-CIRB.

Application Form Sections	Title of Sections	List of Criteria
B2	Study Team - Department, Institution and Designation	• The correct appointment of study team members should be reflected. • Latest Designation of all members in the study team should be reflected, e.g. Senior Consultant.
B2	Study Team - CV	• All CVs should be attached to "CV" column of the correct study team member. (For example Dr A's CV should be uploaded in the same row under Dr A's name and in the "CV" column) • The CIRB does not require personal data such as NRIC, home address, mobile number and date of birth on the CV. To protect your personal data, such information should not be included. CV submitted in iSHaRe with such personal data will be handled in the same manner as other submitted documents.
B2	Study Team - CITI	• The correct CITI certificate should be attached to "CITI" column. Note that CITI certificate (GCP module) is not acceptable. a. Study team from SingHealth and partner institutions should submit the CITI certificate of the required module (i.e. Biomedical Research Investigators and Key Personnel). b. Study team from NHG and partner institutions should submit the CITI certificate according to the NHG DSRB requirements. c. Study team who are not from SingHealth or NHG and partner institutions may upload to "CITI" column the completed Waiver of CITI Certification Form or the CITI certificate of the module required by his/her institution.
B2	Study Team – Local GCP	• Local GCP* Certificate of Attendance for PI and Site-PI conducting clinical trials should be uploaded at "Local GCP" column. Note that CITI certificate (GCP module) is not acceptable. • Local GCP* Certificate of Attendance for non PI or PI not conducting clinical trials need not be attached. *Local GCP workshop organised by SingHealth Academy, National Healthcare Group (Classroom-based or Online) and National University Health System.

Application Form Sections	Title of Sections	List of Criteria
B2 and F16	Study Team and Research Methodology	• If "Yes" is selected at section F16, listing of PI & Co-Is at section B2 of the CIRB Application Form or CIRB Exemption Application Form must tally with the Protocol, if the names of the PI, Co-Is, Study Team Members are listed. (Note: It is not a mandatory requirement to list the PI and Co-Is in the Protocol. E.g. For Pharmaceutical/ Industry Sponsored studies).
B2 and F17	Study Team and Research Methodology	• If the option "Informed Consent will be taken for all study subjects" or "A combination of both Informed Consent and Waiver of Consent is required for different study populations" is selected at section F17, at least one study team member must be checked for the "Involve in Informed Consent" column in section B2.
D1	Nature of Research	• The correct category that describes the research study should be selected. • For clinical trials requiring Clinical Trial Certificate (CTC), Clinical Trial Authorisation (CTA) or Clinical Trial Notification (CTN) from the Health Sciences Authority (H.S.A), the option "Clinical Trials (which includes Drug, Medical Device and Procedure Trials)" should be selected.
F8 and P6	Research Methodology and Consent Process-Consent Required	• If Participant Information Sheet and Consent Form offers the provision for re-identification and return of incidental findings, the plan should be described.
F10	Research Methodology	• "NA/ Not applicable/ Nil/ None/ Not required/ Not necessary/ As above/ Refer to earlier Section" or similar is not acceptable.
F10	Research Methodology	• Data collection form is uploaded. a. If the data collection form is to be used as a case report form, it should not contain any participant identifiers (e.g. Name, NRIC, Date of Birth, etc.) or allow sticker labels containing 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 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 participants and confidentiality of data, as how other types of source documentation (e.g. patient's medical records) are maintained. • Data Collection Form should be paginated, dated and/or version number.

Application Form Sections	Title of Sections	List of Criteria
F16	Research Methodology	• Protocol should be paginated, dated and/or version number. • Protocol Title must tally with that stated in section A1 of the CIRB Application Form or CIRB Exemption Application Form.
M5, O4 and P6	Consent documents for participants including cognitively impaired person and children (assent)	• Participant Information Sheet and Consent Form/ Assent Form should be paginated, dated and/or version number. • Correct Participant Information Sheet and Consent Form is used for different cluster/sites. Ensure that the compensation clause and PDPA statement are in line with the institution policies. • Protocol Title must tally with that stated in section A1 of the CIRB Application Form or CIRB Exemption Application Form. • For human biomedical research regulated under the Human Biomedical Research Act (HBRA), all the mandatory consent elements from Section 12(1) of HBRA are present. If the research involves removal, donation and use of Human Tissue, all the consent elements from Section 12(2) of HBRA are also present. For the mandatory elements, even if the study does not have a provision for it, there must be a negative statement. Refer to Appropriate Consent Checklist for HBR study for the consent elements.
R1(v)	Research Data Confidentiality	• Research data should be retained for a minimum of 7 years after completion of research study or date of publication of the research using the research data, or for a longer period if required by the applicable regulatory requirements or by an agreement with the sponsor, whichever is later. (Source: SingHealth Cluster Research Data Management Policy – General Policy)
Q1	Consent Process-Waiver Required and Other Attachments	• For human biomedical research regulated under the Human Biomedical Research Act (HBRA) requesting for waiver of informed consent under Section Q, the SingHealth PDPA Impracticability Calculator must be completed and uploaded.
Endorsements Page	Endorser	• Click the endorser icon to check if Department Representative (DR) or Institution Representative (IR) is listed. • If it is not listed, the Conflict of Interest (COI) DR or IR needs to be selected before proceeding to click the RDO Check icon.

Application Form Sections	Title of Sections	List of Criteria
All	-	• Attachments must be readable and can be opened using common applications, e.g. pdf, word, excel, etc. • Do not submit blank documents. • Upload attachments to the correct location (e.g. Informed Consent Document should be attached under section P6 and not under 'Other Attachments' section). • The same document should not be uploaded twice (e.g. Participant Information Sheet and Consent Form should attached at Section P6 only not on both Section P6 and 'Other Attachments; section). • The version number and version date stated in the documents should tally with the version number and version date on the CIRB Application Form or CIRB Exemption Application Form. • Do not include table and image in the Application Form. Please submit the table and image as an attachment.

Minimum Training Requirements (CITI certificate)

Study Team Members from SingHealth and Partner Institutions	CITI (Biomedical Research Investigators and Key Personnel or 11 core modules) <u>Core Modules</u> 1. Belmont Report and CITI Course Introduction 2. History of Human Subjects Research 3. Informed Consent 4. Social and Behavioural Research (SBR) for Biomedical Researchers 5. Records-Based Research 6. Genetic Research in Human Populations 7. Populations in Research Requiring Additional Considerations and/or Protections 8. Vulnerable Subjects - Research Involving Prisoners 9. Vulnerable Subjects - Research Involving Children 10. Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates 11. Conflicts of Interest in Research Involving Human Subjects
Study Team Members from NHG and Partner Institutions	CITI (10 core modules and 5 elective modules) <u>Core Modules</u> 1. Introduction 2. History and Ethical Principles 3. Informed Consent 4. Social and Behavioural Research for Biomedical Researchers 5. Records-Based Research 6. Research with Protected Populations - Vulnerable Subjects: An Overview 7. NHG - Singapore. Overview of Domain Specific Review Board (DSRB) Review Process 8. NHG - Singapore. Overview of the Regulatory Framework and Guidelines in Singapore 9. National Healthcare Group – Singapore FCOI CITI Module 10. Conflict of Interest in Research Involving Human Subjects