SingHealth
Defining Tomorrow's Medicine

SingHealth Centralised Institutional Review Board (CIRB)

e-CIRB Application Form and Exemption Application Form

Disclaimer: This document is for reference only and not to be submitted. Please log-in to iSHaRe for submission of CIRB Application Form and Exemption Application Form.

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1. GENERAL INFORMATION

a. Either the CIRB Application Form or CIRB Exemption Application Form can be submitted for IRB review. Depending on the form type or questions selected, only certain sections and questions will be displayed.

Section D	When CIRB Application Form is selected.
Question F1-17	When CIRB Application Form is selected.
Question F1, 2, 8-16	When CIRB Exemption Application Form is selected.
Section G	When CIRB Application Form is selected and "Clinical Trials" is selected in Question D1.
Section J	When CIRB Exemption Application Form is selected.
Section L, M, N,O	When CIRB Application Form is selected and relevant options in Question K7 is selected. The options in Question K7 are: - "Pregnant Women, Foetuses and Neonates" -> Section L displayed - "Children" -> Section M displayed - "Prisoners" -> Section N displayed - "Cognitively Impaired Persons" -> Section O displayed
Section P, Q	When CIRB Application Form/ CIRB Exemption Application Form is selected and relevant options in Question F17/ J2(v) is selected. The options in Question F17/J2(v) are: - "Informed Consent" -> Section P displayed - "Waiver of Informed Consent" -> Section Q displayed - "A combination of both Informed Consent and Waiver of Consent" is selected -> Section P and Q displayed

b. Mandatory fields in this document are indicated by "#".

c. Texts in the boxes include additional information which will be useful during the creation of the application form. These are similar to the orange information bubble ( ) found on iSHaRe e-CIRB.

d. For attachment table, do not enter long strings of text separated by underscore in the "Description" field.

2. APPLICATION FORM SECTIONS

Selection of Application Form

1. Please select the appropriate form for submission to the CIRB. #

- CIRB Application Form

  Principal Investigators should use the CIRB Application Form if their research activity does not qualify under the Exempt Category. Submissions using this Application Form will be reviewed via the Full Board or Expedited route.

- CIRB Exemption Application Form

  1. The criteria for the Exempt category do not apply when the research activity:
     (i) involves prisoners
     (ii) involves children, when the research involves survey or interview procedures or observations of public behaviour, except when the investigator(s) do not participate in the activities being observed.
     (iii) is a US FDA-regulated research activity.

  2. If the application does not fall under any of the following categories and is submitted using the CIRB Exemption Application Form for Exempt Review, the application has to be re-submitted using the CIRB Application Form when it reaches CIRB.

  NOTES: If the information is not publicly available and you wish to collect identifiers, your study will not qualify for Exemption. Please choose the CIRB Application Form.

Please select the Exemption Application categories. ***# (if CIRB Exemption Application Form is chosen)***

[ ] Category 1 - Normal Educational Practices and Settings

Research conducted in established or commonly accepted educational settings, involving normal educations practices, such as:

(i) research on regular and special education instructional strategies; or
(ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

[ ] Category 2 - Anonymous Educational Tests, Surveys, Interviews, or Observations

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observations of public behaviour, unless:

(i) information obtained is recorded in such a manner that human subjects can be identified, directly or indirectly through identifiers linked to the participants; and
(ii) any disclosure of the human subjects' responses outside of the research could reasonably place participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.

To qualify for exemption under this category, you cannot collect information that allows you to identify the participants (whose cells/tissues/data are being used in this study) directly or through identifiers linked to the participants, unless information is publicly available.

NOTES: If the information is not publicly available and you wish to collect identifiers, your study will not qualify for exemption. Please choose the CIRB Application Form.

[ ] Category 3 - Identifiable Participants in Special Circumstances

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behaviour that is not exempt under Exemption Category 2, if:

(i) the human subjects are elected or appointed public officials or candidates for public office; or
(ii) statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

[ ] Category 4 - Collection of Existing Data

Research involving study of existing data, documents, records, pathological specimens, or diagnostic specimens, if:

(i) these sources are publicly available* (e.g. data accessible to general public such as library literature or internet) or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants; and
(ii) the reviewed material should be in existence at the time the research is proposed and should not be prospectively collected.

*Medical records are not publicly available because they are restricted to designated doctors and healthcare professionals only.

NOTES: Data is considered identifiable if any of the following information are present:
a. Participant Name
b. Address - Street
c. Address - Postal Code
d. Elements of Dates related to a participant in combination with other identifiers. For example, date of birth, admission or discharge dates, date of death
e. Telephone Number
f. Fax Number
g. Electronic Mail Address
h. NRIC Number
i. Medical Record Numbers
j. Health Plan Beneficiary Numbers
k. Account Numbers
l. Certificate/License Numbers
m. Vehicle Identification Number and Serial Numbers Including License Plate
n. Medical Device Identifiers and Serial Numbers
o. Web URLs
p. Internet Protocol (IP) Address
q. Biometric Identifiers (finger and voice prints)
r. Full Face Photographic Images
s. Any Unique Identifying Number, Characteristic or Code Link to Identifier (code)

To qualify for exemption under this category, you cannot collect information that allows you to identify the participants (whose cells/tissues/data are being used in this study) directly or

through identifiers linked to the participants, unless information is publicly available.

NOTES: If the information is not publicly available and you wish to collect identifiers, your study will not qualify for exemption. Please choose the CIRB Application Form.

- 1. Identity of subjects is publicly available
- 2. Identity of subjects cannot be determined/ traced

[ ] Category 5 - Public Benefit or Service Programs

Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

(i) public benefit or service programs;
(ii) procedures for obtaining benefits or services under those programs;
(iii) possible changes in or alternatives to those programs or procedures; or
(iv) possible changes in methods or levels of payment for benefits or services under those programs.

[ ] Category 6 - Taste and Food Evaluation and Acceptance Studies

Taste and food quality evaluation and consumer acceptance studies,

(i) if wholesome foods without additives are consumed; or
(ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe.

(With effect from 14 July 2017, studies fall under categories 7-10 no longer require IRB review.)

[ ] Category 7 - Reporting of Individual Patients' Clinical Results

Writing up or reporting of individual patients' clinical results by the patients' doctors, provided that the patients' consent for procedures and interventions in clinical management have been obtained and the patients' privacy protected, for example, the review of a clinical programme that includes demographic, clinical and outcome parameters, which are useful in the audit of the programme; or the review of a procedure or treatment (a surgical technique or drug treatment outcome) by a physician or surgeon, where the choice of the drug or technique is based on the clinical judgment of the physician or surgeon and on best practices and not on any randomisation procedure. Researchers who are not the attending physicians in the programme but wish to have access to such information should send their proposals to the IRB in the usual way.

Exemption does not apply when the research activity is supported by funding from US Federal departments/agencies.

[ ] Category 8 - Research using Unidentifiable Data

Research using appropriately designed data escrow or other arrangements in which personal or other identity information is securely withheld from researchers by a third party provider of information, there being no possibility of researchers by themselves being able to trace or reconstruct significant information on the identity of participant donor.

Exemption does not apply when the research activity is supported by funding from US Federal departments/agencies.

[ ] Category 9 - Commercially Available Cell Lines, Anonymous DNAs, RNAs and Fixed Tissues

Research using established commercially available cell lines or commercially available anonymous DNAs, RNAs and fixed tissues.

Exemption does not apply when the research activity is supported by funding from US Federal departments/agencies.

[ ] Category 10 - Development of Diagnostic Test

The development of diagnostic tests using existing samples for test validation purposes provided that the necessary consent for the taking and use of the samples has been obtained.

Exemption does not apply when the research activity is supported by funding from US Federal departments/agencies.

2. Please determine if the study (or any part of the study) falls under the purview of the Human Biomedical Research Act? #

- Human Biomedical Research
  Select the checkbox(es) that apply.
  NOTES: When there is a selection at i, there should be a corresponding selection at ii. When iii is selected, selection from i and ii are not required unless applicable.

  i. My human biomedical research is intended to study - (if "Human Biomedical Research" is selected)
  - ☐ a. the prevention, prognostication, diagnosis or alleviation of any disease, disorder or injury affecting the human body;
  - ☐ b. the restoration, maintenance or promotion of the aesthetic appearance of human individuals through clinical procedures or techniques; or
  - ☐ c. the performance or endurance of human individuals.

  ii. Where the research involves - (if "Human Biomedical Research" is selected)
  - ☐ a. subjecting an individual to any intervention (including any wilful act or omission) that has a physical, mental or physiological effect (whether temporary or permanent) on the body of the individual;
  - ☐ b. the use of any individually-identifiable human biological material; or
  - ☐ c. the use of any individually-identifiable health information.

  iii. Any research that involves - (if "Human Biomedical Research" is selected)
  - ☐ a. human gametes or human embryos;
  - ☐ b. cytoplasmic hybrid embryos;
  - ☐ c. the introduction of any human-animal combination embryo into an animal or human;

- ☐ d. the introduction of human stem cells (including induced pluripotent stem cells) or human neural cells into an animal at any stage of development (including a prenatal animal foetus or animal embryo);
- ☐ e. any entity created as a result of any process referred to in (c) or (d).

- Restricted Human Biomedical Research
  Select the checkbox(es) that apply.

  My restricted human biomedical research involves – (if "Restricted Human Biomedical Research" is selected)
  Category A
  - ☐ a. human eggs or human embryos
    This includes derivation of new human embryonic stem cell lines from donate human embryos.

  Category B
  Research involving any of the following human-animal combination embryos:
  - ☐ a. cytoplasmic hybrid embryos; or
  - ☐ b. human-animal combination embryos created by the incorporation of human stem cells (including induced pluripotent stem cells); or
  - ☐ c. human-animal combination embryos created in-vitro by using human gametes and animal gametes; or
  - ☐ d. human-animal combination embryos created in-vitro by using one human pronucleus and one animal pronucleus.

  Note: Research involving the development of human-animal combination embryos referred to in (a) or (c) beyond 14 days or the appearance of primitive streak, whichever is earlier, is prohibited.

  Category C
  - ☐ a. the introduction of human stem cells (including induced pluripotent stem cells) into a prenatal animal foetus or animal embryo; or
  - ☐ b. the introduction of human pluripotent stem cells (including inducing pluripotent stem cells) into a living postnatal animal but excludes the introduction of such human pluripotent stem cells into immunodeficient mice solely for the analysis of teratoma induction; or
  - ☐ c. the use of any entity created as a result of (a) and (b) above.

  Category D
  - ☐ a. the introduction of human stem cells (including induced pluripotent stem cells) or human neural cells into the brain of a living postnatal animal; or
  - ☐ b. the use of any entity created as a result of (a) above.

- The study does not fall under the purview of the Human Biomedical Research Act. Please justify.
  -Insert textbox-

Section A: Protocol Title and Protocol Administrators

A1. Please enter the Full Protocol Title and Protocol Number (if available) for this Study

Protocol Title [#]:
Protocol Number:
(Optional)

A2. You may assign Protocol Administrators for this Study below

Protocol Administrators are persons who are responsible for administrative matters related to the Study. They can be the Study Coordinators, Research Nurses or Clinical Research Associates, and are not considered to be part of the study team members from section B2 of the CIRB Application/ Amendment Form.

While the Principal Investigator remains the primary contact person, the CIRB may contact the Protocol Administrators for clarification of administrative matters related to the Study.

Protocol Administrators may also assist the Principal Investigator in drafting the various online forms and reports, however, only the Principal Investigator may 'submit' these online forms and reports to the CIRB.

This section is optional but Principal Investigators are encouraged to nominate at least one Protocol Administrator.

You may select up to 5 Protocol Administrators.

Name	Institution/ Organization	Department	Designation	Office No.	Email

Section B: Study Sites, Study Team & Submission Board

B1. Please select the study sites

(i) SingHealth and Partner Institutions (PI listed in Section B2(i) should be from any of the selected institution(s) under "SingHealth and Partner Institutions".). #
-Refer to the online form for the updated list of institutions-

(ii) NHG and Partner Institutions
-Refer to the online form for the updated list of institutions-

(iii) Other Local Sites and Overseas Sites. (The sites listed is for the IRB's information only. CIRB's approval will not include any of the sites. The sites should apply for their own IRB approval if required.)
-Insert text-

B2. Study Team Members

Name	Study Role	Department	Institution/ Organization	Designation	#CV	#CITI	@Local GCP	Involve in Informed Consent
								[ ]

@ Local GCP is mandatory only when “Clinical Trials” involving “Drug/Biologic” or “Surgical/Radiotherapy Procedure” is selected in Section D1

CV:
Please ensure that the information shown in the CV is accurate and up to date (updated within last 2 years).

The CIRB will use the information contained here to assess the qualifications of the Principal Investigator and Study Team Members who will carry out the Study as described in this Application.

CITI:
Study Team Members who are from SingHealth & Partner Institutions must submit their CITI completion report.

Study Team Members who are not from SingHealth & Partner Institutions are encouraged to complete the CITI online course and attach the CITI completion report under Section B of the CIRB online application form.

However, if you wish to request for waiver of this requirement, please download the Waiver of CITI Certification Form from CIRB Website and attach a copy of the completed form under Section B in place of the CITI completion report.

Local Good Clinical Practices (Local GCP):
Principle Investigators and Site-Principal Investigators are responsible in ensuring the proper conduct of the clinical trial and the safety of the participants by adhering to the relevant local regulations and guidelines. SingHealth PIs and Site-PIs conducting clinical trials are to complete and obtain the local GCP certificate. The certificate obtained after attending the GCP workshop from SingHealth Academy, National Healthcare Group (classroom-based or online), National University Health Systems (NUHS) or the online iGCP course with National University of Singapore is acceptable.

Involve in Informed Consent:
Only Study Team Members or research assistants who have been delegated by the Principal Investigator can obtain consent from the participants. This should be documented in the Study Responsibility Log. It is the responsibility of the Principal Investigator to ensure that the Study Team Members who are delegated to obtain consent have received proper training.

The delegated Study Team Member should also be appropriately qualified to adequately answer questions from potential participants. For clinical trials where a medical opinion is required, a medically trained Study Team Member should conduct the informed consent so that the participant can have his/her questions adequately answered.

Only Study Team Members who have been properly trained to obtain consent and designated with the responsibility of taking informed consent from research participants can obtain consent.

• Informed Consent discussion should be conducted by the Principal Investigator, Co-Investigator or a member of the Study Team Member who is listed in the CIRB Application Form as the designated person for conducting the Informed Consent discussion. Any change to study staff, should be submitted to CIRB for review and approval.
• Informed Consent must be presented in a language that is understandable to the participant.
• Please ensure that the Study Responsibility Log is updated with the names of Study Team Members who are assigned to take Informed Consent.

NOTES:
For multi-centre studies within SingHealth Institutions and/or institutions under the oversight of SingHealth CIRB or NHG DSRB, each institution must have a Site-Principal Investigator (Site-PI) who is responsible for the conduct of the study in his/her institution.

One of the Site Principal Investigators should be designated as Principal Investigator (PI). The Principal Investigator will be the Site-Principal Investigator for his/her own institution, and will also be the primary contact person for the CIRB. The Principal Investigator should be a staff from SingHealth Institutions.

Co-Investigators (Co-Is) are members of the research/clinical trial team designated by the Principal Investigator to perform study-related procedure and/or make important research-related decisions. Study Team Members are personnel responsible for the design, conduct or reporting of the research. All personnel who have a responsibility for the consent process and/or direct data collection for this study must be listed as Study Team Members. Please specify their Study Role and Study Site from the dropdown list.

All Principal Investigators and Study Team Members from SingHealth Institutions or institutions under the oversight of SingHealth CIRB have to complete the mandatory minimum training requirement.

Study Team Members from SingHealth and CIRB's partner institutions should be added through their registered user accounts so that they will be notified of their participation in this study when the Application is submitted.

B3. Submission Board and other IRB

(i) Which CIRB is this application being submitted to? #

-Choose from dropdown list-

The CIRB is based on specialities. Please submit the Application to the Board that is most relevant to the proposed research activity. If you are unable to decide, please contact the CIRB for assistance. The Specialities in the Six Review Boards are as follows:

CIRB A	CIRB B	CIRB C
•Ophthalmology •Psychiatry •Neurology/Neurosurgery (including sleep studies) •Geriatric Medicine •Nursing •Health Service Research	•Oncology	•Cardiovascular Science •Pharmacology •Emergency Medicine •Endocrinology •Diagnostic Imaging •Respiratory Medicine

CIRB D	CIRB E	CIRB F
•Obs/Gynaecology •Anaesthesia(including acupuncture) •Surgery •ENT •Dentistry	•Gastroenterology •Renal Medicine •Rheumatology/Immunology •Dermatology •Paediatric Medicine •Family Medicine	•Genetics •Palliative Medicine •Haematology (including haematological malignancies) •Pathology •Sports & Rehab Medicine •Allied Health •Infectious Disease

(ii) Has the study been submitted to another IRB? #

- No
- Yes
  - NHG DSRB # (if "Yes" is selected)
  - Others # (if "Yes" is selected)

  -Insert text-

(iii) Has the application been previously rejected by any IRB? (Including SingHealth CIRB)#

- No
- Yes

  Please state which IRB rejected the study and provide reason(s) for the rejection. # (if "Yes" is selected)
  Name of the IRB:
  Reason(s):

Section C: Conflict of Interest

Does the Principal Investigator or any Study Team Member have any potential conflict of interest? The Declaration is also for the immediate family members of the Principal Investigator and Study Team Members listed below.

All Study Team Members must complete and submit their Declarations when this application is submitted. The Principal Investigator is responsible for checking and ensuring that accurate information is submitted to the CIRB.

Conflicting Interest – A conflicting interest can be broadly defined to refer to any interest of the investigator or immediate family (includes spouse, children, parent(s) and sibling(s)) that competes with the investigator's obligation to protect the rights and welfare of research participants.

Financial Interest – Financial Interest means anything of monetary value, including but not limited to, salary or payments for services (e.g. consulting fees or honoraria); equity interests (e.g. stocks, stock options or other ownership interests); intellectual property rights (e.g. patents, copyrights and royalties from such rights), and board or executive relationships.

The Conflict of Interest Declaration Section must be submitted to the CIRB via study amendments if any of the circumstances relevant described herein change during the conduct of the research.

Name	Study Role	Department	Institution	Yes/No #	
				o Yes	o No

i. Please tick all the applicable boxes. **# (if "Yes" is selected for any of the Study Team Member(s) above)**

- ☐ Financial interests (e.g. stocks, stock options or other ownership interests) in the assets or liabilities of any organization that may benefit from the research activity.
- ☐ Payments (e.g. salary, consultation fees, speaking fees, or honoraria) from any organisation that may benefit from the research activity.
- ☐ Intellectual property rights or proprietary interests (e.g. patents, copyrights and royalties from such rights) related to the research.
- ☐ Options or other compensation arrangements that could be affected by the outcome of the research.
- ☐ The sponsor company supporting this study offers incentives connected with participant recruitment or completion of research study (e.g. finder's fee, recruitment bonuses etc) that will be paid to the research staff.
- ☐ Others, to specify (financial/non-financial conflict).

ii. Please provide details of all of the above Conflict of Interest. # (if "Yes" is selected for any of the Study Team Member(s) above)

-Insert text-

iii. Please describe the plan to manage all of the above Conflict of Interest. You may include the mechanism and processes in place to manage the Conflict of Interest (e.g. resignation of position, independent data analysis, data safety monitoring, blinded study, ad hoc review committee). You may also include if the Conflict of Interest will be disclosed to the participants (e.g. through the written Informed Consent Form, oral presentation etc.). # (if "Yes" is selected for any of the Study Team Member(s) above)

-Insert text-

Section D: Nature of Research

-Section only appears when "CIRB Application Form" is selected-

D1. Please select one category that best describes your research activities. #

- o Clinical Trials (which includes Drug, Device and Procedure Trials)

Choose this if your research involves:
1. administering a drug, device, or biologic as part of the research intervention, or
2. performing surgical procedures as part of research intervention.

If this category is chosen, please indicate which of the following does the study involve:
1. Drug / Biologic*
2. Device
3. Surgical / Radiotherapy Procedure

*If "Drug / Biologic" is chosen, please indicate the Phase of the trial, e.g. Phase I, Phase IIa.

If a Clinical Trial Certificate, Clinical Trial Authorisation or Clinical Trial Notification is required, the Principal Investigator must be a locally registered doctor or dentist. The Principal Investigator should be at least an Associate Consultant (AC) or above. If the registration condition requires the doctor to "work under supervision", the doctor would require a statement from the doctor's supervisor indicating support for the doctor's involvement as the Principal Investigator of the study.

What does the study involve? **# (if "Clinical Trials" is selected)**

- Drug/Biologic

  Please indicate the Phase of the Trial. **# (if "Drug/ Biologic" is selected)**
  -Insert text-

- Device
- Surgical/Radiotherapy Procedure

- Questionnaire/Survey/Interview

Choose this if your research involves:
Administering questionnaires/surveys/interviews. This type of research may also include a medical records review component.

NOTES: If a combination of medical record review and questionnaire/survey/ interviews are involved, please select "Questionnaire/Survey/Interviews".

- Medical Records Review

Choose this if your research involves:
Collection of data for a specific research project by review of medical records including results of routine diagnostic tests performed for standard clinical purposes. The data collection could be done prospectively and/or retrospectively.

- Clinical Research

Choose this if your research involves:
1. collection of blood by venipuncture, finger stick etc. or
2. prospective collection of biological specimen by invasive or non-invasive means including biopsies, FNAC's, fundoscopy etc. or
3. collection of data through research procedures such as X rays, MRI, ultrasound, ECG, EEG, etc. or
4. any other research categories that are not listed in the options above.

NOTES:
Submission to HSA might be required if you are conducting clinical trials. You should check with HSA if you are unsure.

D2. Is this a US FDA IND/IDE study or data is intended to be reported to FDA in support of an IND/IDE Application?

The current US Federal law requires that a drug be the participant of an approved marketing application before it is transported or distributed across the state lines in US. Because a sponsor will probably want to ship the investigational drug to clinical investigators in many US states, it must seek an exemption from that legal requirement. The Investigational New Drug Application (IND) is the means through which the sponsor technically obtains this exemption from the US Food and Drug Administration (FDA).

An investigational device exemption (IDE) allows the investigational device to be used in a clinical study in US in order to collect safety and effectiveness data required to support a Premarket Approval (PMA) application or a Premarket Notification [510(k)] submission to FDA.

NOTES: US FDA-regulated (IND) research activities cannot qualify for Exemption from CIRB Review and Waiver of Informed Consent. The application must be submitted using the CIRB Application Form.

- o Yes
  Please select the study type. # (if "Yes" is selected)
  - o IND
  - o IDE
- o No

Section E: Study Funding Information

E1. Please give information regarding the study's funding source or sponsor information. #

- o No funding is required for this study to be carried out or Department Fund

- o Pharmaceutical/ Industry Sponsored
  Please refer to the CIRB website for more information on the review fee.

  i. Name of Sponsor Company # (if "Pharmaceutical/ Industry Sponsored" is selected)
  -Choose from dropdown list-
  -Insert text if not in the dropdown list-

  ii. Sponsor Company's Contact Person # (if "Pharmaceutical/ Industry Sponsored" is selected)
  Name #: *-Insert text-*
  Telephone #: *-Insert number-*
  Email address #: *-Insert text-*
  Fax: *-Insert number-*

Address [#]: *-Insert text-*

iii. **Name of Clinical Research organization (CRO) if applicable [# (if "Pharmaceutical/ Industry Sponsored" is selected)]**

-Choose from dropdown list-

iv. **CRO's Contact Details [# (if "Pharmaceutical/ Industry Sponsored" in selected)]**
Name [#]: *-Insert text-*
Telephone [#]: *-Insert number-*
Email address [#]: *-Insert text-*
Fax: *-Insert number-*
Address [#]: *-Insert text-*

v. **Is the sponsor offering any incentive connected with participant recruitment or completion of research study (e.g. finder's fee, recruitment bonuses etc) that will be paid to the research staff? [# (if "Pharmaceutical/ Industry Sponsored" is selected)]**
- No
- Yes
  -Insert text-

- Grant

If "Grant" is selected, please provide the name of Grant agency and Grant name, Amount, Deadline of Grant application, if the Grant application has been approved.

• If Grant application has been approved / successful, please provide the date of grant approval, expiry and the amount awarded. Please attach the approved grant proposal and all relevant documents approved by the grant body (e.g. study protocol, consent form etc.).
• If Grant application is pending approval, please indicate if study's initiation is dependent on Grant approval.
• If you have alternative financial source(s) to fund this study, please indicate.

i. **Name of Grant Agency [# (if "Grant" is selected)]**
-Choose from dropdown list-
-Others chosen, please specify Name of Grant Agency-

ii. **Grant Name [# (if "Grant" is selected)]**
-Choose from dropdown list-
-Please specify Grant Name if "Others" is chosen under "Name of Grant Agency"-

iii. **Amount [# (if "Grant" is selected)]** *-Insert text-*

iv. **Deadline of Grant Application** *-Insert text-*

v. **Has the Grant been approved? [# (if "Grant" is selected)]**
- No
  vi. Is the study's initiation dependent on grant approval? [# (if "No" is selected)]
  - Yes
  - No
    Please indicate source of alternate funding. [# (if "No" is selected)]
    -Insert text-
- Yes
  -Attach Grant Approval Letter- [# (if "Yes" is selected)]
  vii. Grant Reference Number *-Insert text-*

NOTES:
If you choose this option, the CIRB may only start reviewing the study when preliminary result for the Grant Application is available. Please contact the CIRB once you have received information on the grant results to start the CIRB review process. If your grant application was not successful, please advise the CIRB on your next course of action (e.g. withdrawal of the study, look for alternative funding etc.).

E2. Payment of CIRB review fees.
-Question appears only when Pharmaceutical/Industry Sponsored is chosen in E1-
Cheque/ Telegraphic Transfer Number: *-Insert number-*
Bank Name: *-Insert text-*

Information for Invoice:

a) **Company registered name** # *-Insert text-*
b) **Company registration number** # *-Insert number-*
c) **Company registered address** # *-Insert text-*
d) **Company mailing address (if it is different from registered address)** *-Insert text-*
e) **Name and designation of the person to whom we direct the invoice to** # *-Insert text-*
f) **Contact number** # *-Insert number-*

E3. Who will be responsible for the payment and compensation of injury or illness to participants arising from participation in the study? #
-Insert text-

E4. Who will be responsible for research-related costs? For sponsored studies, please list the costs that will be borne by the sponsor. #

Please note that it is generally not appropriate for research participants to pay for research-related procedures. The Principal Investigator should ensure that funding is available to cover these costs (e.g. sponsor by Pharmaceutical Company, Grant, etc.).

For sponsored studies, please attach or include a payment schedule.

For Principal Investigator initiated studies, please include the payment/reimbursement information which will be reflected in the Informed Consent Document.

If there are no research-related costs, kindly indicate “Not Applicable”.

-Insert text-

Section F: Research Methodology

-Only Question F1, 2 and 8-16 appears when “CIRB Exemption Application Form” is selected-

The information contained in this section must be self-contained so that it can serve as a succinct and accurate description of the study when it is read by itself. As far as possible, the technical and medical terms should be explained in simple layman language.

IMPORTANT NOTE: Do not use terms such as "Refer to attached document" or similar.

F1. Please provide an abstract of your proposed research (Up to 300 words). #

Please ensure that your abstract include a brief description of the following items, and must not be more than 300 words:

1. Aims
2. Methodology
3. Importance of proposed research to science or medicine
4. Potential benefits and risks

-Insert text-

F2. What are the specific aims and hypothesis of this study? #

In this section, please concisely describe the specific aims and the hypothesis of the study.

-Insert text-

F3. Please briefly describe the background to the current study proposal. Critically evaluate the existing knowledge and specifically identify the gap that the proposed study is intended to fill. #

In this section, please include the following:

- General introduction of the study (e.g. Describe current international and/or local standards)
- Evidence or any previous literature that suggest current gaps
- Rationale of study / Why are you prompted to do this study?

-Insert text-

F4. Please provide a list of relevant references. #

Please list at least two relevant papers pertaining to the importance of the study.

-Insert text-

F5. Please attach at least two relevant publications that support the conduct of the study.
-Attach publications-

File Name	Description	Upload Date

F6. Please provide an account of the Principal Investigator's preliminary studies and progress reports (if any) pertinent to this application. #

If the Principal Investigator or study team has done related studies for the current submission, please include the relevant information (e.g. short description of the previous study/studies) to support this study.

-Insert text-

F7. Please state concisely the importance of the research described in this application by relating the specific aims to the long term objectives. #

Please describe why this study is important and what possible benefits can be derived from this study.

-Insert text-

F8. Discuss in detail the experimental design and procedures to be used to accomplish the specific aims of the study. #

Notes:
If this study involves a retrospective medical record review, please specify the period of data collection
If this study does provide the provision for re-identification in the case of incidental findings, please describe the management of incidental findings.

Please provide details on the experimental design used to accomplish the specific aims of the project (e.g. two period crossover, case control, placebo controlled). The description should include, but is not limited to, information on blinding, randomization, number of study arms, phase of trial, approximate time to complete study recruitment, expected duration of participant participation, sequence and duration of all trial periods (including follow up), changes in scheduling, single or multi centre, healthy or sick population, in or outpatient etc.

If this study involves a retrospective medical records review, please also specify the period of data collection. Please note that for retrospective studies, all the data to be collected should already be in existence and not prospectively collected.

If this study involves the administration of an anonymous survey, please also describe in details, how the questionnaire/demographic data collection form will be distributed anonymity (e.g. the questionnaire/ demographic data collection forms will be given to participants at the clinic and they can return the completed forms by dropping them into a collection box or by using the return envelope provided).

Please note that incidental findings are not test results. Incidental Findings refers to a finding about a research subject that has potential health or reproductive importance to the research subject and is discovered in the course of conducting research but is unrelated to the purposes, objectives or variables of the study (SHS-RSH-ORIC-CWP-203 Management of Incidental Findings – This document is strictly for internal use by SingHealth Staff members).

-Insert Text-

F9. Please provide details on sample size and power calculation and the means by which data will be analyzed and interpreted (If applicable). #

Details on sample size calculation and the means by which data will be analyzed and interpreted. In particular, specify all of the following:

- Null and alternate hypothesis
- Type I error rate
- Type II error rate

If this is a pilot study and no sample size calculation is performed, please provide a rationale on how the recruitment target is determined.

-Insert text-

F10. List all activities that are carried out as part of research in this study. Please state/ list all procedures involved in this research study and attach the data collection form (if any) which will be used for CIRB review. #

In this section, please list all activities that are performed solely for the purpose of the research.

E.g. The drawing of an extra 20ml of blood for research, or an additional biopsy taken for research purposes.

NOTES: The data collection form 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.

-Insert text-
-Attach data collection form, if applicable-

Data Collection Form:

File Name	Description	Upload Date

F11. Please describe the participant's visits (frequency and procedures involved). For studies with multiple visits, please attach study schedule. #

In this section, please list all participants' visits (frequency and procedures involved). If multiple visits are involved, please attach a study schedule.

-Insert text-
-Attach study schedule, if applicable-

Visit Schedule:

File Name	Description	Upload Date

F12. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. #

List the potential difficulties and limitations of the proposed procedures that may lead to failure to achieve the aims and/or failure to complete the study. In addition, list the corresponding alternative approaches to achieve the aims/overcome the difficulties and limitations.

-Insert text-

F13. What are the potential risks to participants? #

Please list the potential risks to participants (common as well as the rare ones).

-Insert text-

NOTES:
It is not appropriate to provide a nil response as all research procedures have some risks or side effects. For retrospective medical records review or questionnaires study, although the risks are expected to be minimal, there may be a potential risk from the breach of confidentiality.

F14. What are the potential benefits (direct as well as indirect) to participants? Indirect benefit may refer to the medical knowledge gained in the future, from the research. #

Please list the potential benefits to participants (direct as well as the indirect benefits). Indirect benefit may refer to the medical knowledge gained from this research to the participants' disease.

-Insert text-

F15. What is the estimated timeline for this study?

(i) Estimated start date # *-Insert Date-*

NOTES: The start date should be after the study has obtained ethics approval. In a retrospective medical records review study, this is the period when you will conduct the study, not the period for which case notes will be retrieved and reviewed.

(ii) Estimated end date # *-Insert Date -*

F16. Does this study have a Study Protocol? #

If "Yes" is selected, you will be required to attach a copy of the Study Protocol. Click on the "Attach" button to submit a copy of the Study Protocol.

- o Yes

  Please submit a copy of the study protocol. # **(if "Clinical Trials" is selected in Question D1)**

File Name	Description	Upload Date

- o No

NOTES:
Investigators conducting Clinical Trials must submit a Study Protocol for CIRB review. You may refer to the CIRB website for the Protocol template (Clinical Trial) and Protocol Template (Research Study).

http://research.singhealth.com.sg/pages/centralisedinstitutionalreviewboard.aspx

F17. The Principal Investigator is responsible for ensuring that all study participants give informed consent before enrolling into the study.

Please note that the CIRB requires that written informed consent should be obtained from all participants and documented prior to their participation in any research, unless the CIRB approves the waiver of consent or waiver of documentation of consent.

For studies where consent has been obtained for research purposes, please select "Waiver of Informed Consent".

If "A combination of both Informed Consent and Waiver of Consent is required for different study populations" is selected, please elaborate why a combination of both informed consent and waiver of consent is required, and which population(s) will require waiver of consent and which population(s) will be able to give informed consent.

Please select the applicable consent scenarios. For example:
- Select "Waiver of Informed Consent" if consent has been obtained for research purposes previously.
- Select "Informed Consent will be taken" if verbal consent will be taken or the study team is requesting waiver of documentation of informed consent. #

- o Informed Consent will be taken for all study subjects.
- o Waiver of Informed Consent is requested for all study subjects.
- o A combination of both Informed Consent and Waiver of Consent is required for different study populations.

  Please elaborate why a combination of both informed consent and waiver of informed consent is required, and which population(s) will required waiver of consent and which population(s) will be able to give informed consent. # **(if a combination of Informed Consent and Waiver of Consent is chosen)**

  -Insert text-

Section G: Research Details- Clinical Trials

-Section appears only when "CIRB Application Form" is selected and "Clinical Trials" is chosen in D1 -

G1. Describe the study protocol(s) to be used. Include information of the study drug / device / surgical procedures that will be used in the trial. If the study involves the use of study drug / device, describe how you plan to manage the receipt, handling, storage, utilization, and disposal of the study drug/device. #

Examples include, but are not limited to:

- Background information on the trial product, the safety issues and duration of exposure.
- For drugs, also include:
  - Information on dosage. Clearly explain the rationale for the dose used during the study.
  - Describe in what form the study drug will be dispensed to the participants.
  - Describe the drug regimen to be used.
  - State any special precautions or warnings relevant for the study drug administration.
  - If applicable, describe if there will be blinding, the measures that will be undertaken to blind the study participants and/or study staff from participant treatment assignments. State when un-blinding is expected and if/when participants will be told their assignments.
  - Describe product's storage needs. Include storage requirements and stability (temperature, humidity, security and container).

-Insert text-

G2. Please attach the Investigator's Brochure or local product information sheet/leaflet, as applicable.
-Attach Investigator's Brochure/ local product information-

File Name	Description	Upload Date

G3. Describe standard/alternative treatments used at your institution for this condition. #
-Insert text-

NOTES:
If the drug/ device/ procedure is the experimental aspect of the study, please indicate the standard/ alternative treatment available for the condition of the participant.

If this section is not applicable to your study, please indicate "NA".

G4. Is this a placebo controlled trial? #

- Yes
  - **(i) Explain what 'standard of care' therapy is available for this condition.** # **(if "Yes" is selected)**
    -Insert text-
  - **(ii) Discuss the ethical implications of using placebo instead of 'standard of care' therapy in this situation**. # **(if "Yes" is selected)**
    -Insert text-
  - **(iii) Address the issues of safety and efficacy of other available therapies.** # **(if "Yes" is selected)**
    -Insert text-
  - **(iv) What is the total duration the study participant would be on the placebo arm of the study?** # **(if "Yes" is selected)**
    -Insert text-

(v) What is the greatest potential harm that the study participant might be exposed to as a result of not receiving effective therapy? # (if "Yes" is selected)
-Insert text-

(vi) What are the procedures in place to safeguard study participant receiving placebo? # (if "Yes" is selected)
-Insert text-

(vii) Do you have any other comments supporting the use of a placebo in your study? # (if "Yes" is selected)
-Insert text-

- No

Section H: Recruitment Details

-Section only appears when "CIRB Application Form" is selected-

H1. How will potential participants be identified? Please tick all the applicable boxes. #

NOTES:
If you have selected that participants are "Patients of study team", please select "Yes" for K6.

If healthy volunteers are recruited for the study, please select the option "Other methods of participant identification" and describe your method(s) of participant identification.

[ ] Referral by attending healthcare professional

[ ] Patients of study team

[ ] Databases

-Insert text-

[ ] Other methods of participant identification

-Insert text-

H2. Who will make the first contact with participant? #

Please identify the person who will make the first contact with participants.

All patients should be approached (first informed about a study/trial) by their own treating physicians to participate in the project when they come for their regular clinic visits or when they are admitted to the hospital. The treating physicians should seek the patients' consent to be referred to the study team.

However, consent may be obtained by the investigators of this study who may not be the treating physicians of the patients.

-Insert text-

H3. How will the participant be contacted? #

Please indicate if potential participants will be recruited by a face-to-face contact when they come for their prospective regular clinic visits.

If you intend to call back patients who have visited the hospital/clinic in the past, please note that you must obtain permission from the primary physician/head of the department before calling these patients (if you are not the attending physician of these patients).

An invitation letter should be mailed to the potential participants before calling them.

Please submit the invitation letter and a sample telephone script under Section H4 for CIRB review. The documents should contain information on the following:

- title of study,
- purpose and procedures involved in study,
- risks and benefits, and
- the person to contact for more information.

Please enter "NA" if there is no participant interaction in this study.

-Insert text-

H4. Will any advertising/ recruitment materials be used to recruit research participants?#

Guidelines for preparing advertisements:
Any advertisement to recruit participants should be limited to the information the prospective participants need to determine their eligibility and interest.

The following items may be included; however, inclusions of all the listed items are not required:

1. Name and address of the Principal Investigator.
2. Purpose of the research study.
3. Summary of the eligibility criteria of research participants.
4. A straightforward description of potential benefits to research participation.
5. A brief list of procedures involved.
6. The time or other commitment required of the research participants.
7. Any compensation or reimbursement.
8. Location where the research will be conducted.
9. Contact person and details for further information.

The advertisement should not, either explicitly or implicitly:

1. State or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and protocol.
2. Make claims that the drug, device or biologic is safe or effective for the purposes under investigation.
3. Make claims that the test article is known to be equivalent or superior to any other drug, biologic or device.
4. Use terms such as "new treatment," "new medication" or "new drug" without explaining that the test article is investigational.
5. Use of the term “free” in reference to treatment or procedures.
6. Use catchy words like “exciting”, “fast” or “earn”.
7. A statement or an implication of Ethics Committees/Ministry of Health/Health Sciences Authority endorsement of the research.
8. Promise "free medical treatment," when the intent is only to say participants will not be charged for taking part in the investigation, Advertisements may state that subjects will be paid, but should not emphasize the payment by such means as larger or bold type. Advertisements should not state the amount that will paid.
9. Include any exculpatory language.
10. Make claims about the drug, biologic or device under investigation that are inconsistent with currently approved labelling.

- Yes

I Posters

Please state the location(s) where the posters will be placed (e.g. in the hospital lift, in the general waiting area in Clinic X), and attach a copy of the poster. **# (if “Yes” is selected)**

-Insert text-

-Attach poster-

File Name	Description	Upload Date

II Brochures

Please state the location(s) where the brochures will be placed (e.g. in the general waiting area in Clinic X), and attach a copy of the brochure. **# (if “Yes” is selected)**

-Insert text-

-Attach brochure-

File Name	Description	Upload Date

III Advertisements in Newspaper/ Magazines/ Publications
Please state which publications will be carrying the advertisements, how many times the advertisement will run for, and attach a copy of the advertisement. # (if "Yes" is selected)
-Insert text-
-Attach advertisement-

File Name	Description	Upload Date

IV Advertisements on Radio/ TV
Please state which radio / TV stations will be carrying the advertisements, how many times the advertisement will be aired, and attach a copy of the advertisement. # (if "Yes" is selected)
-Insert text-
-Attach advertisement-

File Name	Description	Upload Date

V Letter of Invitation to potential research participants
Letter of Invitation' refers to email, letters or any form of documents used as part of the recruitment strategy, with the intention of inviting the research participants to participate in the study. Please attach a copy of the Letter of Invitation for CIRB Approval before use. # (if "Yes" is selected)
-Insert text-
-Attach Letter of Invitation-

File Name	Description	Upload Date

VI Letter to Doctors requesting referrals
CIRB review and approval is not required for letters to doctor for referring potential participants. # (if "Yes" is selected)
-Insert text-
-Attach Letter to Doctors-

File Name	Description	Upload Date

VII Other types of materials will be used
Please elaborate on the recruitment material(s) that will be used, and attach a copy for CIRB review. # (if "Yes" is selected)
-Insert text-
-Attach recruitment material(s)-

File Name	Description	Upload Date

- No

H5. Will any other recruitment strategies be used (e.g. talks in public place, societies etc.)?#

If you have other method(s) to broadcast/advertise your study to recruit participants, other than recruitment materials, please select "Yes" and elaborate on the method(s).

E.g. Event(s)/Talk(s)/Public Forum(s) at hospitals, schools, and public places (such as Community Centres). Please specify where, when, how and the agenda of the event/talk/forum.

- Yes
  -Insert text-
- No

H6. What is the Recruitment Period (if applicable)? Please provide us with the approximate recruitment period. #

Start Date: *-Insert Date-*

End Date: *-Insert Date-*

If this is a Medical Records Review, please indicate the period of the data that will be extracted for review.
-Insert text-

H7. How long will the participants be directly involved in the study (if applicable)? This includes the time from the screening procedures till completion of follow-up tests or examinations. #

Kindly indicate the time period (e.g. 6 weeks) during which the participants will be involved in study related procedures or taking study medication.

Please enter "NA" if there is no participant interaction in this study.

- Not applicable
- If applicable, please elaborate.
  -Insert text-

Section I: Study Sites & Recruitment Targets

I1. Please state the target number of research participants to be recruited for each study site in Singapore. If exact numbers are not available, please give an approximate number range in the recruitment target. #

When determining the estimated number, please make provisions for participant withdrawals. The total number of participants enrolled does not only refer to the participants who are still in the study. Participants who have withdrawn also count towards the total number of participant recruited into the study.

Please note that a study amendment must be submitted and approved by the CIRB if you would like to recruit additional participants over the estimated maximum number indicated here.

The estimated number of males, females and children is to be indicated for CIRB to have an overview of whether there is any recruitment restrictions based on the gender of the research participants and whether the study will include children whom will need special protections. Please use the estimated maximum number to provide the distribution number of males, females and children.

The study site(s) reflected in this section are based on the sites selected in Section B1. If you would like to include additional site(s), please add them under Section B1.

Please note that recruiting participants beyond the total number without CIRB's approval would constitute a non-compliance. If you intend to recruit beyond the total number, please submit a study amendment to increase the recruitment target. For study site(s) not recruiting any participant, please input "0".

No	Study Site	Total Recruitment Target	Adults (Male)	Adults (Female)	Children

I2. Is this part of an international study? #

If there is any site(s) involved in this study outside of Singapore, please select "Yes".

Then, please state the worldwide total target enrolment number. If an exact number is not available, please give an approximate number.

- Yes
  Please state the total number of worldwide research participants targeted for enrolment into this study. If exact numbers are not available, please give an approximate number.
  -Insert text-

- No

Section J: Exemption Review Criteria

-Section only appears when "CIRB Exemption Application Form" is selected-

J1. Please describe and state the source of your samples/data. #

Please describe where and how you obtain the samples / data.

Please note that for the study to qualify for Exempt Category 2 and/or 4, the source of the samples/ data must fulfil one of the following criteria:

- Information must be recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participant (i.e. the existence of a one-way identifier, such as a code that can be used to identify a participant, disqualifies the research as Exempt) or
- Sources are publicly available (accessible to general public such as library literature or internet). Medical records are not publicly available because they are restricted to designated doctors and healthcare professionals only.

-Insert text-

J2. Criteria to qualify for Exemption from CIRB review.

(i) The research involves no more than minimal risks to the study participants: #

If "Yes" is selected, no further question in J2 (i) will require your response.

If "No" is selected, your study does not qualify for Exempt review. Kindly amend the form to a CIRB Application Form.

- o Yes
- o No

-Insert text-

(ii) The selection of study participants is equitable: #

If "Yes" is selected, no further question in J2 (ii) will require your response.

If "No" is selected, please provide a reason why the selection of study participants is not equitable (e.g. the disease only affect the x population).

- o Yes
- o No

-Insert text-

(iii) Recording of identifiable information: #

- o No recording of identifiable information.
- o Identifiable information is recorded and there are adequate provisions to maintain the confidentiality of the data.

-Insert text-

NOTES:
If you have selected Exempt categories 2, 4 or 8, identifiable information <u>cannot</u> be recorded. If identifiable information is recorded, kindly amend the form to CIRB Application Form.

(iv) Privacy interests of the study participants: #

- o It is not applicable as there are no interactions with study participants.
- o There are interactions with study participants and there are adequate provisions to maintain the privacy interests of the study participants.

-Insert text-

(v) Informed consent: #

- o Informed Consent will be taken for all study subjects.

- Waiver of Informed Consent is requested for all study subjects.
- A combination of both Informed Consent and Waiver of Consent is required for different study populations.
  Please elaborate why a combination of both informed consent and waiver of informed consent is required, and which population(s) will required waiver of consent and which population(s) will be able to give informed consent. # **(if a combination of both is selected)**

  -Insert text-

Section K: Research Participant Characteristics

-Section only appears when "CIRB Application Form" is selected-

K1. Please list the inclusion criteria for research participants in this study. #

Kindly state the inclusion criteria (set of conditions that must be met in order to participate in the study) for research participants relevant to this study (e.g. age, gender, blood sugar levels, blood pressure, type and stage of disease etc.).

-Insert text-

NOTES:
For global studies, please modify the criteria according to local regulations (e.g. persons below the age of 21 and are unmarried are considered minors in Singapore and would require parental consent prior to participation).

Please also ensure that the symbols used are displayed accurately. Use ">=" or "<=" to represent "more than or equals to" or "less than or equals to" respectively.

K2. Please list the exclusion criteria for research participants in this study. #

Kindly state the exclusion criteria (set of conditions that participants must not have) for research participants relevant to this study (e.g. age, gender, blood sugar levels, blood pressure, type and stage of disease etc.).

-Insert text-

NOTES:
For global studies, please modify the criteria according to local regulations (e.g. persons below the age of 21 and are unmarried are considered minors in Singapore and would require parental consent prior to participation).

Please also ensure that the symbols used are displayed accurately. Use ">=" or "<=" to represent "more than or equals to" or "less than or equals to" respectively.

K3. Please state the age group of the research participants.
Lower Age Limit # *-Insert Number-*
Upper Age Limit # *-Insert Number-*

NOTES:
Persons below the age of 21 and are unmarried are considered minors in Singapore and will require parental consent prior to participation.

K4. Are there any recruitment restrictions based on the gender of the research participants (e.g. only males will be included in this study)? #

- Yes

-Insert text-

- No

K5. Are there any recruitment restrictions based on the race of the research participants (e.g. only Chinese participants will be included in this study)? #

- Yes
  -Insert text-
- No

K6. Do the potential research participants have a dependent relationship with the study team (e.g. doctor-patient, employee-employer, head-subordinate, student-teacher, departmental staff relationship)? #

If "Yes" is selected, please state clearly the dependent relationship of Study Team Members with the research participants (e.g. Study Team Members are the primary physicians to the research participants).

In addition, please describe how the study team will manage the dependent relationship to prevent coercion or undue influence (e.g. informed consent will not be taken by the primary physicians, but explained by another Study Team Member who is not the primary physician of the participant).

The CIRB's concern is that due to the relationship, the participant may feel obliged to participate in the research, e.g. out of fear that declining to participate in the study will result in resentment or abandonment by the primary physician.

- Yes
  Describe how the study team will manage the dependent relationship to prevent coercion or undue influence. #
  -Insert text-
- No

NOTES:
If you have selected that participants are "Patients of study team" in H1, then the answer should be "Yes".

K7. Does the study involve any vulnerable research participants? Please select 'Yes' to view the options and select the applicable population(s). #

- Yes
  [ ] If Pregnant Women, Foetuses and Neonates is selected, please respond to Section L.
  [ ] If Children is selected, please respond to Section M.

Children are persons who are less than 21 years of age and are unmarried.

[ ] If Prisoners is selected, please respond to Section N.
[ ] If Cognitively Impaired Persons is selected, please respond to Section O.
[ ] Others
-Insert text-

i) **Why does your research need to involve this group of vulnerable participants?** # **(if "Others" is selected)**
-Insert text-

ii) **What are the additional safeguards that will be provided to protect the rights and welfare of this group of vulnerable participants?** # **(if "Others" is selected)**

-Insert text-

- No

K8. Does the study involve any of the following? #

[ ] Inpatients.
[ ] Outpatients.
[ ] Healthy Volunteers.

A healthy volunteer is someone with no known significant health problems who participates in clinical trial study to test a new drug, device, or intervention.

[ ] Not applicable.

Section L: Research Participants- Pregnant Women, Foetuses & Neonates

-Section appears only when "CIRB Application Form" is selected and "Pregnant Women, Foetuses & Neonates" is chosen in K7-

For research studies that involve pregnant women, foetuses and/or neonates, the research must meet specific criteria. Please provide protocol specific information explaining how your proposed research project meets them.

L1. Please indicate if your research involves: #

[ ] Pregnant Women and Foetuses.

[ ] Neonates of Uncertain Viability and/or Nonviable neonates.

[ ] Viable neonates.

NOTES:
Please ensure that your research does not involve maintaining the vital functions of the neonate artificially or terminating the heartbeat or respiration of the neonate.

L2. Describe if appropriate preclinical studies, including studies on pregnant animals and clinical studies including studies on non-pregnant women, have been conducted and data is available to assess risks to pregnant women and foetus. #
-Insert text-

L3. Describe if the risk to the foetus is the least possible in order to achieve the research objectives. #

Explain how you would minimize the risk to the foetus to attain the research objectives.

-Insert text-

L4. Describe the additional safeguards that will be provided to protect the rights, safety and welfare of these vulnerable participants. #

Kindly state all additional steps that will be taken to minimize coercion and to protect the rights, safety and wellbeing of study participants.

-Insert text-

L5. Special Informed Consent Requirements (Check all that apply). #

[ ] I will obtain consent from the pregnant women because:

[ ] Research holds out the prospect of direct benefits to the pregnant women.

[ ] Research holds out the prospect of direct benefits to both the pregnant women and the foetus.

[ ] Risk to the foetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means.

[ ] I will also obtain consent from the father because the research holds out the prospect of direct benefit solely to the foetus.

[ ] The Informed Consent document(s) will provide information regarding the reasonably foreseeable impact of the research on the foetus or neonate.

L6. Assurances by Principal Investigator.

• There will be no inducements, monetary or otherwise, offered to terminate a pregnancy.

• Individuals engaged in the research will not have any part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.

• Individuals engaged in the research will not have any part in determining the viability of a neonate.

I agree with the above statements. Kindly select response "Yes" or "No". #

- Yes
- No

Section M: Research Participants- Children

-Section appears only when "CIRB Application Form" is selected and "Children" is chosen in K7-

M1. Describe if appropriate studies have been conducted on animals and adults first, and data is available to assess risks to children participating in the research. #

Describe if appropriate studies have been conducted on animals and adults first and data is available to assess risks to children participating in the research. If such studies have been published, please provide a copy of the paper.

-Insert text-

M2. Please justify the need to involve children. Can the research question be answered through alternative means (e.g. involving adults only)? #

Kindly explain why the research has to be conducted in children e.g. research question is related to disease or treatment in children.

NOTES:
Research involving children will be classified into one of the following three categories:

Category 1 – Research that does not involve more than minimal risk.

Category 2 – Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual participant and the relation of the anticipated benefit to the risk is at least as favourable to the participants as that presented by alternative approaches.

Category 3 – Research involving greater than minimal risk and no prospect of benefit to the individual participant. In order to approve research in this category, the CIRB must determine that:

i. The risk of the research presents no more than a minor increase over minimal risk.
ii. The intervention or procedure presents experiences to the participants that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social or educational situations.
iii. The intervention or procedure is likely to yield generalisable knowledge about the participant's disorder or condition which is of vital importance for the understanding or the amelioration of the disorder or condition.

-Insert text-

M3. Describe how the relation of potential benefits to risks is at least as favourable as that presented by alternative approaches. #

Please justify if the potential benefits of participation are comparable to the risks of standard treatment or other alternatives (e.g. use of medication other than study drugs or undergoing procedures other than those listed in the study).

-Insert text-

M4. Describe any additional safeguards that will be provided to protect the rights, safety and welfare of these vulnerable participants. #

Please state if steps will be taken to minimize risks and to protect rights, safety and wellbeing of research participants (e.g. a child advocate will be present during the consent taking process).

-Insert text-

M5. What are the provisions for obtaining the child's assent and parental permission? #

NOTES:
PARENTAL PERMISSION – CIRB will use the following guidelines to determine parental permission/ consent requirements:

a. If both parents are available and willing to provide permission, the Principal Investigator should obtain consent from both parents.

b. For research approved under Category 1 and 2 (see Section M2), permission from at least one parent or legal guardian must be obtained.

c. For research approved under Category 3 (See Section M2), permission must be obtained from both parents, unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

ASSENT BY THE CHILD – In general, the CIRB recommends that assent be obtained from children who are over six years old. Primary school aged children (6–12 years old) should be provided with a short assent document that clearly explains discomforts and inconveniences that the child may experience if he or she agrees to participate. The document should also emphasize the voluntary nature of the research and that the child may refuse to participate without any consequences. For research involving children of secondary school age and older children (13-20 years old), provision may be made in the same consent document that will be signed by the parents for the signature of the child. The CIRB must review and approve the assent document and the consent document prior to initiation of the study.

NOTES:
For studies recruiting participants aged 6-12 years old, the participants should be provided an assent form to document their agreement regarding participation. The assent form should be written using simple words which an average 6-12 years old is able to understand. If an investigator deems that the children age 6 to 12 years, has sufficient understanding and intelligence, Participant Information Sheet and Consent Form may be used instead.

For studies recruiting participants aged 13-20 years old, the participants' assent should be sought and documented using the Participant Information Sheet and Consent Form.

For participants aged 6-20 years old, their agreement regarding participation should be documented together with the documented informed consent of their Legal Representative (e.g. Deputy, Adult Parent, Legal Guardian).

Please check all sections which are applicable for this study. [#]

- Assent will be obtained from all children above 6 years old and Parental Permission will be obtained.
  [ ] Please provide a separate Assent Form to document assent for children aged 6-12 years old.
  -Attach Assent Form-

  [ ] Please provide provision for Signature of Child on Parental Consent Form for children aged 13-20 years old.

File Name	Description	Upload Date

- Assent will not be obtained from the children. Only Parental Permission will be obtained.
- Parental Permission will not be obtained from the parents. Only assent will be obtained.

-Attach Assent Form-

File Name	Description	Upload Date

- Neither the child's Assent nor Parental Permission will be obtained.

Section N: Research Participants- Prisoners

-Section appears only when "CIRB Application Form" is selected and "Prisoners" is chosen in K7-

Please provide protocol specific information explaining how your proposed research project meets the following criteria.

N1. How does the research purpose justify enrolling prisoners? #

Kindly justify the reason for including prisoners in this study (e.g. particular research question can only be addressed by involving prisoners).

-Insert text-

N2. Is there any evidence of duress, coercion, or undue influence in the particular prison(s) from which participants will be recruited? #

Please state if there will be any duress, coercion, or undue influence in the particular prison(s) from which participants will be recruited and provide the justification.

-Insert text-

N3. Are potential research related risks to prisoners comparable to risks that would be accepted by non-prisoner volunteers? #

Please justify if the risks of participating in a study to prisoners will be acceptable by non-prisoner research volunteers.

-Insert text-

N4. Describe the systems in place to ensure participant and data confidentiality. #

Kindly explain all steps which will be taken to ensure the privacy of research participants and confidentiality of data e.g. where and how consent will be taken, where the data will be stored, if the data is coded, who will have access to the data etc.

-Insert text-

N5. Describe any additional safeguards that will be provided to protect the rights, safety and welfare of these vulnerable participants? #

Kindly indicate if any additional steps are taken to ensure the rights, safety and wellbeing of research participants.

-Insert text-

Section O: Research Participants- Cognitively Impaired Persons

-Section appears only when "CIRB Application Form" is selected and "Cognitively Impaired Persons" is chosen in K7-

O1. Is this research relevant to this group of participants who are cognitively impaired? #

If "Yes" is selected, please state and justify the reason for including cognitively-impaired persons in this study (e.g. particular research question can only be addressed in cognitively-impaired persons).

If "No" is selected, it is recommended that the study be conducted in mentally competent participants instead.

- Yes
  -Insert text-
- No

O2. Are adequate procedures for evaluating the mental status of prospective participants employed to determine if they are capable of providing consent? #

If "Yes" is selected, please provide details on the procedures for evaluating the mental status of prospective participants (e.g. with validated assessment such as Mini-Mental State Examination (MMSE)).

If "No" is selected, please justify the reason for not evaluating the mental status of prospective participants.

- Yes
  -Insert text-
- No

O3. Will legal representatives (LRs) be approached to give consent on behalf of the individuals judged incapable of providing consent? #

If "No" is selected, please elaborate why a legal representative could not be approached to give consent on behalf of the individuals judged incapable of providing consent.

- Yes
- No
  -Insert text-

O4. Will a separate Consent Form be used for cognitively impaired persons? #

If "Yes" is selected, please attach a copy of the Separate Assent Form. This should be a separate assent form written in simple words for cognitively impaired persons to understand.

If "No" is selected, please justify the reason for not obtaining assent from the participants.

- Yes
  -Attach Consent Form-

File Name	Description	Upload Date

- No
  -Insert text-

O5. If a participant is incapable of giving valid consent, will his/her objection to participation be overridden? #

- Yes
  -Insert text-
- No

O6. Will an advocate or consent monitor be appointed to ensure that the preferences of potential participants are elicited and respected? #

If "No" is selected, please justify the reason for not appointing an advocate or consent monitor.

A patient advocate or an advocacy group can provide an understanding of the participant population and how the research is likely to impact them. Advocates or consent monitors are appointed to monitor the consent process, to assess the participant's level of impairment, and to determine whether the participant is capable of providing, and has in fact provided the requisite consent or assent.

- Yes
- No
  -Insert text-

O7. Will an advocate or consent monitor be appointed to ensure the continuing agreement of participants to participate as the research progresses? #

If "No" is selected, please justify the reason for not appointing an advocate or consent monitor to ensure the continuing agreement of participants to participate as the research progresses (e.g. the research study only involves a single visit).

A patient advocate or an advocacy group can provide an understanding of the participant population and how the research is likely to impact them. Advocates or consent monitors are appointed to monitor the consent process, to assess the participant's level of impairment, and to determine whether the participant is capable of providing, and has in fact provided the requisite consent or assent.

- Yes
- No
  -Insert text-

O8. Will the patient's physician or other health care provider be consulted before any individual is invited to participate in the research? #

If "No" is selected, please justify the reason for not consulting the patient's physician or other health care provider (e.g. the participant's participation in the research study does not interfere with his/her routine clinical care).

- Yes
- No
  -Insert text-

O9. Is there a possibility that the request to participate itself, may provoke anxiety, stress or any other serious negative response? #

If "Yes" is selected, please provide details on the additional measures that will be taken to manage this (e.g. a psychiatrist will be present during the consent taking process to monitor the signs and symptoms displayed by the potential participants, and the consent taking process will be stopped if potential participants show any signs of distress).

- Yes
  -Insert text-
- No

O10. Are there any other additional safeguards in place to protect the rights, safety and well-being of these vulnerable participants? #

- Yes
  -Insert text-
- No

Section P: Consent Process- Consent Required

-Section appears only when "Informed Consent" or "A combination of both Informed Consent and Waiver of Consent" is chosen in F17 ("CIRB Application Form) or J2(v) (CIRB Exemption Application Form))-

The Principal Investigator is responsible for ensuring that all Study Participants give informed consent before enrolling into the study. Please describe the consent process below.

P1. Describe when the consent process will take place with the potential participant. #

Participants should be approached prior to the initiation of any study procedures and should not be approached in a situation where they may feel compromised (e.g. while in labour, just prior to a surgical procedure or under sedation).

NOTES:
• Informed Consent should be obtained before initiation of the study, i.e. Before any procedures that are being performed solely for the research.

• Participants should not be approached when participants are under duress, for example, it would not be appropriate to approach a participant immediately before a procedure or surgery, while in labour, while under sedation and any other situation where a participant might feel compromised.

-Insert text-

P2. Where will the consent process take place with the potential participant (e.g. in room ward, outpatient clinic etc.)? Please justify why the place chosen for the consent process is suitable.#

NOTES:
• Participants should be approached in a quiet and conducive environment. It would not be appropriate to approach a participant in an Operating Theatre for a study when he/she is getting ready for a procedure, even though the study is not related to the procedure.

• Investigator should also protect the privacy of the participant when approaching the patients to participate in research (e.g. when approaching participants for survey involving sexually transmitted diseases, approaching the participant in the Waiting Area of a General Clinic may violate the participant's privacy).

-Insert text-

P3. Please describe the consent process as follows:

NOTES:
• Please explain, if the time which you plan for the consent process to take place would give the participant sufficient time to consider and discuss with family members etc.

• Please explain, if the place where you plan for the consent process to take place would allow the participant to be comfortable, and have the right frame of mind to consider participation.

• Please explain how the person who would be assigned to take consent would minimize the possibility of coercion or undue influence.

The investigator must take precaution that in the process of obtaining consent from participants, the time and place must be suitable and comfortable for the participant to discuss the research with the investigator, and must not be made to feel compelled to participate. The participant must also be given sufficient time to decide whether or not to participate in the research, and have the option of further discussing with their family members before making the decision.

It is also advisable that the attending physician of the participant should not obtain the consent of their own patient for research, as the participant may feel obliged to join the research, or have a heightened sense of faith and trust in their own physician, and may be more likely to participate.

(i) Explain if adequate time will be given to the participant to consider their participation. #
-Insert text-

(ii) Please explain if the place where consent will be taken is suitable. This place should allow the participants to be comfortable and have the right frame of mind to consider participation. #
-Insert text-

(iii) Please explain how the person taking consent would minimise the possibility of coercion or undue influence. #
-Insert text-

(iv) **Will the consent process be taken in the presence of a witness?** #

NOTES: The witness here does not apply to impartial witness required under special circumstances. This section refers to studies where all consent will be obtained in the presence of witness.

- Yes
- No

P4. Does your study involve potential vulnerable participants whereby obtaining informed consent from the participant is not possible and informed consent is required from a Legal Representative (LR)? #

If "Yes", please explain:
i. why the study requires the informed consent of a LR (e.g. participants are minors, cognitively impaired or unconscious) and
ii. state who LR is (e.g. spouse, parents, guardian etc.).

• A LR may give consent on behalf of the individual for participation in a research only when the individual is not capable of giving legally effective informed consent, such as:

a. A child as defined - Persons who have not attained legal age for consent to treatments or procedures involved in the research, which under Singapore law is an individual under the age of 21 years, excluding persons who are below the age of 21 but are married.
b. An individual who is cognitively impaired, or
c. An individual who is unconscious.

- No
- Yes
  -Insert text-

P5. Please describe the provisions to protect the "privacy interest" of the participants (e.g. consent will be obtained in a separate room, free from intrusion and participants are comfortable with the proposed settings). #

The manner in which the participants are identified and approached for participation in research may constitute an invasion of privacy. The investigator should take precaution that in the process of obtaining consent from a research participant, it is preferable that consent be conducted in a private consultation room to ensure and protect the privacy of the participant from others' intrusion. The wishes of the participant must also be respected if they choose not to participate in the research.

-Insert text-

P6. Will consent be documented in the form of a written and signed Research Participant Information Sheet and Consent Form? #

- Yes

-Attach Research Participant Information Sheet and Consent Form-

File Name	Description	Upload Date

- No

Documentation of consent will only be waived if certain conditions are fulfilled. Please select the appropriate category.

- Category A

Category A

• The only record linking the participant and the research would be the consent document.
• The principal risk would be potential harm resulting from a breach of confidentiality.

• If the research is subjected to FDA regulations, your study does not qualify for waiver of documentation of consent under Category A.
• If the subject will not be asked whether the participant wants documentation linking the participant with the research, your study do not qualify for waiver of documentation of consent under Category A.

(i) The only record linking the participant and the research would be the consent document. **# (if "Category A" is chosen)**
-Insert text-

(ii) The principal risk would be potential harm resulting from a breach of confidentiality. **# (if "Category A" is chosen)**
-Insert text-

(iii) The research is not subjected to FDA regulations. **# (if "Category A" is chosen)**
- o No. The research is subjected to FDA regulations.
- o Yes. The research is not subjected to FDA regulations.

(iv) Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participants' wishes will govern. **# (if "Category A" is chosen)**
- o No. The participant will not be asked.
- o Yes. The participant will be asked.

- o Category B

Category B

• The research presents no more than minimal risk of harm to participants.
• The research involves no procedures for which written consent is normally required outside of the research context.

(i) The research presents no more than minimal risk of harm to participants. **# (if "Category B" is chosen)**
-Insert text-

(ii) The research involves no procedures for which written consent is normally required. **# (if "Category B" is chosen)**
-Insert text-

P7. Will research participants receive any monetary payments (including transportation allowances) or gifts for their participation in the study? #

If "Yes" is selected, kindly state the anticipated reimbursement amount (per visit and total) for travel, meal or other expenses incurred due to participation in the research (e.g. Participants will be reimbursed $50 for transportation fare for each study visit).

Please note that payment to participants should be pro-rated and participants should not be paid only at the end of the study to minimise coercion / inducement to complete the study.

- No
- Yes
  -Insert text-

P8. Besides the Research Participant Information Sheet and Consent Form, will any other materials or documents be used to explain the study to potential Research Participants (e.g. scripts, hand outs, brochures, videos, logs etc.)? #

- No
- Yes, please attach the document(s) for review.
  -Attach documents-

File Name	Description	Upload Date

P9. Will the study enroll non-English speaking participants? #

- No
- Yes
  (a) What are the possible languages that will be understood by the prospective participant or the legal representative? # **(if "Yes" is selected)**
  [ ] Chinese
  [ ] Malay
  [ ] Tamil
  [ ] Others
  -Insert text-
  (b) Will the consent be communicated in a language that is understood by the prospective participant or the legal representative? # **(if "Yes" is selected)**
  - No
  - Yes

  (c) How will the Non-English consent be documented?
  Consent Document translated to the language understood by the prospective participant or the legal representative. You may attach the translated consent document, if available. Otherwise, please submit the translated document after the English version has been approved by CIRB. Submission of the translated consent forms to CIRB should preferably be accompanied by a Certification of Translation from the translator or translation service.

  The template of Certificate of Translation is available in the CIRB website.
  -Insert text-
  -Attach translated document(s)-

File Name	Description	Upload Date

P10. Will the study be recruiting participants under emergency situations, when prior consent of the participant is not possible, and the consent of the participant's legal representative, if present, should be requested? #

Emergency Situations

• In emergency situations, when prior consent from the participant him/herself is not possible, the consent of the participant's legal representative, if present should be requested.
• When prior consent of the participant is not possible, and the participant's legal representative is not available, enrolment of the participant should require measures described in the protocol to protect the rights, safety and wellbeing of the participant and to ensure compliance with applicable regulatory requirements. The latter includes written certification from the Principal Investigator who is a specialist and 1 independent specialist who is not conducting the trial certify in writing that:

- The potential participant is facing a life-threatening situation which necessitated intervention;

- That person is unable to give his consent as a result of his medical condition;

- It is not feasible to request consent from that person or to contact his legal representative within the crucial period in which treatment must be administered;

- Neither that person or his legal representative nor any members of that person's family has informed the Principal Investigator of his objection to that person being used as a participant in the clinical trial.

• The participant or the participant's legal representative should be informed about the research as soon as possible and consent to continue should be requested.

- Yes
  -Insert text-
- No

P11. Do you have any additional comments regarding the Informed Consent process? #

- No
- Yes
  -Insert text-

Section Q: Consent Process- Waiver of Consent

-Section appears only when "Waiver of Informed Consent" or "A combination of both Informed Consent and Waiver of Consent" is chosen in F17 (CIRB Application Form) or J2(v) (CIRB Exemption Application Form)-

Q1. Please select the type of waiver required. #

☐ I. Waiver of informed consent for non-HBR studies.

a. The study poses no more than minimal risk to research participants. Please justify how your study meets this criterion.

The investigators must provide all the following:

- Verification that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life;

- Affirmation that the information collected is not sensitive in nature; and

- Assurance that the data has been collected and are derived from standard clinically indicated procedures.

-Insert text-

b. Waiver of informed consent will not adversely affect the rights and welfare of research participants. Please justify how your study meets this criterion.

The investigators must provide assurance that regardless of being part of the research or not, the information will still be collected as part of patients' clinically indicated procedures or as part of the normal running of business operations. None of the information collected would affect the clinical decisions about the individual's care, and patients are not being deprived of clinical care to which they would normally be entitled to.

-Insert text-

c. The study cannot be practically conducted without the waiver of informed consent. Please justify how your study meets this criterion.

Investigators must assure the CIRB that identifying and contacting thousands of patients / participants, although not impossible, would not be feasible for a collection of information that would not change the care they would already have received.

-Insert text-

d. Whenever appropriate, will the research participants be provided with additional pertinent information after participation?

Investigators must provide assurance that the participants will be informed of vital information if there is a means of identifying the participant. Otherwise investigator must justify why it is not appropriate to provide the information to the participant, for example there are no identifiers collected that would enable the investigator to identify the participant, or information cannot be verified due to the experimental nature of the protocol and would be of the patients' best interest not to receive the information.

- ○ No
- ○ Yes

-Insert Text-

e. Do you have any additional comments supporting the waiver of informed consent?

- ○ No
- ○ Yes

-Insert text-

☐ II. Waiver of appropriate consent under HBRA Fifth Schedule, Part 2, Section 3.

a. The research cannot reasonably be carried out without the use of the human biological material or health information in an individually‑identifiable form. Please justify how your study meets this criterion.
-Insert text-

b. The process of obtaining consent from the person, to which the individually‑identifiable human biological material or health information relates, will involve a disproportionate amount of effort and resources relative to the research requirements. Please justify how your study meets this criterion. Please also submit the SingHealth PDPA Impracticability Calculator to demonstrate whether it is impracticable to obtain informed consent from participants.

The SingHealth PDPA Impracticability Calculator can be downloaded here.

Please note that the SingHealth PDPA Impracticability Calculator is strictly for internal use by SingHealth staff only.

-Insert text-

File Name	Description	Version Date

c. The use of the individually-identifiable human biological material or health information, as the case may be, involves no more than minimal risk to the research subject or donor. Please justify how your study meets this criterion.
-Insert text-

d. The waiver concerned will not otherwise adversely affect the rights and welfare of the research subject or donor. Please justify how your study meets this criterion.
-Insert text-

e. The human biomedical research or health information research would reasonably be considered to contribute to the greater public good. Please justify how your study meets this criterion.

Please refer to the SingHealth Office of Research Integrity and Compliance (ORIC) "Guidance on Greater Public Good" here.

Please note that the "Guidance on Greater Public Good" is strictly for internal use by SingHealth staff only.

-Insert text-

☐ III. Waiver of appropriate consent under HBRA Fifth Schedule, Part 2, Section 3A – individually identifiable health information obtained or compiled before 1 November 2017.

a. The research cannot reasonably be carried out without the use of the health information in an individually‑identifiable form. Please justify how your study meets this criterion.
-Insert text-

b. The use of the individually‑identifiable health information involves no more than minimal risk to the research subject. Please justify how your study meets this criterion.
-Insert text-

c. The waiver concerned will not otherwise adversely affect the rights and welfare of the research subject. Please justify how your study meets this criterion.
-Insert text-

d. The process of obtaining consent from the person, to which the individually‑identifiable health information relates, will involve a disproportionate amount of effort and resources relative to the research requirements. Please justify how your study meets this criterion. Please also submit the SingHealth PDPA Impracticability Calculator to demonstrate whether it is impracticable to obtain informed consent from participants.

The SingHealth PDPA Impracticability Calculator can be downloaded here.

Please note that the SingHealth PDPA Impracticability Calculator is strictly for internal use by SingHealth staff only.

-Insert text-

File Name	Description	Version Date

☐ IV. Waiver of appropriate consent under HBRA Fifth Schedule, Part 2, Section 3B – individually identifiable health biological material obtained or compiled before 1 November 2017.

a. The research cannot reasonably be carried out without the use of the human biological material in an individually‑identifiable form. Please justify how your study meets this criterion.

-Insert text-

b. The use of the individually‑identifiable human biological material involves no more than minimal risk to the research subject. Please justify how your study meets this criterion

-Insert text-

c. The waiver concerned will not otherwise adversely affect the rights and welfare of the research subject. Please justify how your study meets this criterion.

-Insert text-

d. Reasonable effort has been made to re‑contact the person to which the individually‑identifiable human biological material relates for the purpose of obtaining his or her consent. Please justify how your study meets this criterion.

It is stated in the "Guidance on Appropriate Consent" released by MOH on 17 May 2019, researchers may consider convenient and practical means of seeking consent from the research subject, such as replying to a letter, email or recording of voice call. Generally, it can be considered that reasonable effort has been made if the research subject remains uncontactable or have not responded after two attempts (reasonably spaced at approximately 30 days apart) have been made to re-contact the subject.

-Insert text-

☐ V. Consent was obtained from research participant(s) previously.

a. Please state the source. For CIRB approved study, please state the protocol title and reference number.

- Insert text -

b. Please provide supporting document(s), if any. For CIRB approved study, please submit a copy of the approved Participant Information Sheet and Consent Form and highlight in the document the section regarding future research.

-Insert text-

File Name	Description	Version Date

Section R: Research Data Confidentiality

-Section only appears when "CIRB Application Form" is selected-

In general, to protect the participant's confidentiality, research data should be coded, and the links between the participant's identifiers and the codes should be stored separately from the research data.

R1. Will coded/anonymous research data be sent to the study sponsor (e.g. pharmaceutical-sponsored studies)? #

If "Yes" is selected, this would mean that coded/ anonymous research data will be sent to study sponsor.

If "No" is selected, this would mean that the research database will be created and research data stored in SingHealth or institutions under the oversight of SingHealth CIRB.

- Yes, the study team would send research data to the study sponsor.
- No, the study team would store all research data within the Institution.

(i) Please state where the research data (soft copy and/or hardcopy) will be stored and indicate if the location storage is secured. (i.e. Password Protected PC or laptop, data stored in physical location with lock and key access.) # (if "No" is selected)

Describe the physical location where the research data will be stored (e.g. network or stand-alone PC, and the allocated storage room).

-Insert text-

(ii) Who will have access to the research data, and how will access to the research data be controlled and monitored? (Please state the personnel who will have access to the study data e.g. Principal Investigator, Co-investigator, study coordinator.) # (if "No" is selected)

There should be limited access to the study data in order to maintain the confidentiality of the research data and participant identities. Please state how will access be controlled and monitored (e.g. research data will be kept in password-protected file or under lock and key, only Study Team Members have access to password/key, password will be changed periodically etc.).

-Insert text-

(iii) Are there any other measures in place to protect the confidentiality of the research data? # (if "No" is selected)

Some measures may include password protection, security under lock and key, access controlled office, etc. Common measures employed by investigators to protect confidentiality include storage of records in locked file cabinets, in locked offices, on computers protected by a password, or on computers that are not linked onto a network. Another common protection is to code the data with an identifier, and to keep the key to the code located in another physical location or on a separate computer.

-Insert text-

(iv) Are there any research data sharing agreements with individuals or entities outside the institution, to release and share research data collected? # (if "No" is selected)

- No
- Yes

Please describe the agreement. Submit a copy of the agreement if available. **# (if "Yes" is** selected)

-Insert text-

-Attach copy of agreement, if available-

File Name	Description	Upload Date

(v) Describe what will happen to the research data when the study is completed. # (if "No" is selected)

Research data should be retained in a secured storage facility for a minimum of 7 years after completion of research study or date of publication of the research using the research data, whichever is later. (SingHealth Cluster Research Data Management Policy - Clinical Trial and Clinical Research – This document is strictly for internal use by SingHealth Staff members)

These documents should be retained by the Principle Investigator in a secure storage facility. They should be accessible for inspection and copying by authorized authorities.

For clinical trials, according to ICH GCP E6 (R2), the essential documents should be retained until:

i. At least 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region; or
ii. At least 2 years have lapse since the formal discontinuation of clinical development of the investigational product; or
iii. These documents should be retained for a longer period if required by the applicable regulatory requirements or by an agreement with the sponsor.

-Insert text-

R2. Will any part of the study procedures be recorded on audiotape, film/video, or other electronic medium? #

- No
- Yes

(i) What is the medium (audio tape/ video etc) used for recording? # (if "Yes" is selected)

-Insert text-

(ii) Please describe the contents of the recording (e.g. audio-recoding of interview/ focus group discussion, images of facial feature, etc). # (if "Yes" is selected)

-Insert text-

Restricted, Sensitive (Normal)

(iii) Explain how the recorded information will be used in the study. # **(if "Yes" is selected)**

Please explain how the recorded information will be used (e.g. photographs will be taken to assess / compare the disease condition, interviews with the participant will be audio-taped and later transcribed).

-Insert text-

(iv) For how long and where will the recording medium be stored? Who will have access, how will access be controlled and monitored? # **(if "Yes" is selected)**

- Please state location of storage of medium.
- Please state how long the recording medium will be stored.
- If copies are made, who will have access to them, and what are the procedures for accessing and using the data in the recording medium.

-Insert text-

(v) How will the recording medium be disposed? # **(if "Yes" is selected)**

Please describe how the recording medium will be destroyed.

-Insert text-

Section S: Biological Materials Usage & Storage

-Section only appears when "CIRB Application Form" is selected-

S1. Will any human biological materials (e.g. blood, tears, urine, saliva and tissue) be used as part of the study? #

- o No
- o Yes

□ a. Human biological materials will be obtained prospectively **(if "Yes" is selected)**

i. Please state the type of human biological materials used and describe how they will be obtained. Please include the frequency of collection, the amount to be collected in each visit and the total amount required for the research study.
-Insert text-

ii. How are the human biological materials identified?

- o No identifiers
- o Human biological materials are coded and the code is maintained at the source
- o Identifiers present
- o Other methods

Please elaborate.
-Insert text-

□ b. Existing human biological materials will be used **(if "Yes" is selected)**

Please indicate the source(s) of the human biological materials.

□ I. Tissue bank

i. Please state the name of the tissue bank(s).
-Insert text-

ii. Please state the type of human biological materials that will be used.
-Insert text-

☐ II. Other sources

i. Please state the source. If there are any relevant supporting document(s), please attach.
-Insert text-

File Name	Description	Version Date

ii. Please state the type of human biological materials that will be used.
-Insert text-

S2. What tests will be performed on these biological materials? #(if "Yes" is selected)

-Insert text-

S3. Will results from the tests be communicated to the research participants? If not, please explain. #(if "Yes" is selected)

Please indicate if test results will be conveyed to participants. If not, please indicate the reason/s for not divulging the information to the participants (e.g. the information would not affect the clinical decisions about the individual's care and have no effect on the participants).

Please note that test results are not incidental findings. For the definition on incidental findings, please refer to Section F8.

-Insert text-

S4. Will any cell lines be created from the human biological materials? #(if "Yes" is selected)

- o No
- o Yes

i. How will the cell lines be identified? (if "Yes" is selected)

- o The cell lines are stripped of any identifiers and cannot be linked or traced back to its donor.
- o The cell lines are coded.
- o By other methods.
  - Insert text -

S5. Will the biological materials be destroyed at the completion of the study, or will they be stored for future use or future research? #(if "Yes" is selected)

The informed consent of the participant must be obtained for storage and future use of their biological materials.

The Informed Consent document should clearly document whether the participant agree or not to the use of their samples for future research. Only samples from participants who have consented should be stored.

- o Yes, the biological materials will be destroyed at the completion of the study.
- o No, the biological materials will be stored after completion of the study.
  i. **Please indicate the duration and purpose of the storage.**
  -Insert text-

ii. **Please indicate the location of storage.**

□ I. Tissue Bank under oversight or custodian of SingHealth

Name of the tissue bank.
-Insert text-

□ II.. Other location

a. Please state the reason for storage on this location.
-Insert text-

b. How will these stored biological materials be identified?

- The stored human biological materials are stripped of any identifiers and cannot be linked or traced back to its donor.

- The stored human biological materials are coded.
  Who will maintain the codes linking the stored human biological materials and its donor?
  - Insert text –

- By other methods.
  - Insert text -

Section T: Data & Safety Monitoring

-Section only appears when "CIRB Application Form" is selected-

T1. The purpose of the Data and Safety Monitoring Plan is to ensure the safety and well-being of participants, and the integrity of the data collected for the study. Depending on the type and risk level of the study, this may include the Principal Investigator, experts within the department or institution, independent consultants or a combination of the said persons.

Who will perform the data and safety monitoring? #

For studies that are less than minimal risk, the investigator could perform the data and safety monitoring.

For investigator-initiated trials, the data and safety monitoring should be performed by the investigator and a team of Co-investigators.

For Sponsored or Global studies, if there is a Data Safety Monitoring Board (DSMB), please submit the charter of the DSMB.

A Data Safety Monitoring Board (DSMB) would be required for the monitoring of complex or potentially risky studies. Factors that suggest that a DSMB is the most appropriate way to monitor data include:

1. A large study population.
2. Multiple study sites.
3. Highly toxic therapies or dangerous procedures.
4. High expected rates of morbidity or mortality.
5. High chance of early termination.

-Insert text-

If the DSMB/DMC is an external committee, please include information/details of the composition of the external DSMB/ DMC. Kindly attach relevant file(s).

File Name	Description	Upload Date

T2. Please describe the frequency of review (e.g. daily, weekly, quarterly) and what data (e.g. adverse events/serious adverse events) will be monitored for safety. #
-Insert text-

T3. How is data integrity monitored to ensure that study data is authentic, accurate and complete, and if data correlates with the case report forms? #
-Insert text-

T4. Please describe the stopping criteria for the research study based on efficacy, futility and safety criteria. #
-Insert text-

T5. Please state the route of dissemination of any data and safety information to the study sites, as well as the person/ team responsible for doing so? #
-Insert text-

Other Attachments

Note:
1. Additional documents may be attached here. Documents relevant to the respective sections should not be attached here.

File Name	Description	Upload Date

Section U: Declaration of Principal Investigator

Declaration of Principal Investigator

This is the Principal Investigator's Declaration.

I will not initiate this study until I receive approval notification from CIRB and regulatory authority approval (if applicable).

I will not initiate any change in the protocol without prior written approval from CIRB, except when it is necessary to reduce or eliminate any immediate risks to the Study Participant. Thereafter, I will submit the proposed amendment to the CIRB and other relevant authority for approval.

I will promptly report any unexpected or serious adverse events, unanticipated problems or incidents that occur in the course of this study.

I will maintain all relevant documents and recognize that the CIRB staff and regulatory authorities may inspect these records.

I understand that failure to comply with all applicable regulations, institutional and CIRB policies and requirements may result in the suspension or termination of this study.

I declare that there are no existing or potential conflicts of interest for any of the study team members participating in this research study and their immediate family members. If there are, I have declared them in the relevant section of this application form.

Site	Principal Investigator	Study Role	Email	Declaration	Date

Endorsements Page

Department Representative Endorsement

The Department Representative can be the Head/ Chief/ Research Head of the PI's Department. Should the Head or Chief be the PI or Site-PI, then their reporting officer should complete this Section. It is assumed that all Departments involved concur with the Pi's Department Representative. The validity of this assumption rests solely on the PI.

1. **Significance:**

Does the study address an important problem? Will the study affect concepts and methods that drive the field? ○ **Yes** ○ **No**

2. **Approach:**

Is the conceptual framework adequately developed? Are the design, methods, and analyses adequately developed and appropriate? ○ **Yes** ○ **No**

3. **Innovation:**

Does the study challenge existing paradigms? Does it employ novel concepts, approaches and methods? ○ **Yes** ○ **No**

4. **Principal Investigator:**

Is the Principal Investigator appropriately trained to conduct this study? Does the Principal Investigator have evidence of commitment (e.g. previous track record)? ○ **Yes** ○ **No**

5. Environment:

Is the Principal Investigator's environment suited to conduct the study? Is there an adequate patient pool and are there adequate resources?	○ **Yes**	○ **No**

6. Budget:

Are the projected costs appropriate (i.e. accurate)? Is the overall budget reasonable for the significance of the study?	○ **Yes**	○ **No**

7. Time

Does the Principal Investigator have adequate resources and time to conduct and complete the study?	○ **Yes**	○ **No**

Comments:

-Insert text-

☐ I acknowledge that this research is in keeping with standards set by the Principal Investigator's Department.

Date:

Full Name:

Department:

Institution:

Institution Representative Endorsement

The Institution Representative has been determined by your institution as the authority that declares whether your research is in keeping with the institution's research objectives, reputation and standards. The role of the Institution Representative is not to evaluate the scientific or ethical aspects of your study, although they may offer their comments.

Comments:

-Insert text-

☐ I acknowledge that this research is in keeping with standards set by my Institution.

Date:

Full Name:

Department:

Institution: