Mutual Recognition of Research Ethics Review between SingHealth CIRB and NHG DSRB

Frequently Asked Questions

General

1. What types of cross-cluster studies are eligible for single IRB reviews?

All new research applications involving both SingHealth and NHG* sites are eligible to benefit from the CIRB-DSRB mutual recognition arrangement and have their studies reviewed by only 1 IRB.

Note: Research studies involving only SingHealth or NHG sites will continue to be reviewed by the respective cluster IRBs (i.e. SingHealth CIRB or NHG DSRB).

**including partner institutions under NHG DSRB purview (only for those who has appointed SingHealth CIRB as the reviewing IRB).*

Under the Oversight of SingHealth CIRB	Under the Oversight of NHG DSRB
SingHealth Institutions: Changi General Hospital (CGH) KK Women's and Children's Hospital (KKH) National Cancer Centre (NCC) National Dental Centre (NDC) National Heart Centre (NHC) National Neuroscience Institute (NNI) Sengkang General Hospital (SKH) Singapore Eye Research Institute (SERI) Singapore General Hospital (SGH) Singapore Health Services (SingHealth) SingHealth Community Hospitals • Bright Vision Hospital (BVH) • Outram Community Hospital (OCH) • Sengkang Community Hospital (SKCH) Singapore National Eye Centre (SNEC) SingHealth Investigational Medicine Unit (IMU) SingHealth Polyclinics	National Healthcare Group (NHG) Institutions: Institute of Mental Health (IMH) Tan Tock Seng Hospital (TTSH) National Skin Centre (NSC) NHG Polyclinics (NHGP) NHG Pharmacy NHG HQ NHG Diagnostics NHG College NHG Eye Institute Khoo Teck Puat Hospital (KTPH) Yishun Community Hospital (YCH) Admiralty Medical Centre (AdMC) Geriatric Education & Research Institute (GERI) Woodlands Health Campus (WHC) (To open from 2022) National University Health System (NUHS) Institutions: National University Hospital (NUH) National University Polyclinics (NUP) Ng Teng Fong General Hospital (NTFGH) Jurong Community Hospital (JCH) Jurong Medical Centre (JMC) Alexandra Hospital
	Dover Park Hospice (DPH)
	Health Sciences Authority (HSA)

Note: List of institutions may be subject to changes.

2. Which IRB do I submit to?

From 1st October 2014 onwards, cross-cluster research applications can be submitted to either SingHealth CIRB or NHG DSRB, depending on the Overall Principal Investigator's (PI) cluster and subject to the agreement between the parties involved.

Example:

- If it is a grant-awarded study, the Overall PI, would be the person who is awarded the grant, and the application should be submitted to his/ her cluster's IRB.
- If it is an industry or commercially sponsored study, the Overall PI would have to be selected and application to be submitted to his/her cluster's IRB.
- If it is an investigator-initiated study (no grant/ funding required), the Overall PI would be the person who initiated the study, and the application should be submitted to his/ her cluster's IRB.

Note:

- The Overall PI's institution will be the Lead Research Institution (RI) for the cross-cluster research application (Lead RI is for the purpose of coordinating the research as defined in Section 16 of the Human Biomedical Research Act).
- There should be proper documentation on the appointment of the Lead RI and common IRB. The common IRB will be the primary appointed IRB of the Overall PI (i.e. the primary appointed IRB of SingHealth PIs is SingHealth CIRB and for NHG PIs is NHG DSRB).
- For restricted research, the Lead RI will put up the application in TIARAS.
- The respective RIs will still be responsible for the reporting of contravention and SAE to MOH.

3. What are the charges?

There is no direct charge for ethics review for cross-cluster studies initiated by SingHealth and NHG staff.

The following charges^ are applicable for cross-cluster studies initiated by industry or commercial entities (with effect from 1st April 2018).

Types of Review	New Cross-Cluster Studies	Single-Cluster Studies (submitted from 1 Jul 2014)
Initial Review	$2,750	$1,750
Subsequent Amendments	$200	(i)$200 (for amendments) (ii)$1,000 (for addition of 1st cross-cluster site)

^ All Charges are subject to prevailing GST rate

4. How does this affect current studies?

All new research applications, approved from 1st July 2014 onwards, are eligible to benefit from the CIRB-DSRB mutual recognition arrangement and have their studies reviewed by only 1 IRB.

Current studies approved before 1st July 2014 will remain under the oversight of the respective IRBs until study closure.

5. Can single cluster studies add on additional sites from a different cluster, and continue to be reviewed by the original IRB?

New single cluster studies approved from 1st July 2014 onwards can add on additional sites from different cluster, and have these amendments reviewed by the initial approving IRB.

The request should be submitted as a cross-cluster site(s) addition amendment to the initial approving IRB. This is subjected to a review fee of $1,000 (subject to prevailing GST rate), for studies initiated by industry or commercial entities only.

Single cluster studies approved before 1st July 2014 do not meet the criteria for the CIRB-DSRB mutual recognition arrangement. A new application should be submitted to the respective cluster IRBs (i.e. SingHealth CIRB or NHG DSRB) for the review of the new site(s).

6. Who and how should the application be submitted?

Submission to the SingHealth CIRB
The Overall PI for cross-cluster studies should be from SingHealth. The CIRB application should be submitted by the SingHealth PI via the iSHaRe e-CIRB portal.

URL: http://ishare.singhealth.com.sg

NHG Site PI(s) should furnish the necessary information to the SingHealth PI for the submission.

User guides can be obtained from the following CIRB website:
http://research.singhealth.com.sg/pages/centralisedinstitutionalreviewboard.aspx

Submission to the NHG DSRB
The Overall PI for cross-cluster studies should be from NHG. The DSRB application should be submitted by the NHG PI via the NHG Research Online Administration & Management (ROAM) portal.

URL: https://www.research.nhg.com.sg/sop/process/ROMP/Admin_Intranet_Login

SingHealth Site PI(s) should furnish the necessary information to the NHG PI for the submission.

User guides can be obtained from the following NHG website:
https://www.research.nhg.com.sg/wps/wcm/connect/romp/nhgromp/resources/research+online+guidebooks

Note:
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), and 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.

7. Does everyone in the study team need to create an account to access either the iSHaRe e-CIRB or ROAM portal?

Yes. All users submitting to either SingHealth CIRB or the NHG DSRB are required to set up an iSHaRe e-CIRB or ROAM account prior to logging into the respective system.

To access iSHaRe e-CIRB (SingHealth)
All NHG Site PIs and Study Team Members are required to set up an iSHaRe e-CIRB account via the iSHaRe e-CIRB portal.

NHG Site PIs and Study Team Members should be added into the applications using their registered iSHaRe e-CIRB accounts. This will allow them to view the applications, download study-related documents such as approval letters and receive communications from SingHealth CIRB.

URL: https://ishare.singhealth.com.sg

Should you have any iSHaRe system enquiries, please contact ishare@singhealth.com.sg.
For CIRB related matters, please contact irb@singhealth.com.sg.

To access ROAM portal (NHG)
All SingHealth Site PIs and Study Team Members are required to set-up a ROAM account via the NHG Research Online Administration & Management (ROAM) portal.

SingHealth Site PIs and Study Team Members should be added into the applications using their registered ROAM accounts. This will allow them to view the applications, download study-related documents such as approval letters and receive communications from NHG DSRB.

URL: https://www.research.nhg.com.sg/sop/process/ROMP/Admin_Intranet_Login

For **ROAM portal related questions**, please email to researchonline@nhg.com.sg. Please provide your Full Name, NRIC/FIN, Institution/Department and a description of the problem.

8. How do DR and IR access the portals for endorsement?

All DRs and IRs are required to set up iSHaRe e-CIRB and ROAM accounts prior to logging into the respective system.

Please refer to Question 7 for links for account creation with iSHaRe e-CIRB and ROAM portal respectively.

For studies submitted to a different cluster's IRB, the DR and IR would have to log into the account with the other cluster's portal, in order to endorse applications submitted by their institution's PI.

To endorse studies submitted to the iSHaRe e-CIRB (SingHealth)
DRs and IRs guidebooks can be obtained from the following CIRB website:
http://research.singhealth.com.sg/pages/centralisedinstitutionalreviewboard.aspx

To endorse studies submitted to the ROAM portal (NHG)
DRs and IRs guidebooks can be obtained from the following NHG website:
https://www.research.nhg.com.sg/wps/wcm/connect/romp/nhgromp/resources/research+online+guidebooks

9. How do I report local serious adverse events to SingHealth CIRB, and unanticipated problems involving risks to subjects or others (UPIRTSOs) and Expected SAEs to NHG DSRB?

For submissions to SingHealth CIRB

Local Serious Adverse Events have to be reported to the CIRB using the LSAE form from iSHaRe e-CIRB.

For submissions to NHG DSRB

Unanticipated problems involving risks to subjects or others (UPIRTSOs) and Expected SAEs have to be reported to the DSRB using the UPIRTSO form or Expected SAE form from the ROAM portal.

10. Are there any differences in the minimum training requirements across clusters?

Yes. The minimum training requirements for the two clusters are slightly different. You may refer to the tables below for the respective minimum training requirements.

Minimum Training Requirements for Staff from SingHealth and Partner Institutions

Study Roles	Training
PIs and Site PIs conducting clinical trials	GCP and CITI (Biomedical Research Module - Refer to list below)
PIs and Site PIs conducting non- clinical trials	CITI (Biomedical Research Module - Refer to list below)
Everyone else in Study Team (Co-Investigators and Collaborators)	CITI (Biomedical Research Module) Modules include: 1. Belmont Report and CITI Course Introduction 2. History and Ethics of Human Research 3. Informed Consent 4. Social and Behavioral Research (SBR) for Biomedical Researchers 5. Records-Based Research 6. Genetic Research in Human Populations 7. Populations in Research Requiring Additional Considerations and/or Protections 8. Vulnerable Subjects – Research Involving Prisoners 9. Vulnerable Subjects – Research Involving Children 10. Vulnerable Subjects – Research Involving Pregnant Women, Human Fetuses, and Neonates 11. Conflicts of Interest in Research Involving Human Subjects

Minimum Training Requirements for Staff from NHG and Partner Institutions

(a) Minimum Training Requirements for study team members submitting studies to DSRB Biomedical Domains (i.e. DSRB Domains A to E)

Study Roles	Training
PIs and Site PIs conducting clinical trials	GCP and CITI (Refer to list below)
PIs and Site PIs conducting non- clinical trials	CITI (Refer to list below)
Co-Investigators	CITI (10 core modules and 5 elective modules) Core Modules 1. Introduction 2. History and Ethical Principles 3. Informed Consent 4. Social and Behavioral Research for Biomedical Researchers 5. Records-Based Research 6. Research With Protected Populations - Vulnerable Subjects: An Overview 7. NHG - Singapore. Overview of Domain Specific Review Board (DSRB) Review Process 8. NHG-Singapore. Overview of the Regulatory Framework and Guidelines in Singapore 9. National Healthcare Group – Singapore FCOI CITI Module 10. Conflict of Interest in Research Involving Human Subjects

(b) Minimum Training Requirements for NHG Staff submitting studies to Population Health Domains (i.e. DSRB Domain F1 and F2)

Study Roles	Training
PIs, Site PIs and Co-Investigators	To complete the CITI modules (10 core modules [stated above] and 5 elective modules) Investigators completing min. training requirements for submission to Population Health domains must complete any of the 5 out of the 11 Social and Behavioural Research (SBR) CITI Modules below:

	Elective Modules 1. History and Ethical Principles -SBE 2. Informed Consent - SBE 3. International Research - SBE 4. Internet-Based Research - SBE 5. Defining Research with Human Subjects - SBE 6. Privacy and Confidentiality - SBE 7. Research in Public Elementary and Secondary Schools - SBE 8. Research with Children - SBE 9. Research with Prisoners - SBE 10. The Federal Regulations - SBE 11. Assessing Risk - SBE

For further information regarding minimum trainings, please refer to our NHG website: https://www.research.nhg.com.sg/wps/wcm/connect/romp/nhgromp/06+conducting+research/intro+min+training+requirements

11. Submission to SingHealth CIRB

(i) Who should be listed under Study Team Members (Section B2), other than the Principal Investigator?

For SingHealth study sites, all staff who are directly involved in the research should be listed in this section. With effect from 12 Feb 2015, the following study personnel should be listed as study team members and submitted for CIRB review and approval. The study team members should only carry out research-related activities upon obtaining approval from CIRB.

Definition of Study Team Members:

- 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 study team members (e.g. Co-Investigators and Study Team Members).
- 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 need not be listed as Co-Investigators or Study Team Member.

Note:
It is not mandatory to add external collaborators, if they are not involved in the conduct of the research at the SingHealth research site. However, if the study team wishes to add them, the external collaborators will need to create and activate an iSHaRe account in order to be added.

(ii) How should CVs be uploaded?

All study team members would need to upload their CVs under **Section B2(i)** of the CIRB online Application Form, after their names have been included. This is a mandatory upload for all members listed in the study team.

(iii) How should the minimum training status for study team members be declared or updated?
All study team members would need to upload their CITI or GCP certificates under **Section B2(i)** of the CIRB online Application Form after their names have been included.

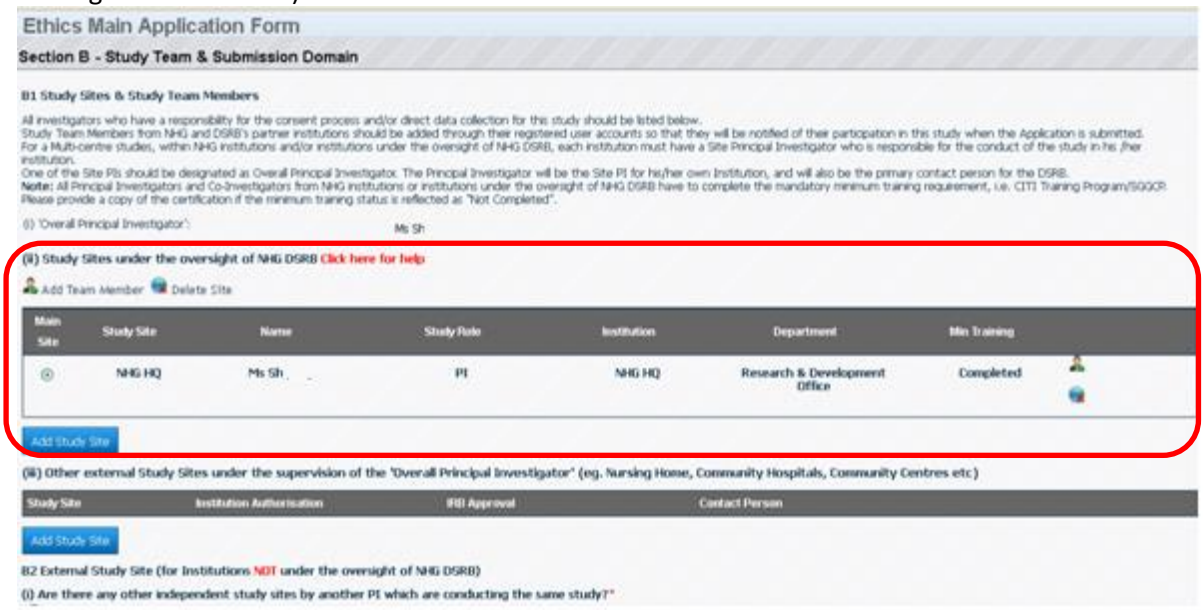
(iv) Is CITI (Biomedical Research Module) mandatory for everyone in the study team?
Please refer to Question 10 for the minimum training requirements of the different clusters.

Study Team Members from NHG and Partner Institutions may request for waiver of CITI training. 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 B2(i) in place of the CITI completion report.

The IRB will review this request for waiver and approve it if the course content is comparable to the content of CITI required.

12. Submission to NHG DSRB

(i) Section B1(ii): How should SingHealth sites be added?
SingHealth sites should now be added under **Section B1(ii) – Study Sites under the oversight of NHG DSRB** instead of Section B2 – External Study Site (for Institutions not under the oversight of NHG DSRB).



(ii) How should DR and IR endorsements be obtained for SingHealth sites?
From 1st October 2014 onwards, the application will be auto-routed to the SingHealth's DR and IR for endorsement through the ROAM portal.

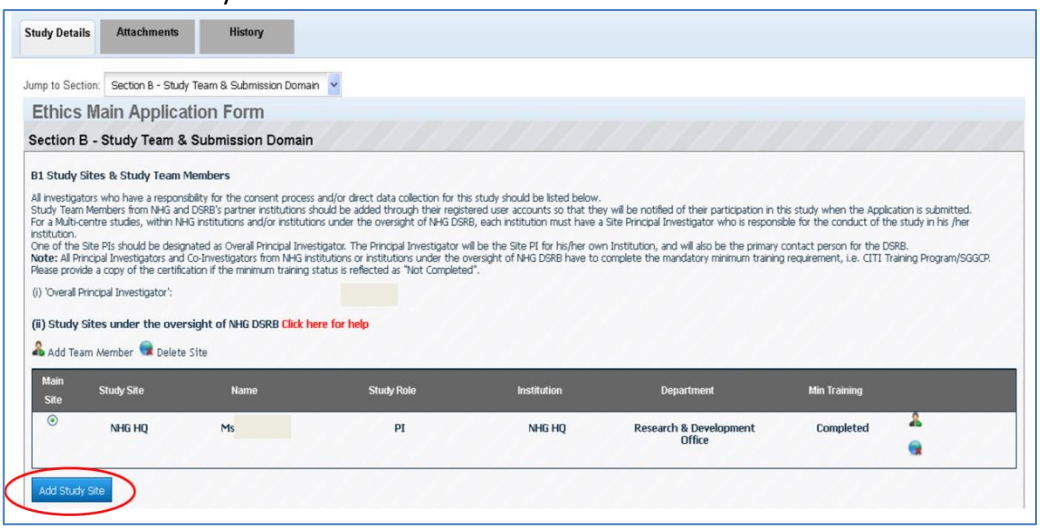
DR and IR endorsements for NHG and partners' sites will be auto-routed as per normal.

(iii) Additional IR endorsement is required if the study involves the use of SingHealth Investigational Medicine Unit (IMU) facilities.

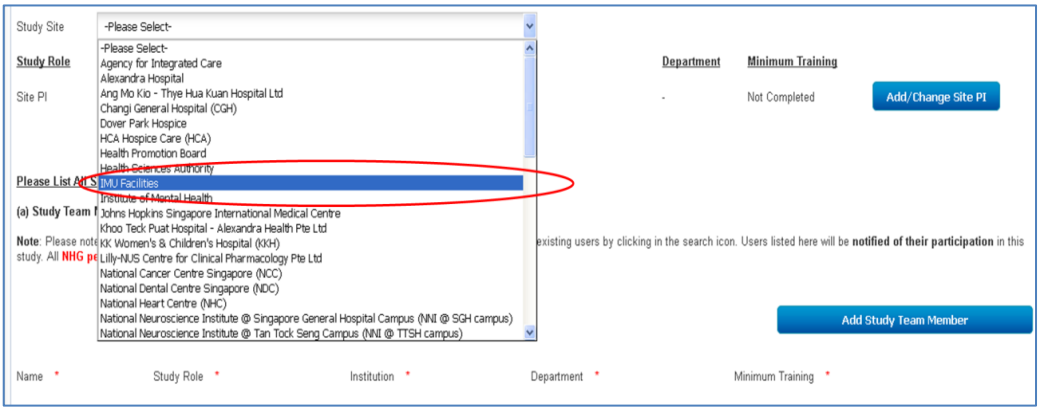
a. How should I reflect the involvement of SingHealth IMU in the DSRB Application Form?

SingHealth IMU should be added as a site under Section B1(ii) – Study Sites under the oversight of NHG DSRB.

1. Click on “Add Study Site”.

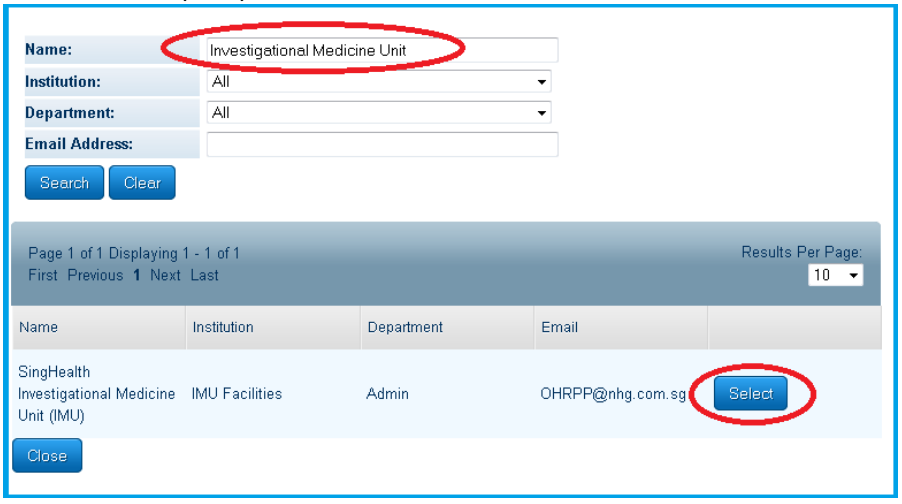


2. Select “IMU Facilities” as the study site.
(Note: The selection “IMU Facilities” is only used for the purpose of reflecting involvement of SingHealth IMU in the DSRB Application Form. Please do not select “IMU Facilities” as your department or institution during the creation of your ROAM account.)

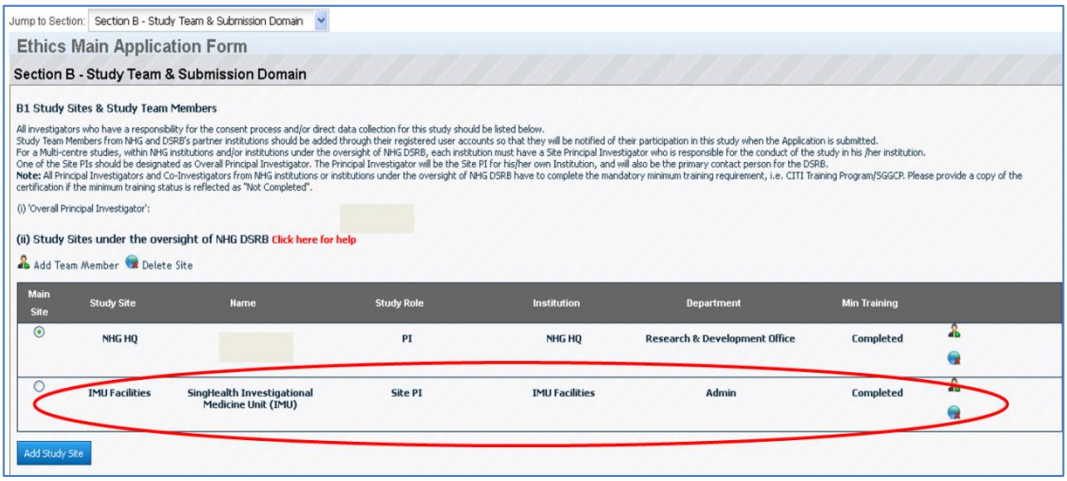


3. Click on “Add/Change Site PI”.

4. Search for “Investigational Medicine Unit”, select “SingHealth Investigational Medicine Unit (IMU)” and save.



5. SingHealth Investigational Medicine Unit (IMU) should appear in Section B1(ii) of the DSRB Application Form.

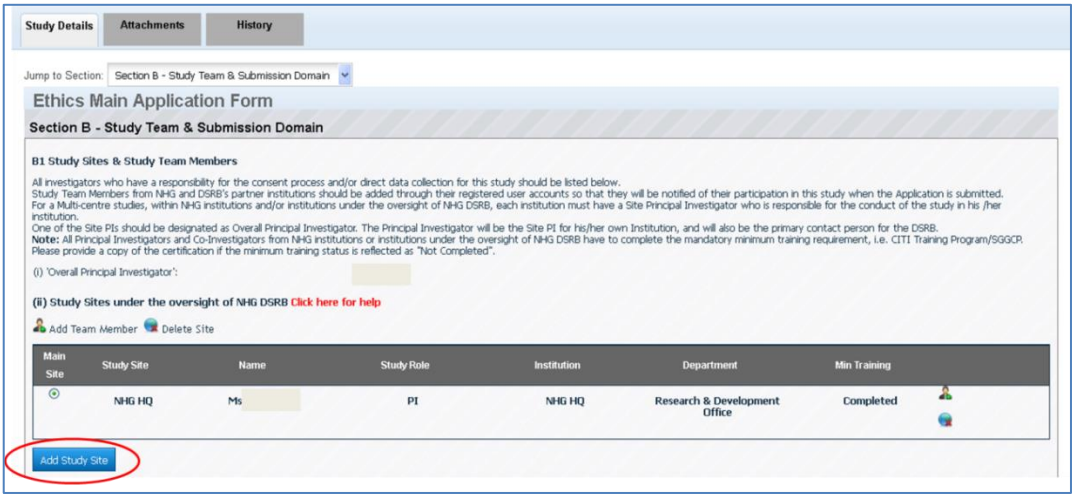


(iv) Additional IR endorsement is required if a cross cluster study involves National Cancer Centre (NCC) recruiting inpatients from Singapore General Hospital (SGH).

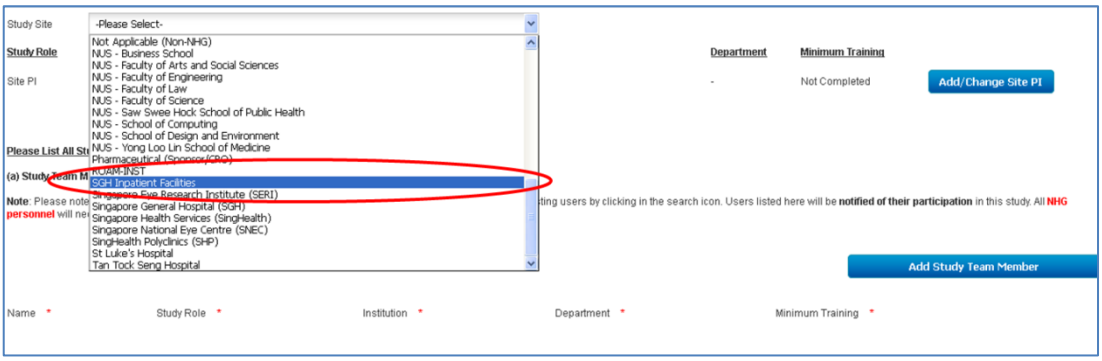
a. How should I reflect the involvement of SGH in the DSRB Application Form?

SGH should be added as a site under Section B1(ii) – Study Sites under the oversight of NHG DSRB.

1. Click on "Add Study Site".

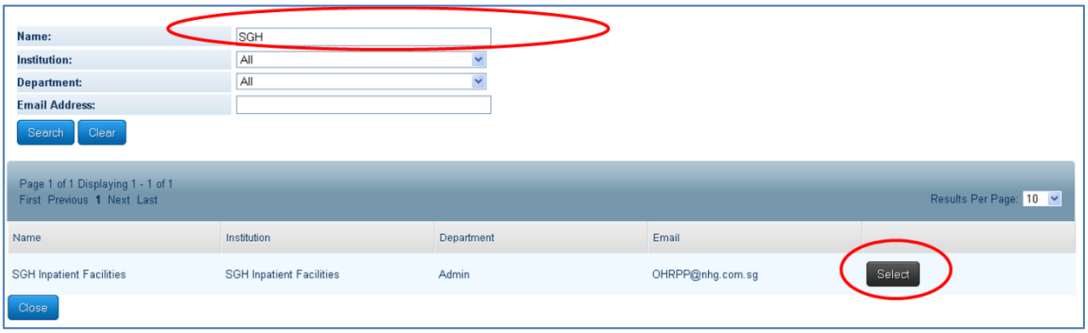


2. Select "SGH Inpatient Facilities" as the study site.
(Note: The selection "SGH Inpatient Facilities" is only used for the purpose of reflecting involvement of SGH Inpatient Facilities in the DSRB Application Form. Please do not select "SGH Inpatient Facilities" as your department or institution during the creation of your ROAM account.)

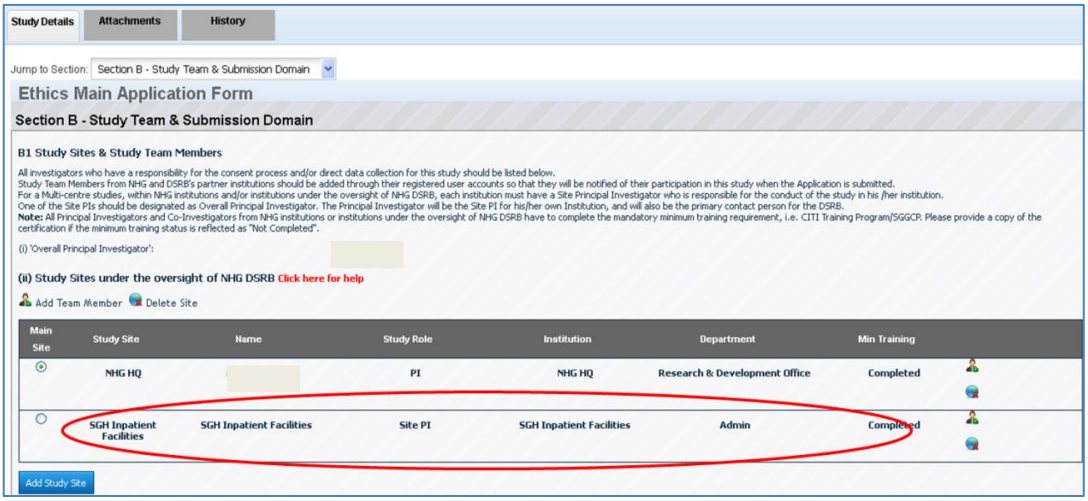


3. Click on “Add/Change Site PI”.

4. Search for “SGH”, select “SGH Inpatient Facilities” and save.



5. SGH Inpatient Facilities should appear in Section B1(ii) of the DSRB Application Form.



(v) Section B1(ii): The minimum training status of study team members from SingHealth sites are not reflected in Section B1(ii).

How should the minimum training status for study team members from SingHealth sites be declared or updated?

When you have completed your CITI course, you will need to upload a copy of the completion certificate onto your ROAM profile under ‘Personal Info’ -> ‘Upload Minimum Training Status Proof’.

Upon receipt and verification, we will update your Minimum Training Status in ROAM portal to ‘Completed’. Please allow some time for verification and processing.

If you have completed the GCP course, you will need to forward a copy of the completion certificate to the Administrator for Investigator's Minimum Training.

For more information and queries, please contact:
Administrator for Investigator's Minimum Training
Email: min_ethics_training@nhg.com.sg
DID: 6471 3266)
Office of Human Research Protection Program (OHRPP)
NHG Research & Development Office

(vi) Section U: How should CVs be uploaded?

All study team members would need to upload their CVs under their profiles of their ROAM accounts. This is a mandatory upload to complete the creation of ROAM accounts. The CVs will automatically be reflected in Section U of the DSRB Application Forms that the study team members are added to.

Informed Consent Documents

13. The Informed Consent Form templates from SingHealth CIRB and NHG DSRB are different. Which Informed Consent Template should I use?

The SingHealth CIRB Informed Consent Form templates should be used for SingHealth and partners' sites while the NHG DSRB Informed Consent Form templates should be used for NHG and partners' sites.

The SingHealth CIRB Informed Consent Form template can be downloaded here and the NHG DSRB Informed Consent Form template can be downloaded at: https://www.research.nhg.com.sg/wps/wcm/connect/romp/nhgromp/resources/ethics+forms+and+templates+

14. Are there any other 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. Which IRB contact detail should be listed on the Informed Consent Forms - the reviewing IRB or the respective cluster IRB?

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

i. If the study is reviewed by NHG DSRB, the Contact Details section of the Informed Consent Form for study sites from the respective clusters should be reflected as follows:

Informed Consent Forms for NHG and Partners' Sites
The study has been reviewed by the NHG Domain Specific Review Board (the central ethics committee) for ethics approval.

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.

If you have any complaints or feedback about this research study, you may contact the Principal Investigator or the NHG Domain Specific Review Board Secretariat.

Informed Consent Form for SingHealth and Partners' Sites
This study has been reviewed by the NHG Domain Specific Review Board (the central ethics committee) for ethics approval. This 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 6323 7515 during office hours (8:30 am to 5:30pm).

If you have any complaints about this research study, you may contact the Principal Investigator or the SingHealth Centralised Institutional Review Board.

ii. If the study is reviewed by SingHealth CIRB, the Contact Details section of the Informed Consent Form for study sites from the respective clusters should be reflected as follows:

Informed Consent Forms for NHG and Partners' Sites

The study has been reviewed by the SingHealth Centralised Institutional Review Board for ethics approval. This 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.

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If you have any complaints about this research study, you may contact the Principal Investigator or the SingHealth Centralised Institutional Review Board.

Please be reminded to check the SingHealth CIRB and NHG DSRB websites regularly for updates.

If you have any enquiries, please contact the SingHealth CIRB Hotline at 6323 7515 (office hours) or NHG DSRB Hotline at 6471 3266 (office hours).