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 SingHealth CIRB purview, i.e. Changi General Hospital, HCA Hospice Care, Singapore Civil Defence Force*

***including partner institutions under NHG DSRB purview, i.e. National University Hospital, NUS – Yong Loo Lin School of Medicine, NUS – Saw Swee Hock School of Public Health, NUS – Faculty of Dentistry, Alice Lee Centre for Nursing Studies, Khoo Teck Puat Hospital, Jurong Health Services at Alexandra Hospital, Health Sciences Authority, Ang Mo Kio Thye Hua Kwan Hospital, Dover Park Hospice, Agency for Integrated Care, Health Promotion Board*

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.

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.

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 May 2017).

Types of Review	New Cross-Cluster Studies	Single-Cluster Studies (submitted from 1 Jul 2014)
Initial Review	$2,500	$1,500
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 and DSRB by the 1st working day of the month before these applications will be considered for review during the Full Board Meeting of the same month.

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 1st working day of the month.

Submissions received after the 1st working day 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/Ehics_User_Register

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) 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) have to be reported to the DSRB using the UPIRTSO 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	SG-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

Study Roles	Training
PIs and Site PIs conducting clinical trials	SG-GCP and CITI (Refer to list below)
PIs and Site PIs conducting non- clinical trials	CITI (Refer to list below)
Co-Investigators	CITI (9 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

11. Submission to SingHealth CIRB

(i) 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.

(ii) 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 SGGCP certificates under **Section B2(i)** of the CIRB online Application Form after their names have been included.

(iii) 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.

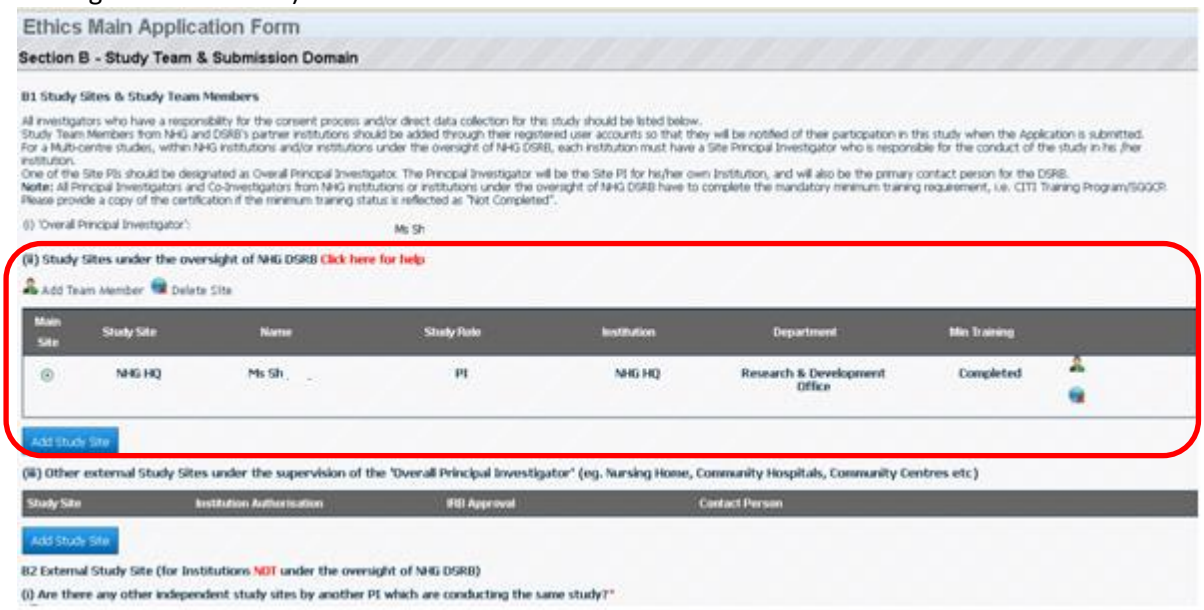
Study Team Members from NHG and Partner Institutions may request for waiver of CITI training. If you wish to request for waiver of this requirement, please download the Waiver of CITI Certification Form from CIRB Website and attach a copy of the completed form under Section B2(i) in place of the CITI 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.

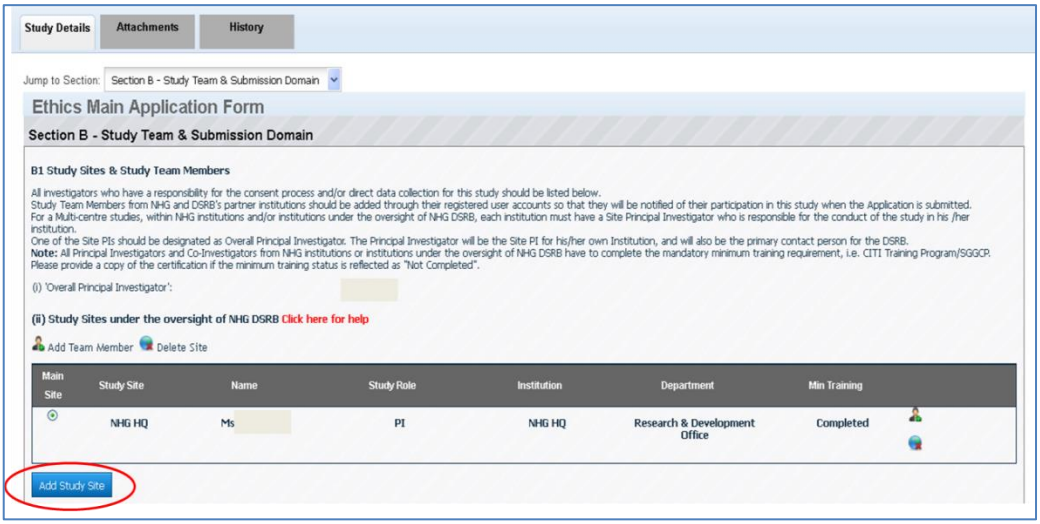
DR and IR endorsements for NHG and partners' sites will be auto-routed as per normal.

(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?

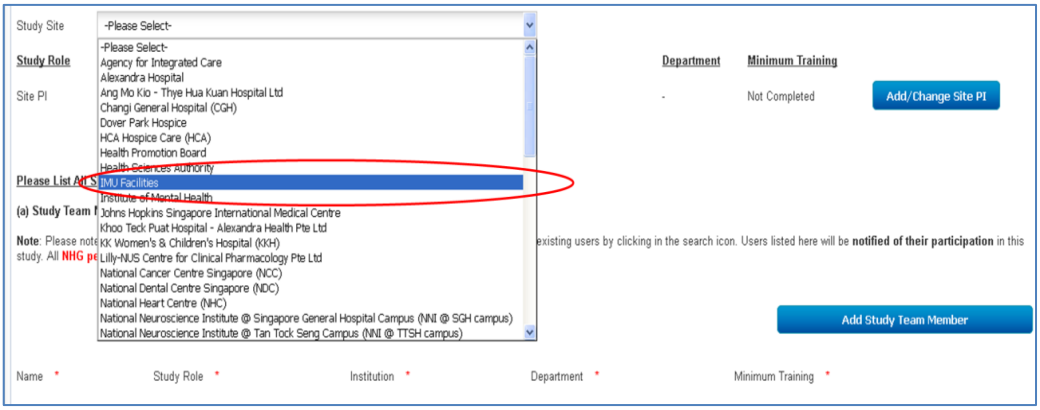
SingHealth IMU should be added as a site under Section B1(ii) – Study Sites under the oversight of NHG DSRB.

1. Click on "Add Study Site".



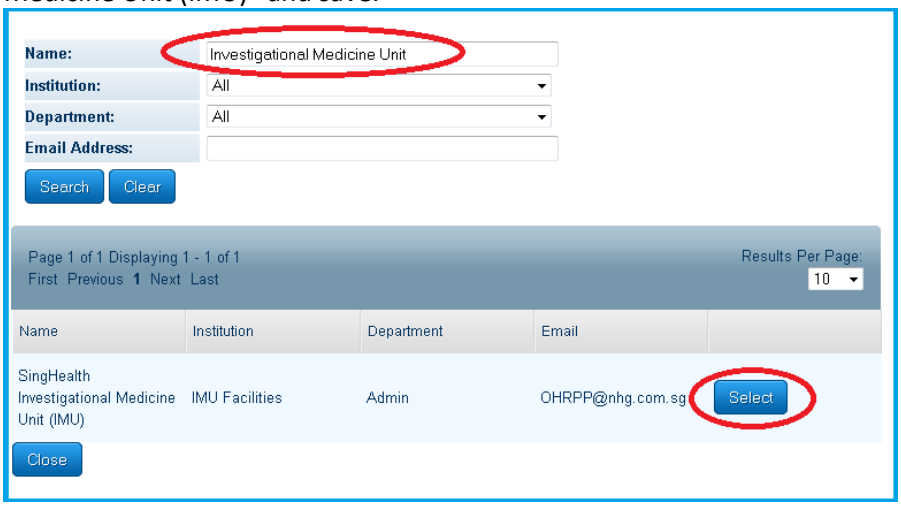
2. Select "IMU Facilities" as the study site.
   (Note: The selection "IMU Facilities" is only used for the purpose of reflecting involvement of SingHealth IMU in the DSRB Application Form. Please do not select

"IMU Facilities" as your department or institution during the creation of your ROAM account.)

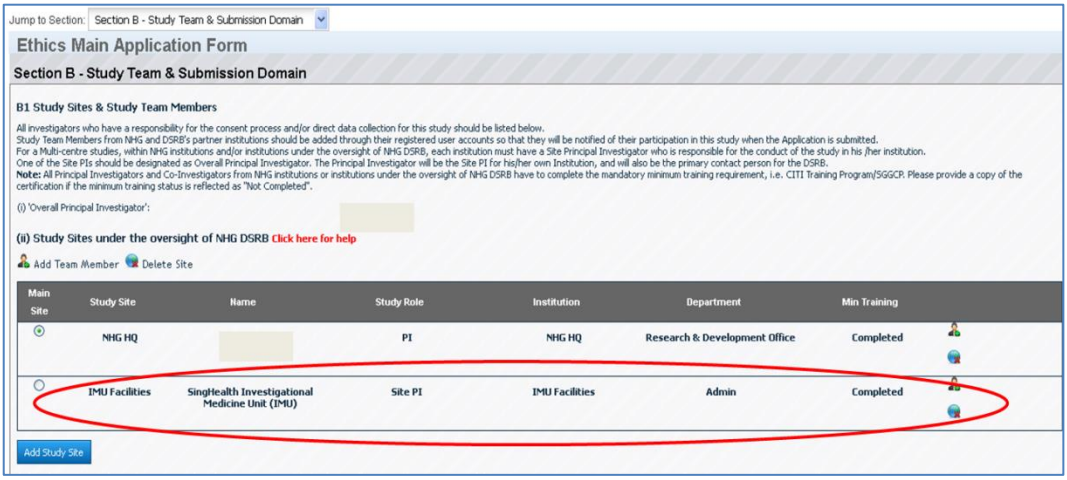


3. Click on "Add/Change Site PI".

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.

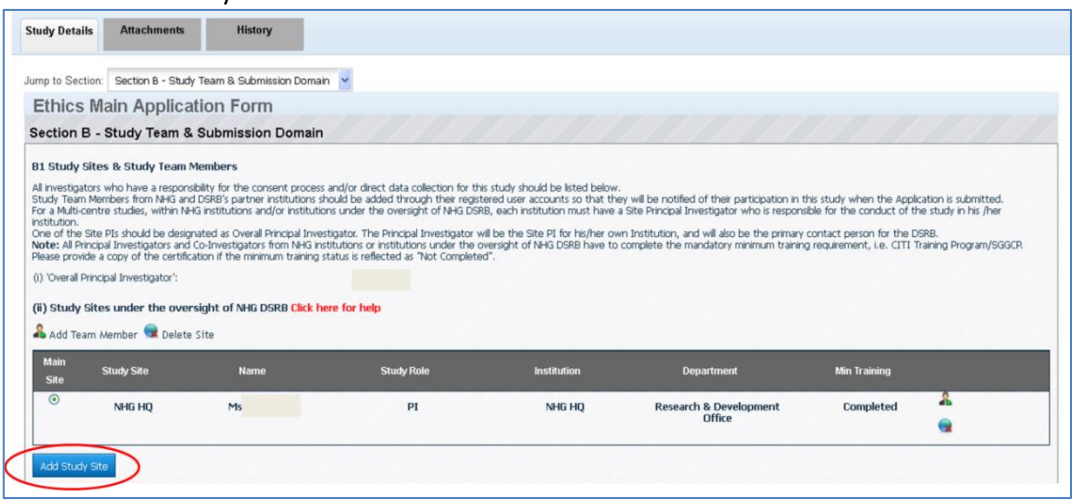


(iv) Additional IR endorsement is required if a cross cluster study involves National Cancer Centre (NCC) recruiting inpatients from Singapore General Hospital (SGH).

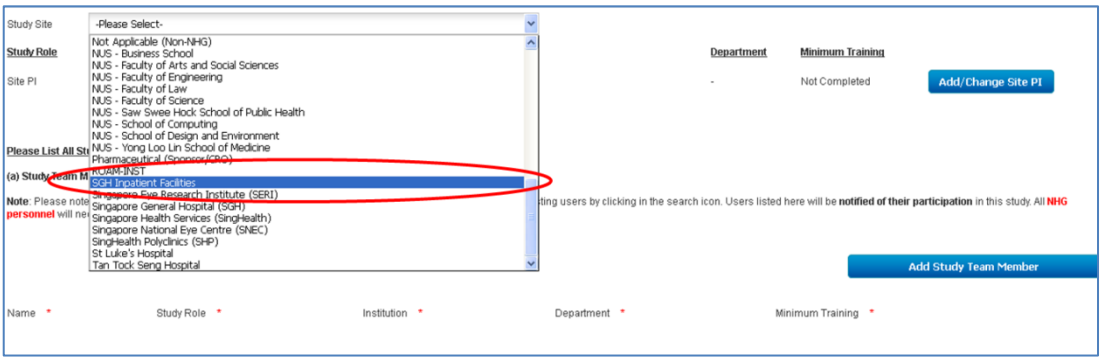
a. How should I reflect the involvement of SGH in the DSRB Application Form?

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".

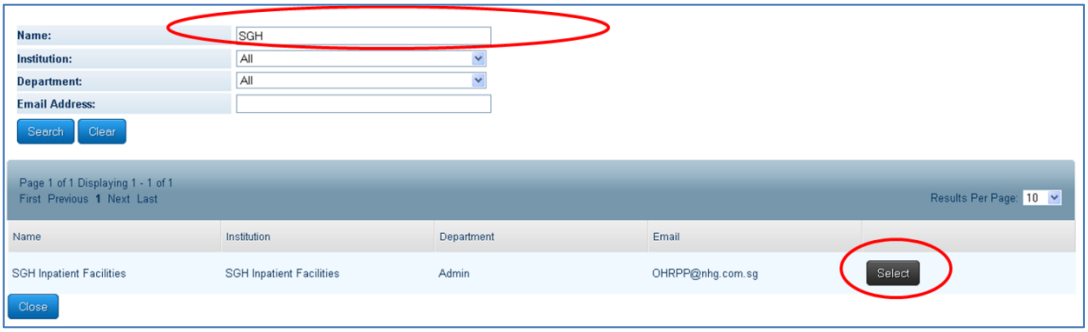


2. Select "SGH Inpatient Facilities" as the study site.
(Note: The selection "SGH Inpatient Facilities" is only used for the purpose of reflecting involvement of SGH Inpatient Facilities in the DSRB Application Form. Please do not select "SGH Inpatient Facilities" as your department or institution during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

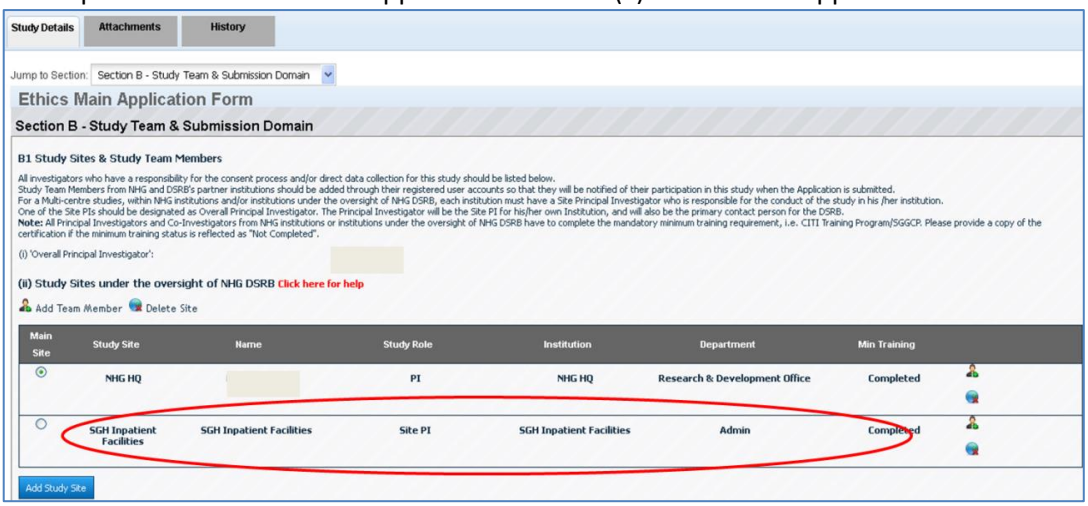


3. Click on "Add/Change Site PI".

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 SGGCP course, you will need to forward a copy of the completion certificate to the Administrator for Investigator's Minimum Training.
Email: min_ethics_training@nhg.com.sg
Fax: 6496 6257 (Attention: Ms Huda Rahmat / Ms Eswari Rajendran)

For more information and queries, please contact:
Administrator for Investigator's Minimum Training
Email: min_ethics_training@nhg.com.sg
DID: 6471 3266 Fax: 6496 6257 (Attention: Ms Huda Rahmat / Ms Eswari Rajendran)
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?

As the compensation clause and circumstances of compensation are different for the SingHealth and NHG clusters, 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 here.

14. Are there any other significant differences or revisions to the Informed Consent Form templates that I should take note of?

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

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

a. The compensation clauses and circumstances of compensation are different for the NHG and SingHealth clusters. What is the difference?

The compensation clauses and circumstances of compensation for the NHG cluster, SingHealth cluster and Changi General Hospital are different.

The compensation clauses and circumstances of compensation for each cluster/ institution is detailed as follows. The differences are highlighted in red:

NHG Cluster

If you follow the directions of the doctors in charge of this study and you are physically injured due to the trial substance or procedure given under the plan for this study, the *(name of institution/ sponsor)* will pay the medical expenses for the treatment of that injury.

Payment for management of the normally expected consequences of your treatment will not be provided by the *(name of institution / sponsor)*.

(For PI-Initiated studies, please use this statement):
(Name of Institution) without legal commitment will compensate you for the injuries arising from your participation in the study without you having to prove (Name of Institution) is at fault. There are however conditions and limitations to the extent of compensation provided. You may wish to discuss this with your Principal Investigator. (Note for PI: Please refer to the Investigator Manual)

(For sponsored studies, following the APBI Guidelines for compensation, please use this statement):
Compensation for the research related injury shall be paid by *Institution / Sponsor Name* according to the Association of the British Pharmaceutical Industry's Clinical Trial Compensation Guidelines. Broadly speaking, the ABPI guidelines recommend that without legal commitment, subjects should be compensated by *Institution / Sponsor Name* without having to prove that *Institution / Sponsor Name* is at fault. *There are limitations to compensation in the ABPI guidelines.* A copy of the ABPI guidelines will be provided to you upon request.

By signing this consent form, you will not waive any of your legal rights or release the parties involved in this study from liability for negligence.

SingHealth Cluster

(For PI-Initiated studies, please use the following 2 paragraphs):

The Hospital does not make any provisions to compensate study participants for research related injury. However, compensation may be considered on a case-by-case basis for unexpected injuries due to non-negligent causes.

By signing this consent form, you will not waive any of your legal rights or release the parties involved in this study from liability for negligence.

(For sponsored studies, following the ABPI Guidelines for compensation, please use the following 2 paragraphs):

Compensation for the research related injury shall be paid by *Institution/ Sponsor Name* according to the Association of the British Pharmaceutical Industry's Clinical Trial Compensation Guidelines. Broadly speaking, the ABPI guidelines recommend that without legal commitment, subjects should be compensated by *Institution/ Sponsor Name* without having to prove that *Institution/ Sponsor Name* is at fault. There are limitations to compensation in the ABPI guidelines. A copy of the ABPI guidelines will be provided to you upon request.

By signing this consent form, you will not waive any of your legal rights or release the parties involved in this study from liability for negligence.

Changi General Hospital

(For PI-Initiated studies, please use the following 2 paragraphs):

If you follow the directions of the doctors in charge of this Research Study and you are physically injured due to the trial substance or procedure given under the plan for the Research Study, our institution will provide you with the appropriate medical treatment.

Payment for management of the normally expected consequences of your treatment will not be provided by the (name of institution / sponsor company).

You still have all your legal rights. Nothing said here about treatment or compensation in any way alters your right to recover damages where you can prove negligence.

(For sponsored studies, following the ABPI Guidelines for compensation, please use the following 2 paragraphs):

Compensation for the research related injury shall be paid by *Institution/ Sponsor Name* according to the Association of the British Pharmaceutical Industry's Clinical Trial Compensation Guidelines. Broadly speaking, the ABPI guidelines recommend that without legal commitment, subjects should be compensated by *Institution/ Sponsor Name* without having to prove that *Institution/ Sponsor Name* is at fault. There are limitations to compensation in the ABPI guidelines. A copy of the ABPI guidelines will be provided to you upon request.

By signing this consent form, you will not waive any of your legal rights or release the parties involved in this study from liability for negligence.

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 of 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 the NHG Domain Specific Review Board at www.research.nhg.com.sg.

If you have any complaints 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 of 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 the NHG Domain Specific Review Board at www.research.nhg.com.sg.

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

Informed Consent Forms for SingHealth and Partners' Sites
This study has been reviewed by the SingHealth Centralised Institutional Review Board for ethics approval.

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.

c. In view of the recent Personal Data Protection Act (PDPA), are there any revisions to the Informed Consent Form templates?

Yes, changes are made to the NHG DSRB, SingHealth CIRB and Changi General Hospital Informed Consent Form templates to provide web links to the Data Protection Policy statement.

Section 13. Confidentiality of Study and Medical Records

By signing the Informed Consent Form attached, you (*or your legally acceptable representative, if relevant*) are authorizing (i) collection, access to, use and storage of your "Personal Data", and (ii) disclosure to authorised service providers and relevant third parties.
"Personal Data" means data about you which makes you identifiable (i) from such data or (ii) from that data and other information which an organisation has or likely to have access. This includes medical conditions, medications, investigations and treatment history.
Research arising in the future, based on this "Personal Data", will be subject to review by the relevant institutional review board.

Data collected and entered into the Case Report Forms are the property of *(Institution or Company)*. In the event of any publication regarding this study, your identity will remain confidential.

(If Investigators intend to transfer biological samples and/or data out of Singapore, please include either of the statements where relevant):
Any biological samples and/or information containing your "Personal Data" that is collected for the purposes described in this Informed Consent Form will be stored in Singapore. Only anonymised biological samples and/or data will be transferred out of Singapore to *(Insert Name of overseas collaborator/company)*.
OR
Your biological samples and/or information containing your "Personal Data" will be transferred out of Singapore to *(Insert Name of overseas collaborator/company*) for the purposes described in this Informed Consent Form. *(Name of institution transferring the samples and/or data)* will take appropriate steps to ensure it complies with the data protection requirements in the Personal Data Protection Act while your 'Personal Data" to be transferred remains in its possession or under its control.

(Please use this statement, if relevant):
By participating in this research study, you are confirming that you have read, understood and consent to the Personal Data Protection Notification available at (provide hyperlink to institution's website on Personal Data Protection Notification).

Consent Page

(Please use this statement, if relevant):
By participating in this research study, I confirm that I have read, understood and consent to the (Institution) Personal Data Protection Notification. I also consent to the use of my Personal Data for the purposes of engaging in related research arising in the future.

SingHealth CIRB Informed Consent Form
The changes are made to the following sections as follows:

Section: Confidentiality Of Study And Medical Records

By signing the Consent Form, you consent to (i) the collection, access to, use and storage of your Personal Data by (*Name of Institution*), and (ii) the disclosure of such Personal Data to our authorised service providers and relevant third parties for the purpose of future research studies ("Future Studies").

Where required, such Future Studies will be submitted for review and necessary approval by the relevant institutional review board.

"Personal Data" means data about you which makes you identifiable (i) from such data or (ii) from that data and other information which an organisation has or likely to have access. Examples of personal data include medical conditions, medications, investigations and treatment history.

By signing the Consent Form, you also confirm that you have read, understood and consented to the SingHealth Data Protection Policy, the full version of which is available at www.singhealth.com.sg/pdpa.

Data collected and entered into the *(Case Report Form(s) or Data Collection Form(s))* are the property of *(Institution or Company)*. In the event of any publication regarding this study, your identity will remain confidential.

Consent Page

By participating in this research study, I confirm that I have read, understood and consent to the SingHealth Data Protection Policy. I also consent to the use of my Personal Data for Future Research.

Changi General Hospital Informed Consent Form
The changes are made to the following sections as follows:

Section: Confidentiality Of Study And Medical Records

Information collected for the Research Study will be kept confidential. Your records, to the extent of the applicable laws and regulations, will not be made publicly available. Only your Investigator(s) will have access to the confidential information being collected.
However, the Funding Agency *(Name of company, if relevant)*, regulatory agencies, relevant Institutional Review Board and Ministry of Health will be granted direct access to your original medical records to check study procedures and data to ensure compliance with applicable laws and regulations, without making any of your information public.

By signing at the end of Part 1 of "Informed Consent by Research Subject" of this RESEARCH STUDY INFORMATION & PARTICIPANT CONSENT FORM attached, you or your legal representative consents to and authorizes the collection, access to, use, storage and disclosure of your personal data, including information on your medical conditions, medications, investigation details and results and treatment history ("Research Subject Personal Data") to the parties set out in this form, their authorized service providers and relevant third parties (including, as may be applicable, Eastern Health Alliance Pte Ltd (EHA)). You also confirm a copy of the CGH data protection policy has been made available to you, which is otherwise available at http://www.cgh.com.sg/Pages/pdpa.aspx.

Research conducted based on this Research Subject Personal Data will be subject to review by the relevant Institutional Review Board. Subject always to the requirements of applicable law, such

research and Research Subject Personal Data may be used and/or disclosed where relevant for the purposes of engaging in research studies related to this present Research Study, whether arising now or in the future.

Data collected and entered into the *(Case Report Form(s) or Data Collection Form(s))* are the property of *(Institution or Company)*. In the event of any publication regarding the Research Study, your identity will remain confidential and the data used in any such publications will be anonymised.

Section: Who to Contact if You Have Questions

To include the following statement:
If you have questions about your Research Subject Personal Data or questions about personal data generally, please contact dpo@cgh.com.sg for more information.

Consent Page

Part I – Participant's Statement

I, the undersigned, have read and understood the contents set out in the RESEARCH INFORMATION & PARTICIPANT INFORMED CONSENT FORM and agree to participate in the Research *S*tudy as described therein.

I have fully discussed and understood the purpose and procedures of the Research Study. I have been given the Research Study Information Participant Information & Consent Form and the opportunity to ask questions about the Research Study including the possible risks, discomforts and inconveniences and potential benefits and have received satisfactory answers and information. I agree to everything explained above.

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reasons and without my future medical care being affected. I also give permission for information in my Research Subject Personal Data, including medical records (as defined in the Research Study Information statement) to be used for research for the purposes set out in the Research Study Information statement. In any event of publication, I understand that this information will not bear my name or other identifiers and that due care will be taken to preserve the confidentiality of this information.

I give permission to any of the investigator(s) involved in the Research Study ("Investigators") for requesting and collecting any relevant information and/or documentation regarding my medical care/investigations if they took place in another institution. If needed, I agree to retrieve documents/information related to my hospitalization and/or medical care/investigation in another institution and which are necessary for my follow-up in this Research Study.

I also give permission to the Investigator(s) for contacting my relatives or acquaintances, as well as my general practitioner or other physicians in charge of my general medical care that is related to this Research Study.

In the event that I withdraw consent or my participation in the Research Study is pre-maturely terminated for whatever reason, I agree to provide information on my health status. If I choose not to continue any follow-up visits required for the Research Study, I agree to be contacted by the Investigator(s) at the end of the Research Study to enquire about and collect information on my general health status for the purposes of the Research Study. If I cannot be reached, the person indicated by me or my general practitioner or any other physician in charge of my general medical care may be contacted directly by the Investigator(s) in order to enquire about and collect information about my general health status. Alternatively, in accordance with local legislation, I agree that my public health records may be accessed by the Investigator(s) in order to collect information about my health for the purposes of the Research Study. For purposes of this Informed Consent, all such information referred to in this Part 1 shall be deemed Research Subject Personal Data.

Part II – Participant's Parent/ Legally Acceptable Representative (LAR) Statement, where applicable

I, the undersigned, warrant and represent I am duly authorised to legally represent the above Participant and hereby give consent for the above Participant to participate in the Research Study as set out in the Research Study Information statement. I also consent to the collection, use, disclosure and/or processing of the Participant's Research Study Personal Data as set out in the Research Study Information statement and confirm that I have read and understood the CGH's data protection policies. The nature, risks and benefits of the Research Study have been explained clearly to me and I fully understand them.

Part IV – Research Doctor Statement

I, the undersigned, certify to the best of my knowledge that the above Participant/Participant's Parent/LAR signing this Informed Consent by Participant form had the Research Study fully explained and clearly understands the nature, risks and benefits of the Research Study.

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).