SingHealth CIRB: Illuminaté
"To Énlighten... Ethics, above all"
Adapted version for researchers, investigator and study
SingHealth
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Introduction to IRB Application Form

Ethics and Compliance Online System (ECOS) was jointly developed by SingHealth and NHG to support the research lifecycle from Study Initiation to Completion, enabling a more efficient management of research portfolios and ethics applications. This internet-based platform replaces the iSHaRe Institutional Review Board (IRB) system and NHG ROAM. It is accessible to both internal and external users. With ECOS, the application form was revised.

Overview of IRB Application Form

Key changes are as follows:

- "Research Methodology", "Recruitment Target" and "Research Participant Characteristics" have been combined into one section – Section E/G. Section E is appliable for Exemption Application Form and Section G is applicable for Application Form.
- "Recruitment Details", "Consent Process – Consent Required" have been combined into one section – Section J.
- 5 new sections have been added:
  - Section I (Medical Device)
  - Section O (Wavier of Documentation of Informed Consent)
  - Section P (Wavier of Informed Consent during Emergency Situation – Clinical Trial)
  - Section Q (Wavier of Informed Consent during Emergency Situation – HBR)
  - Section V (Use of Software/Mobile Applications)

Do note that only applicable sections will appear in the Application Form.

Key Section to note when reviewing Application Form:

- Section C: Study Funding Information
- Section E1/G1: Specific aims of the study
- Section E1/G2: Hypothesis of the study
- Section E3/ G7: Study Design and Research Activities
- Section E5/ G12: Enrolment Target
- Section G13: Inclusion Criteria
- Section G14: Exclusion Criteria
- Section E7/G16: Potential Risk
- Section E10/G19: Protocol
- Section H5: Investigator's Brochure (IB)
- Section I: Medical Device
- Section J2: Advertisement Materials
- Section J5/J6/ J7: Consent Process
- Section J13: Informed Consent Document
- Section L6: Assent Form
- Section R/S: Wavier of Consent
- Section T/U/V: Research Data Confidentiality
- Section W: Biological Materials and Usage
- Section X: Data & Safety Monitoring
- Other Attachments

Please refer to the IRB Guidebook: Application Form for more information.

Section B2: Study Sites

- For study site with more than one location, available options will appear in Section B2 (ai). Please select the location(s) involved in the study, where applicable.

For Example: If the study would be conducted in three different locations under SNEC, namely SNEC, SNEC Eye Clinic @Bedok and SNEC Eye Clinic @NHCS, please select the three locations accordingly (as per the example shown above).

- For studies involving SingHealth Polyclinics, please indicate in table if endorsement is required. Only one SingHealth Polyclinic site is required to perform the endorsement if the study involves more than 1 SingHealth Polyclinic sites.

Note: This is only applicable for SingHealth Polyclinic. For other sites, the default selection would be "Yes" for Endorsement needed.

For Example: If the study involves SingHealth Polyclinic – Head Office and SingHealth Polyclinic – Bedok, only 1 of the Polyclinic site is required to perform the endorsement. Please refer to the example shown above.

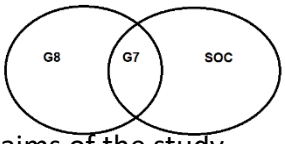
Section G1: Specific Aims & Section G2: Hypothesis

Section G1 (Specific Aims)	**Section G2 (Hypothesis)**
Broad statements of research goals which outline what the study intends to accomplish (may include multiple objectives within a single study).	Specific, testable predictions, based on existing theory or observations.

Note: Responses in G1 and G2 should not be same. Specific aims and hypothesis should be different.

Section G7 & G8: Research Activites

- **Section G7: Discuss in detail the experimental design and procedures to be used to accomplish the specific aims of the study. To list all procedures/activities that are carried out as part of research in this study and attach documents used for the purpose of this research.**



➔ To describe the experimental design and procedures used to accomplish the specific aims of the study [includes all research activities].

- **Section G8: Please list all activities that are performed for routine diagnostic or standard medical treatment as part of the research participant's standard care.**

➔ To describe the research activities which are also part of research participants standard of care.

Case 1: Clinical Trial involving oral drug A. As part of the study, participants are required to do blood test to check on full blood count and PK samples every 3 months. Patient standard of care also includes full blood count every 3 months.
Section G7: Blood test for full blood count and PK samples.
Section G8: Blood test for full blood count.

Case 2: Study involving collection of urine from participants. This collection of urine is not part of standard of care.
Section G7: Urine collection
Section G8: No study procedure performed in the study is part of standard care.

Note for Section G8:

1. Do not include research activities which are done specifically for the research.
2. Do not list the standard of care treatment for the potential participants.

Section G9: Participants' Involvement in Study

Visit Schedule should be submitted in Section G9 instead of G7. Due to data migration from iSHaRe, the visit schedule may be migrated to Section G7. Please remove the attachment in G7 and attach it in G9 when you submit the first amendment on ECOS.

Section G16: Potential Risk

Due to data migration from iSHaRe, "social risk" is selected for all studies in Section G16. Please review and select the appropriate type of risk for your study when you submit the first amendment on ECOS.

Section J2: Advertisement Materials

Responses for Section J2 should only be specific to the advertisement strategies/ materials (e.g. poster, advertisement in social media platform). Recruitment strategies (i.e. who make first contact with participants/ how participants are contacted/ consent process) should be elaborated in J4, J5, J6 and J7 (where applicable).

Section W1: Human Biological Materials

If the study would be collecting more than 1 type of Human Biological Materials (HBM): Different type of HBM should be separated into different entries in Section W1.

Section T4/W5: Management of Research Data and Human Biological Materials After Study Completion

- Management of research data after the study is completed (Section T4) should tally with the information stated in the Informed Consent Document.
- Management of HBM after the study is completed (Section W5) should tally with the information stated in the Informed Consent Document.

Takeaway message...

Applications should be reviewed and ensure that all the relevant sections are properly completed before submission. This will reduce the need for clarifications by IRB and also the IRB review time.

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