SingHealth CIRB:

Illuminaté

"To Énlighten... Ethics, above all"

Adapted version for researchers, investigator and study

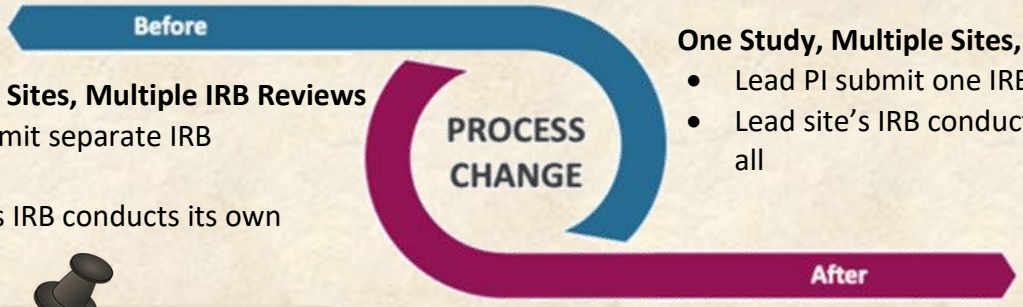
SingHealth
Defining Tomorrow's Medicine

Issue 20
Apr 2025

Single IRB Review for Cross-Clusters Collaborative Research

As part of the RIE2025 Governance Framework initiatives, SingHealth CIRB, A*STAR IRB, NHG DSRB, NTU-IRB, and NUS-IRB are jointly establishing Single IRB Review for multi-site collaborative research. It is an extension of the mutual recognition agreement between NHG DSRB and SingHealth CIRB.

Effective from
1 April 2025



One Study, Multiple Sites, Multiple IRB Reviews

- Multiple PIs submit separate IRB applications
- Respective site's IRB conducts its own review

One Study, Multiple Sites, One IRB Review

- Lead PI submit one IRB application
- Lead site's IRB conducts the review for all

ECOS Official Launch and Mutual Recognition Signing Ceremony

On 18 March 2025, Singapore's research landscape saw a significant advancement with the ECOS Official Launch and Mutual Recognition Signing Ceremony. The event marked the introduction of a unified research application platform (ECOS) and the signing of an IRB Mutual Recognition Agreement between NHG, NUS, NTU, and A*STAR, streamlining research processes and enhancing collaboration across institutions. Click here for more information.

Key Benefit

- Eliminate duplicative ethics review
- Reduce administrative burden
- Save time and resources
- Enhance collaboration

Scan the QR code or visit https://for.sg/moa2025 Guidelines and Submission Requirements for Single IRB Review

Participating IRBs: Agency for Science, Technology and Research (A*STAR) SINGAPORE; National Healthcare Group; Nanyang Technological University Singapore; National University of Singapore; SingHealth

Study Status Report Form (SSR)

The study status report form is to be used for the following purpose:

1. Study Renewal
2. Study Reactivation
3. Study Status Update
4. Study Closure

Note: Only one Study Status Report Form can be submitted by the PI at any one time.

Study Renewal

- ✓ Use for renewing IRB approval.
- ✓ PI is responsible to submit the study status report form (study renewal) with sufficient time prior to the expiration of the current IRB approval, to prevent lapses in the study approval.
- ✓ PI should review the study (including protocol and informed consent document) to ensure that the study remains in compliance with the latest applicable guidelines and regulations. Amendment should be submitted if required.
- ✓ Recommended for the form to be submitted at least 2 months (60 days) before the expiry.

The approval period granted by CIRB for approved applications is one year (12 months). For research studies which will continue beyond one year, renewal requests should be submitted via ECOS for review.

Continuing review of expedited or full board approved applications will be conducted with the same diligence as utilised during the initial review of the research. Continuing review of full board approved applications may be considered for expedited review if

(i) the enrolment of new participants is permanently closed, all participants have completed all research-related interventions, and the research remains active only for long-term follow-ups.
(ii) no participant has been enrolled and no additional risk has been identified.
(iii) the remaining research activities are limited to data analysis.

For studies approved under the exemption, the requirement for continuing review is waived. However, study closure should be submitted upon study completion or termination.

Study Expiry Reminders

ECOS will send email and system notifications beginning 3 months (90 days) before the study expiration. The notifications sent are as follows.

- 1st Study Expiry Reminder – 90 days prior to expiry of ethics approval
- 2nd Study Expiry Reminder – 60 days prior to expiry of ethics approval
- Final Study Expiry Notification – 30 days prior to expiry of ethics approval

PI and study team should also monitor the expiry of the studies closely though reminders would be sent.

Study Reactivation

- ✓ Use for re-activating a study which was previously closed or where the approval has lapsed.
- ✓ All studies must retain an active IRB approval in order for research activities to be carried out.
- ✓ PI should review the study (including protocol and informed consent document) to ensure that the study remains compliance with the latest applicable guidelines and regulations. Amendment should be submitted if required.

Review of the form by IRB will be conducted with the same diligence as utilised during the initial review of the research.

Study Status Update

- ✓ Study Status Update should be used when there is an update to the study status.
  For example:
  For multi-site study, to update one of the site statuses from "Ongoing" to "Completed", while the other sites status remains "Ongoing".
- ✓ Study Status Update can be submitted at any time.

Question: Do I need to submit study status updates if my study had temporarily suspended the recruitment?
Answer: Yes, please use the study status update to notify IRB of the temporarily suspension of recruitment. As there is no change in site status, please explain the temporarily suspension of recruitment under question 4. (a).

Question: Should I submit the study status update if my study resumed recruitment?
Answer: Yes, please use the study status update to notify IRB of the lifting of suspension of recruitment. As there is no change in site status, please explain lifting of suspension of recruitment under question 4. (a).

Question: Which form should I be using if I need to update the site status (study would be expiring in 1 months' time)?
Answer: Please use the study renewal form for the purpose of updating the site status and study renewal.

Question: Which form should I be using if I need to update the site status (study will only expire in 9 months' time)?
Answer: Please use the study status update for the purpose of updating the site status.

Study Closure

- ✓ For the reporting of study completion or termination.
  - **Study Completion:** The study may be completed when all research-related interventions or interactions with participants have been completed and data analysis involves only unidentifiable data. For multi-site studies, the study may be closed regardless of the completion status of the global study. For study completion, please submit the Study Status Report Form within 30 days.
  - **Study Termination:** The study may be terminated by the PI, institution or sponsor if the study sites has stopped after IRB approval. For study termination, please submit the Study Status Report Form within 7 days

Note: In the event where the approval has lapsed and research activities was conducted during that period, study deviation/non-compliance report form has to be submitted to CIRB.

What happen when the study expired?

Study Expiry Notification

All research activities – including, but not limited to, recruitment, advertising, screening, enrolment, interventions, interactions, and the collection of identifiable data – must be stopped immediately. Any research activity is strictly prohibited under the IRB policy.

If the study team wish to continue with any research activities, please log-in to ECOS and submit a Study Status Report Form (Study Reactivation) for IRB's review. If the study is completed/terminated, please submit a Study Status Report Form for study closure.

Takeaway message...

It is the responsibility of investigators to review the study regularly to ensure protocol adherence, safety, progress, resource adequacy, regulatory compliance, data quality, and ethical standards are maintained throughout the research process.

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