IRB Mutual Recognition Guidebook:

Guidelines and Submission Requirements for Collaborative Studies Under Single IRB Review

Introduction

A*STAR IRB, NHG DSRB, NTU-IRB, NUS-IRB and SingHealth CIRB have entered into a mutual recognition agreement streamlining the ethics review procedures for Collaborative Studies to avoid duplicative review.

The Parties to the Mutual Recognition Agreement ("MOA") are A*STAR Research Entities (ARES), National Healthcare Group (NHG), Nanyang Technological University (NTU), National University of Singapore (NUS) and SingHealth (SHS).

Research Institution or RI means a Party or Partner Institution acting as research institutions, as defined in the Human Biomedical Research Act 2015.

Partner Institution means a third-party institution with formal arrangement with any of the Parties for ethics review services, as listed in Schedule 1.

A collaborative study ("Collaborative Study") refers to a study involving at least two or more Research Institutions (RIs) or Partner Institutions whose review purview is under one of the five (5) IRBs in the agreement. The study should be led by a Lead PI from one of the RIs and supervised by a Site PI from at least one of the other RIs.

With effect from 1 April 2025, all new IRB applications involving A*STAR, NHG, NTU, NUH, NUS and SingHealth sites, or their Partner Institutions, are eligible to benefit from the IRBs mutual recognition arrangement (Single IRB Review) and have their studies reviewed by one (1) IRB.

Research studies involving a single site, or multiple sites that are under the purview of only one (1) IRB, will continue to be reviewed by the respective cluster/ institution IRBs.

Please refer to the List of Institutions and Partner Institutions of the IRBs under Schedule 1.

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1. Which IRB do I submit to?

From 1st April 2025 onwards, IRB applications can be submitted to A*STAR IRB, NHG DSRB, NTU-IRB, NUS-IRB and SingHealth CIRB, subject to the agreement between the parties involved.

Category A

Collaborative Studies falling under **Category A Studies** shall be reviewed by either **NHG DSRB or SingHealth CIRB** (Healthcare Cluster IRBs) affiliated to the Healthcare Institution employing the Lead PI of the Study.

Studies involving any one of the following:

(1) Medical records review under waiver of consent.

(2) An invasive procedure, interventional procedure or administration of medical device or product which is to be conducted at a site in a hospital, outpatient clinic or polyclinic.

(3) Research participants who are either not Healthy Volunteers or are Vulnerable Populations (such as minors, mentally incapacitated, pregnant women and prisoners).

The exception is where the subject participation is low risk, such as participating in surveys, interviews and focus group discussions, in which case the study can be considered as a Category B study.

(4) Where research activities will be conducted in a clinical setting.

Studies under Category B description, if conducted in a clinical setting with a Healthcare cluster Lead PI, should continue to be submitted to the Healthcare cluster IRB.

Category B

Collaborative Studies falling under **Category B Studies** shall be reviewed by either **A*STAR IRB, NTU-IRB or NUS-IRB** (Non-Clinical IRBs) where the Lead PI is an employee from an A*STAR / NTU / NUS institution.

No more than minimal risk studies involving any one or more of the following:

(1) Medical records reviews requiring informed consent of the research participants to be obtained.

(2) Surveys, questionnaires, and/or interviews only.

(3) Where research activities are not conducted in a clinical setting.

Studies under Category A description, if conducted in a non-clinical setting with a Non-Clinical cluster Lead PI, should continue to be submitted to the Non-Clinical IRB.

Category C

Collaborative Studies that will be out of scope of this MOA are Studies involving only unidentifiable/anonymized or de-identified human subject data or human biological material samples. Researchers should refer to their own institution's policies and procedures.

Note:

- The Lead PI's institution will be the Lead RI for the IRB application (Lead RI is for the purpose of coordinating the research as defined in Section 16 of the Human Biomedical Research Act).
- For restricted research, the Lead RI will put up the application in TIARAS.
- For occurrences of contraventions and SAEs at the various sites/ institutions, the respective RIs will still be responsible for the reporting of contravention and SAE to MOH.
- Referral of participants for recruitment is not deemed as collaborative research and is not under the MOA.
- If a Partner Institution employee is appointed as the Lead PI of the Study, the Reviewing IRB shall be the IRB affiliated to the Lead PI's Partner Institution.
- IRBs cannot grant approval for Partner Institutions of the Healthcare Institutions or Non-Clinical Institutions, if they were not appointed by those Partner Institutions to review their application.

2. How does this affect current studies?

Studies submitted on and/or approved before 1st April 2025 will remain under the oversight of their respective IRBs until study closure. However, if the study has additional sites to add from different cluster(s), these additional sites must obtain IRB approval from their respective IRBs.

3. Can collaborative studies under the MOA add on additional sites from a different cluster, and continue to be reviewed by the original IRB?

Studies submitted on or after 1st April 2025 will be eligible for Single IRB review. PIs may submit amendments to add additional sites from different cluster(s), and have these amendments reviewed by the initial reviewing IRB. This is provided that the study still falls within Category A (reviewed by Healthcare Cluster IRBs) or Category B (reviewed by Non-Clinical IRBs).

4. How should the application be submitted?

The Lead PI for collaborative study should submit the IRB application via the IRB portal of his/her cluster/ institution's IRB.

Lead PI's Cluster/ Institution	Cluster/ Institution's IRB	IRB Portal
ARES	A*STAR IRB	No portal used. Submit IRB application dossier via hbro@hq.a-star.edu.sg. Refer to instructions on A*STAR Intranet.
NTU	NTU-IRB	Ethics Review Management Portal (ERMP) User Guides: (1) How to submit an IRB application? (2) NTU-IRB Guidelines
NUS	NUS-IRB	Integrated Research Information Management Suite (iRIMS-IRB) Guides (accessible via NUS intranet only): (1) User Guides (2) Video Guides

NHG NUHS	NHG DSRB	Ethics and Compliance Online System (ECOS) https://www.ecos-research.com.sg/login/ User Guides: (1) NHG (2) SingHealth
SingHealth	SingHealth CIRB	

5. Does everyone in the study team need to create an account to access the ECOS portal?

A*STAR IRB: Studies requiring A*STAR IRB review should be submitted via hbro@hq.a-star.edu.sg. It will not be managed on ECOS.

NTU-IRB: Studies requiring NTU-IRB review should be submitted via ERMP and not ECOS. Non-NTU personnel do not need to create ERMP accounts to be listed in the study team.

NUS-IRB: Studies requiring NUS-IRB review should be submitted via iRIMS-IRB and not ECOS. Non-NUS personnel do not need to create iRIMS-IRB accounts to be listed in the study team.

NHG DSRB and SingHealth CIRB: Studies requiring DSRB and CIRB review should be submitted via ECOS. Users requiring access to ECOS must create an account before logging into the system.

All PIs, Site PIs and Co-Investigators should be added into the IRB application using their registered ECOS accounts and should only carry out research-related activities upon obtaining approval from the reviewing IRB. Study Team Members, Study Administrators and Sponsors may be added via the Clinical Research Management System (CRMS) as needed.

This will allow the study team to view the applications, download study-related documents such as approval letters and receive communications from the IRBs.

Definition of study roles:

- Co-Investigators – 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 – 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 the study must be listed as part of the research/ clinical trial team via delegation log.
- If an individual's role on the study is part of his/ her regular duties (i.e. radiographer, imaging technologist) and involvement in the study is limited to performing those duties without contributing to the study goal, such individuals are not considered part of the research/ clinical trial team.

6. How do Department Rep (DR) and Institutional Rep (IR) access the portals for endorsement?

A*STAR IRB:
Studies requiring A*STAR IRB review should be submitted via hbro@hq.a-star.edu.sg. It will not be managed on ECOS.

For collaborative studies submitted to A*STAR IRB:

- The lead ARES PI and their Institution Representative would need to endorse the application.

- All site PIs and their Institution Representative would need to complete the PI Declaration and Institution Endorsement Form and submit it as part of the application dossier.
- If the PI's Institution requires endorsement from a Department Representative, the site PI must ensure that the necessary approval is obtained either through a separate email from the Department Representative or by having them sign on the same page as the Institution Representative's Endorsement.

Refer to instructions stated in the IRB Application Form.

NTU-IRB: This section is not applicable for studies submitted to NTU-IRB via ERMP. DRs and IRs do not need to access NTU's Ethics Review Management Portal (ERMP). Where necessary, PIs submitting ethics applications into ERMP can upload the endorsed (or signed) DR/IR forms from the respective partner institutions.

NUS-IRB: Studies requiring NUS-IRB review should be submitted via iRIMS-IRB. It will not be managed on ECOS.

For collaborative studies submitted to NUS-IRB:

- The lead NUS PI and Organizational Approver (or HOD or designee) must endorse the application via the iRIMS-IRB system. All NUS staff may log in to the iRIMS-IRB system via their NUS ID account.
- All site PIs, along with their Department and/or Institution Representatives, where applicable, must complete the PI Declaration and Department and/or Institution Endorsement Form(s). The endorsed forms can be uploaded onto the Attachments section of the online application form.

NHG DSRB and SingHealth CIRB:
All DRs and IRs are required to set up ECOS accounts prior to logging into the respective system.

Please refer to Question 4 for links to account creation with ECOS portal.

For collaborative studies submitted to NHG DSRB or SingHealth CIRB, if there is a A*STAR, NTU and/or NUS site, the A*STAR/NTU/NUS DR and IR would have to log into their ECOS accounts to endorse applications submitted by the NHG / SingHealth institution's PI.

DRs and IRs guidebooks can be obtained from the following websites:
NHG: Please click here for ECOS User Guides
SingHealth: Please click here for "IRB Guidebook: Endorsement"

7. What are the Submission Deadlines for the IRBs?

A*STAR IRB: Studies which are subject to Full Board review for any particular month must be received by A*STAR IRB by the 1st of the previous month.

NHG DSRB: Studies which are subject to Full Board Review must be received by DSRB by the 15th working day of the month (or the next earliest working day if it falls on a weekend) before these applications will be considered for review during the Full Board Meeting of the same month.

This is with the exception of DSRB Domain B1 whereby the submission deadline for Full Board studies would be on the 1st working day of the month or the next earliest working day if it falls on a weekend.

The PIs are strongly encouraged to factor in sufficient lead time for the DR and IR to endorse the application, so that their applications will reach CIRB and DSRB on the on the stipulated deadlines described above.

Submissions received after the deadlines would be tabled for the subsequent full board meeting.

NTU-IRB: Please refer to resource here.

NUS-IRB: Studies which are subject to Full Board Review must be received by NUS-IRB by the 1st working day of the month (or the next earliest working day if it falls on a weekend) before these applications will be considered for review during the Full Board Meeting of the same month.

SingHealth CIRB: Studies which are subject to Full Board Review must be received by CIRB by the 1st working day of the month (or the next earliest working day if it falls on a weekend) before these applications will be considered for review during the Full Board Meeting of the same month.

Studies which require exemption and expedited review can be submitted anytime, for the 5 IRBs.

8. Submission of Special Sites

(i) What are the Special Sites to take note of?

The Special Sites for submission are:
- P.H. Feng Research Centre
- TTSH Facility Site for NNI Study

(ii) When should these Special Sites be added?

'P.H. Feng Research Centre' and 'TTSH Facility Site for NNI Study' are facility sites under NHG, and should be added in the following scenarios:

- P.H. Feng Research Centre: When PHFRC is engaged as a facility site in a study.
- TTSH Facility Site for NNI Study: When NNI is the Main Site, and the research involves TTSH Neurosurgery/ Neurology inpatients.

(iii) Who should be the Site PIs of these Special Sites?

The Site PIs of these Special Sites should be from NHG institutions, and from TTSH or NNI for the TTSH Facility Site for NNI Study.

9. Are there any differences in the IRB minimum training requirements?

The minimum training requirements across the IRBs are slightly different, but training programs are cross-recognised among the 5 IRBs (A*STAR IRB, NHG DSRB, NTU-IRB, NUS-IRB, and SingHealth CIRB). The PI and delegated study team member(s) should meet the minimum training requirements set by the reviewing IRB and/or the RI and be adequately trained on all delegated study tasks (e.g., protocol/ study specific training) prior to performing any research procedure. Please refer to the respective minimum training requirements of the IRBs and/or RIs:

A*STAR-IRB: Please click here for A*STAR-IRB min training requirements (accessible via A*STAR intranet only).

NHG DSRB: Please click here for NHG DSRB min training requirements.

NTU-IRB: Please click here for NTU-IRB min training requirements.

NUS-IRB: Please click here for NUS-IRB min training requirements.

SingHealth: Please click here for SingHealth min training requirements.

(i) How should the minimum training status for study team members be declared or updated on ECOS?

A*STAR IRB: This section is not applicable for studies submitted to A*STAR IRB, as ECOS will not be used.

NTU-IRB: This section is not applicable for studies submitted to NTU-IRB via ERMP.

NUS-IRB: This section is not applicable for studies submitted to NUS-IRB via iRIMS-IRB.

NHG DSRB and SingHealth CIRB:

- All PIs, Site PIs and Co-Investigators involved in collaborative studies would need to submit their minimum training certificates for validation and issuance of 'labels' on ECOS. 'Labels' enable users to see the type of studies he/she has met the minimum training to conduct.

- Other study team members **NOT** listed in the Application Form (e.g., Clinical Research Coordinators, Study Administrators and Sponsors) can be added into CRMS study site User Authorisation List (UAL) if they require access to the IRB documents and submissions. The PI should ensure that study team members are adequately trained for their delegated role, even though the training is not required to be submitted.

(ii) Who can issue the Min Training Labels on ECOS?

A*STAR IRB: This section is not applicable for studies submitted to A*STAR IRB, as ECOS will not be used.

NTU-IRB: This section is not applicable for studies submitted to NTU-IRB via ERMP.

NUS-IRB: This section is not applicable for studies submitted to NUS-IRB via iRIMS-IRB.

NHG DSRB and SingHealth CIRB:
Each cluster will have their Institution Minimum Training Secretariat to verify the minimum training records of their investigators / users and labels will be issued according to their oversight IRB and/or the institutions' training requirement.

(iii) Will my training completion status in one cluster, be accepted under another Reviewing IRB?

Yes. Although the min training requirements across the IRBs and RIs may differ, the IRBs will mutually recognise the training completion labels that had been granted to an investigator by their cluster. For e.g. an NHG investigator (with training completion labels) may be involved in a collaborative study submitted to SingHealth CIRB. The NHG training completion will be accepted for the study reviewed under SingHealth CIRB.

10. Which Informed Consent or Assent Template should I use?

Each study site should use the Informed Consent (ICF) and Assent Template provided by their own IRB.

A*STAR-IRB: Please click here for ICF and Assent template (accessible via A*STAR intranet only).

NHG DSRB: Please click here for ICF and Assent Template.

NTU-IRB: Please click here for ICF and Assent Template (accessible via NTU intranet only).

NUS-IRB: Please click here for ICF and Assent Template (accessible via NUS intranet only):

- For HBRA regulated research
- For other types of research

SingHealth CIRB: Please click here for ICF and Assent Template.

11. Are there any significant differences to the Informed Consent Form templates that I should take note of?

Yes. Please take note of the following differences to the Informed Consent Form templates.

a. **The Data Protection Policy Statement**
b. **The Research Compensation Statement**
c. **Who has reviewed the study? Which IRB contact details should be listed on the Informed Consent Forms - the reviewing IRB or the respective cluster / institution IRB?**
The IRB that has reviewed the study should be reflected on the Informed Consent Form.

The contact details of the respective cluster / institution IRB should also be listed on the Informed Consent Form, in the event that the participants from the cluster / institution sites have any questions or complaints about the study.

Study Sites	Cluster / Institution IRB	Statement for Who Has Reviewed The Study and IRB Contact Details
ARES	A*STAR Institutional Review Board (IRB)	This study has been reviewed by the <Insert the name of the Reviewing IRB> for ethics approval. The approval is mutually recognised by A*STAR Institutional Review Board (IRB). If you have questions about your rights as a participant, you can contact the A*STAR IRB at hbro@hq.a-star.edu.sg.
NTU	NTU Institutional Review Board	The study has undergone ethics approval by the <Insert the name of the Reviewing IRB>. The approval is mutually recognised by NTU Institutional Review Board. If you want an independent opinion to address concerns, questions, complaints, or feedback; or require information regarding your rights as a research participant, please contact: **NTU-Institutional Review Board** Research Integrity and Ethics Office Blk N1.2, B1-02A 62 Nanyang Drive Singapore 637459 Email: irb@ntu.edu.sg, Tel: 6904 1293

NHG	NHG Domain Specific Review Board (the central ethics committee)	The study has been reviewed by the <Insert the name of the Reviewing IRB> for ethics approval. The approval is mutually recognised by NHG Domain Specific Review Board (DSRB). If you want an independent opinion to discuss problems and questions, obtain information and offer inputs on your rights as a research subject, you may contact the NHG Domain Specific Review Board Secretariat at 6471-3266. You can also find more information about participating in clinical research, the NHG Domain Specific Review Board and its review processes at www.research.nhg.com.sg.
NUHS		
NUS	National University of Singapore Institutional Review Board (NUS-IRB)	This study has undergone an ethics review by the <Insert the name of the Reviewing IRB>. The approval is mutually recognised by National University of Singapore Institutional Review Board (NUS-IRB). For an independent opinion specifically regarding the rights and welfare of research participants, you may contact a staff member of the National University of Singapore Institutional Review Board at telephone (+65) 6516 1234 [Mondays to Thursdays from 8.30am to 6pm, and Fridays from 8.30am to 5.30pm, except public holidays] or email at irb@nus.edu.sg.
SingHealth	SingHealth Centralised Institutional Review Board (CIRB)	This study has been reviewed by the <Insert the name of the Reviewing IRB> for ethics approval. The approval is mutually recognised by SingHealth Centralised Institutional Review Board (CIRB). If you have questions about your rights as a participant, you can call the SingHealth Centralised Institutional Review Board at 8126 3660 during office hours (8:30 am to 5:30pm).

12. How do I report Study Deviations / Non-Compliances to the IRBs?

A*STAR-IRB: Please click here for Non-Compliance reporting requirements (accessible via A*STAR intranet only). Refer to instructions in the non-compliance report.
NHG DSRB: Please click here for Non-Compliance reporting requirements.

NTU-IRB: Please refer here for Incident Reporting Guidelines.

NUS-IRB: Deviations / Non-Compliances to be reported to NUS-IRB should be submitted via iRIMS-IRB as soon as possible, within 1 working day.

SingHealth CIRB: Please refer to "Study Deviation & Non-Compliance Report Form" here.

13. How do I report Safety Events to the IRBs?

A*STAR-IRB: Please click here for safety reporting requirements (accessible via A*STAR intranet only). Refer to instructions in the SAE report.

NHG DSRB: Please click here for safety reporting requirements.

NTU-IRB: Please refer here for Incident Reporting Guidelines.

NUS-IRB: Serious Adverse Events (SAEs) to be reported to NUS-IRB should be submitted via iRIMS-IRB as soon as possible, within 1 working day. Please refer here for NUS Policy on Reporting of Serious Adverse Events, Contraventions and Other Reportable Events (accessible via NUS intranet only).

SingHealth CIRB: Please refer to "Reporting Requirement and Timeline for SAE" here.

14. Who do I contact if I require IRB or technical support?

For ECOS-related technical issues:

- PHI user to contact institution IT Helpdesk -
  NHG users: ITDHELP@nhg.com.sg
  NUHS users: ITDHELP@nuhs.edu.sg
  SingHealth users: it.helpdesk@singhealth.com.sg

- Non-PHI user to contact the ECOS Support team.

Should you have any IRB related enquiries, please contact the related IRB:
(Do not copy all IRBs. E.g. If your IRB application is to be reviewed by NHG DSRB, please write to NHG DSRB only)
NHG DSRB: ohrpp@nhg.com.sg
SingHealth CIRB: irb@singhealth.com.sg
A*STAR-IRB: hbro@a-star.edu.sg
NTU-IRB: irb@ntu.edu.sg
NUS-IRB: irb@nus.edu.sg

SCHEDULE 1

LIST OF INSTITUTIONS AND PARTNER INSTITUTIONS OF THE PARTIES

S/N	The Parties	Institutions under the Parties	Partner Institutions of the Parties
1	A*STAR Research Entities	• All research institutes and centres, research entities, and programmes funded and/or managed by A*STAR	• Nil

2	NHG	• Geriatric Education & Research Institute (GERI)
		• Institute of Mental Health (IMH)
		• National Skin Centre (NSC)
		• NHG Polyclinics (NHGP)
		• NHG Pharmacy
		• NHG HQ
		• NHG Diagnostics
		• NHG Cares
		• NHG College
		• NHG Eye Institute
		• Khoo Teck Puat Hospital (KTPH)
		• KTPH@AdMC
		• P.H. Feng Research Centre (PHFRC)
		• Tan Tock Seng Hospital (TTSH)
		• Woodlands Health (WH)
		• Yishun Community Hospital (YCH)
			• National University Health System Pte Ltd, which include:
			  ○ Alexandra Hospital (AH)
			  ○ Jurong Community Hospital (JCH)
			  ○ Jurong Medical Centre (JMC)
			  ○ National University Hospital (NUH)
			  ○ National University Polyclinics (NUP)
			  ○ National University Primary Healthcare (NUPH)
			  ○ Ng Teng Fong General Hospital (NTFGH)
			• Health Promotion Board (HPB)
			• Health Sciences Authority (HSA)
			• Agency of Integrated Care (AIC)
			• Dover Park Hospice
			• Ang Mo Kio - Thye Hua Kuan Hospital Ltd (AMKH)
			• Lilly Centre for Clinical Pharmacology Pte Ltd

3	NTU	• Nanyang Technological University (NTU) and its autonomous institutes and subsidiaries • National Institute of Education (NIE) • Lee Kong Chian School of Medicine (LKCMedicine) • Rehabilitation Research Institute of Singapore (RRIS) • S. Rajaratnam School of International Studies (RSIS) • Singapore Centre for Chinese Language (SCCL) • National Institute of Early Childhood Development (NIEC)	• Nil
5	NUS	• All NUS faculties, institutions and research centres, including Duke-NUS medical school	• Nil

6	SingHealth	• Changi General Hospital (CGH)
		• Eastern General Hospital (EGH)
		• KK Women's and Children's Hospital (KKH)
		• National Cancer Centre Singapore (NCCS)
		• National Dental Centre Singapore (NDCS)
		• National Heart Centre Singapore (NHCS)
		• National Neuroscience Institute (NNI)
		• Sengkang General Hospital (SKH)
		• Singapore General Hospital (SGH)
		• Singapore Health Services (SingHealth)
		• Singapore National Eye Centre (SNEC)
		• SingHealth Community Hospitals:
		  ○ Outram Community Hospital (OCH)
		  ○ Sengkang Community Hospital (SKCH)
		• SingHealth Investigational Medicine Unit (IMU)
		• SingHealth Polyclinics
			• Assisi Hospice
			• HCA Hospice Limited (HCA)
			• National Kidney Foundation (NKF)
			• Singapore Management University (SMU)

Note: ARES, NHG, NTU, NUS and SingHealth may notify in writing to the other Parties, to include any institution that becomes a part of a Party's cluster or becomes a Partner Institution of a Party after the Effective Date of the MOA.