Co-operative Agreement for Research Ethics Review between NHG DSRB and NTU IRB

Frequently Asked Questions

1. What type of collaborative studies is eligible for single IRB reviews?

All new collaborative research applications involving both NTU* and NHG**sites are eligible to benefit from the DSRB-NTU Co-operative Agreement and have their studies reviewed by only 1 IRB.

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

*Includes institutions under NTU IRB purview, i.e. National Institute of Education, Lee Kong Chian School of Medicine and other autonomous institutes of NTU.

**NHG sites refer to Tan Tock Seng Hospital, Institute of Mental Health, and National Skin Centre, National Healthcare Group Polyclinics as well as any other institution under the National Healthcare Group Pte Ltd.

2. (a) Which IRB do I submit to?

From 1st October 2017 onwards, collaborative research study applications can be submitted to either NHG DSRB or NTU IRB, depending on the Overall Principal Investigator (PI).

(i) Where the Overall Principal Investigator is from NHG, the submission should go to NHG DSRB.

(ii) Where the Overall Principal Investigator is from NTU, the submission should go to NTU IRB.

Despite (ii), NHG DSRB will act as the IRB for studies involving **1)** patients and/or **2)** medical and/or **3)** dental records or databases from NHG's institutions. In such instances, submissions of these studies should be made by a NHG PI or a NTU PI under his/her NHG's appointment.

(b) What are the responsibilities of the Research Institution (RI) for these studies?

The Overall PI's institution will be the Lead Research Institution (RI) for the cross-cluster research application. The Lead RI will coordinate the research (as defined in Section 16 of the Human Biomedical Research Act).

For submissions to NHG DSRB, the Lead RI will be NHG.

For submissions to NTU IRB, the Lead RI will be NTU.

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?

For collaborative studies which are initiated by staff from NHG's institutions, there is no direct charge for the ethics review of their initial applications and any subsequent amendments submitted to DSRB.

For studies which are sponsored by industry / commercial entities, please refer to the DSRB FAQ website https://www.research.nhg.com.sg/wps/wcm/connect/romp/nhgromp/02+ethics+and+quality/dsrb+faq/dsrb+faq

Similarly, for collaborative studies which are initiated by staff from NTU, there is no direct charge for the ethics review of their initial applications and any subsequent amendments submitted to NTU IRB.

4. How does this affect current studies?

All new collaborative research applications, approved from 1st October 2017 onwards, are eligible to benefit from the DSRB- NTU Co-operative Agreement and have their studies reviewed by only 1 IRB.

Current studies approved before 1st October 2017 will remain under the oversight of the respective IRBs until study closure.

5. Can NTU or NHG studies add on additional sites from either NTU or NHG, and continue to be reviewed by the original IRB?

If the study team intends to add NHG or NTU sites for a study that was previously reviewed by either NHG DSRB or NTU IRB, the scope of the research project will determine if the study can continue to be reviewed by the same IRB.

For studies previously reviewed by NHG DSRB

If the revised scope of the NHG's research project would require additional NTU sites, the NHG PI can submit these amendments to NHG-DSRB for review.

For studies previously reviewed by NTU IRB.

If the revised scope of the NTU's research project would involve **1)** patients and/or **2)** medical and/or **3)** dental records or databases from NHG institutions, the study would need to be submitted to NHG-DSRB instead.

In such instances, submissions of these revised studies can proceed in EITHER of the following ways:

1) NTU site may remain under the purview of NTU-IRB, and the NHG site should submit a separate application to NHG DSRB for review.

2) The existing NTU study can be withdrawn from NTU IRB and a new study application needs to be submitted to NHG DSRB with the addition of NTU and NHG sites.

If the revised scope of the NTU's research project does not involve **1)** patients and/or **2)** medical and/or **3)** dental records or databases from NHG institutions, study amendments to include additional NHG sites can continue to be reviewed by NTU-IRB.

The above arrangement would take effect for NHG and NTU research studies which are approved from 1st October 2017.

6. Who and how should the application be submitted?

For submission to NHG DSRB

The Overall PI for collaborative 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

NTU 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

For PIs who have NHG and NTU-LKC appointments, the PI should submit his/her studies under his/her NHG's appointment. The main study site should be a NHG institution in the study application.

Submission of studies to NHG DSRB by PIs who have double appointments

PIs who have NHG and NTU-LKC appointments should update their ROAM profiles to indicate his/her secondary appointment to facilitate the submissions of their studies to ROAM.

Steps to update secondary appointments in the ROAM profile:

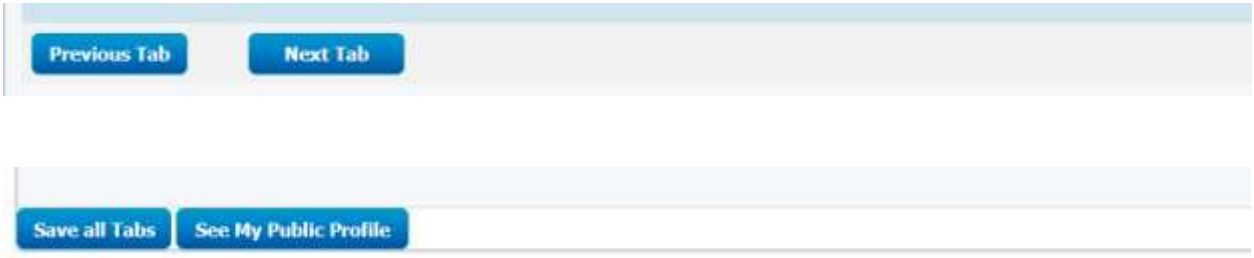
1. After logging in to their ROAM accounts, PIs should select the "Profile" tab on the top right hand corner, and select the "Personal Info" tab as shown below:

2. Scroll down to the section on "Primary Appointment' and select "Yes" for the question "Do you hold any other concurrent appointments?" as shown in the screenshot below:

3. Scroll further down to the section on “Additional Appointment” to select “Nanyang Technological University” as the Organization and Institution and, ‘Lee Kong Chian School of Medicine” as the Department. Please select your NTU-LKC Appointment accordingly as well, as shown in the screenshot below:

4. Please click the button “Add” as shown in the above screenshot.

5. Please continue clicking the button “Next Tab” at the bottom of the webpage, until you reach the button “Save All Tabs”, as shown below:



6. Please click the “Save All Tabs” button to save the updated information.

7. Your ROAM profile is now updated with your secondary appointment.

<u>For submissions to NTU IRB</u>

The Overall PI for collaborative studies should be from NTU. The application should be submitted by NTU PI through Nanyang Online Research Administration (NORA) via Stafflink.

NHG Site PI(s) should furnish the necessary information to the NTU PI for the submissions.

7. When should the application be submitted?

<u>For submission to NHG DSRB</u>

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 in the following month.

The PIs are to factor in sufficient lead time for the Department Representatives (DR)* and Institutional Representative (IR)** or Associate Chair of Research (ACR) to endorse the applications, so that their applications will reach DSRB on the stipulated deadlines.

Domain B1

This is with the exception of 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 to factor in sufficient lead time for the DR and IR to endorse the applications, so that their applications will reach Domain B1 on the stipulated deadlines.

For more information on tentative Full Board dates, please refer to DSRB website via this URL link https://www.research.nhg.com.sg/wps/wcm/connect/romp/nhgromp/02+ethics+and+quality/apply+ethics+approval/ethics+review+meeting+dates

* Department Representative (DR) is normally the Head of Department (HoD), Chief, Department Research Head or equivalent of the Principal Investigator's and Site PI's Department.

** Institution Representative (IR) has been determined by each institution as the authority that considers that the proposed research activity is keeping with the institution's research objectives, image and standards. The IR can be your institution's Director of Research (or equivalent), the Chairman of a specifically appointed committee for this purpose, or the Chairman Medical Board (CMB) of your institution.For submissions to NTU IRB

Studies which are subject to Full Board Review must be received by NTU-IRB before 15th of each month, before these applications will be considered for review during the Full Board Meeting in the same month. Applications that qualify for Exempt or Expedited Review should reach NTU-IRB by Monday 8 am each week.

The PIs are to factor in sufficient lead time for the Associate Chair of Research (ACR), Vice Dean of Research (VDR) or Director of Research Centres to endorse the applications, so that their applications will reach NTU-IRB on time for review. PI is also encouraged to factor in sufficient lead time for research involving student final year project and grant utilisation.

For more information on tentative Full Board dates, please refer to NTU IRB website via this URL link https://research.ntu.edu.sg/rieo/IRB/Pages/Submission-Timeline.aspx

8. Does everyone in the study team need to create an account to access ROAM or NORA?

For ROAM portal (NHG)

All users submitting study applications to NHG DSRB are required to set up a ROAM account prior to logging into the respective system.

All Site PIs and Study Team Members are required to set-up a ROAM account via the NHG Research Online Administration & Management (ROAM) portal.
User guides can be obtained from the following NHG website to set up ROAM accounts:
https://www.research.nhg.com.sg/wps/wcm/connect/romp/nhgromp/resources/roam+guidebooks

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

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.

For NORA (NTU)

Creation of NORA account is not required. Collaborators can check with NTU IRB or NTU PI for updates.

For **NORA related questions**, please email to IRB@ntu.edu.sg

9. How do DRs and/or IRs access the applications for endorsement?

To endorse collaborative studies submitted to the ROAM portal (NHG-DSRB)
All DRs, IRs or ACRs are required to set up ROAM accounts prior to logging into the respective system. The application will be auto-routed to NTU's and NHG's DRs, IRs,ACRs or VDRs for endorsement through the ROAM portal.

Please refer to Question 6 and 8 for links for account creation with ROAM portal.

Guidebooks related to NHG's DRs and IRs endorsements can be obtained from the following NHG website:

https://www.research.nhg.com.sg/wps/wcm/connect/romp/nhgromp/resources/research+online+guidebooks

To endorse collaborative studies submitted to NTU IRB

All NTU IRB applications have to be endorsed by the ACR or VDR of the School or Directors of the Research Centres before it is routed to NTU IRB. All ACRs, VDRs or Directors are required to log into NORA via Stafflink to endorse the applications. Once NTU PI submits the ethics application online, it will be automatically routed to the ACR, VDR or Director of the School or Research Centres for endorsement.

DR and IR Endorsement templates (Documents ID: E04 and E05) can be found in the following NHG website:
https://www.research.nhg.com.sg/wps/wcm/connect/romp/nhgromp/resources/ethics+forms+and+templates+

10. Are there any differences in the minimum training requirements in NHG or NTU?

Yes. The minimum training requirements for NTU and NHG are slightly different. You may refer to the tables below for the respective minimum training requirements.

For NHG-DSRB

(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 Non-Biomedical Domain (i.e. DSRB Domain F)

Study Roles	Training
PIs, Site PIs and Co-Investigators	To complete the CITI modules (10 core modules and 5 elective modules) stated above. In addition, to complete any of the 5 out of the 11 Social and Behavioural Research (SBR) CITI Modules below <u>Elective Modules</u> 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

(c) Financial Conflict Of Interest (FCOI) Training and Declaration

All investigators and study team members involved in the design, conduct or reporting of research in institutions will have to declare if they and/or their immediate family members have any financial interests related to their research studies through the submission of an annual FCOI Declaration Form, and Study Team Member list.

You are encouraged to submit your declarations to the DSRB FCOI Secretariat (DSRB_FCOI@nhg.com.sg) to facilitate the review of your future study/studies.

You may download the FCOI form (Document ID: 205-003) and study team member list (Document ID: 205-034), and find out more information on the Financial Conflict of Interest Policy and training requirements at:
https://www.research.nhg.com.sg/wps/wcm/connect/romp/nhgromp/06+conducting+research/fcoi+intro

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

To note for NTU Co-Is: NTU Co-Is would need to complete CITI modules under:

1. Conflicts of Interest (COI)
2. Good Clinical Practice (GCP)
3. Human Subjects Research (HSR)
4. Responsible Conduct of Research (RCR)

For more information, please contact NTU IRB at IRB@ntu.edu.sg

For NTU IRB

All NTU PIs and NTU Co-Is should provide CITI Certification or equivalent ethics certification upon submission of their ethics application.

Student researchers should complete the "Students conducting no more than minimal risk research" module.

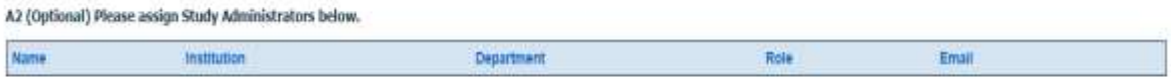
To note for NHG Co-Is: NHG CITI Training requirements and Financial Conflict Of Interest (FCOI) Training and Declaration form would fulfil the training requirements for NTU IRB.

11. (i) Section B1(ii): How should NHG and NTU sites be added in the application form?

For submissions to NHG DSRB

NTU sites can now be added under Section B1 (ii) of the ROAM application– Study Sites under the oversight of NHG DSRB

Note: It is recommended that PIs, Co-Is, Site PIs and Collaborators should be added in section B1 (ii). Study administrators can be added in section A2 of the application form. Please refer to the screenshots below for more information.



For submissions to NTU IRB

Generally, the PI is required to include all research sites in the NORA application form.

11. (ii) Section B1 (ii): The minimum training status of study team members from NTU or NHG sites are not reflected in Section B1 (ii) of the ROAM application.

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

CITI minimum training status for collaborative studies

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 Group Research

11. (iii) Section U: How should CVs be uploaded in ROAM?

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.

For submissions to NTU IRB

All study team members' CV should be uploaded in NORA during the submission.

Informed Consent Documents

12. (a) The Informed Consent Form templates from NTU IRB and NHG DSRB are different. Which Informed Consent Template should I use?

NHG's Informed Consent Form template should be used if the research studies involve NHG's institutions' subjects.

NTU's Informed Consent Form template should be used if the research studies does not involve NHG/and or NHG's institutions and the research is conducted under NTU's institutions.

The NHG DSRB Informed Consent Form template (Document No. 207-001) can be downloaded via this URL link:
https://www.research.nhg.com.sg/wps/wcm/connect/romp/nhgromp/resources/ethics+forms+and+templates+

The NTU-IRB Informed Consent Form Templates can be downloaded from via the URL link:
https://research.ntu.edu.sg/rieo/IRB/Pages/Forms.aspx

(b) Which IRB contact detail should be listed on the Informed Consent Forms?

The contact details of the respective IRB should be listed on the Informed Consent Form, in the event that the participants 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 should be reflected as follows:

   Informed Consent Forms for NHG 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 NTU 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 Nanyang Technological University Institutional Review Board (NTU IRB).
If you have questions about your rights as a participant, you can call the Nanyang Technological University Institutional Review Board at 6592 2495 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 Nanyang Technological University Institutional Review Board.

ii. If the study is reviewed by NTU IRB, the Contact Details section of the Informed Consent Form for study sites should be reflected as follows:

The study has been reviewed by NTU Institutional Review Board 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 NTU IRB Secretariat at 6592-2495.