CIRB review for collaborative research studies between Duke-NUS and SingHealth Institutions

Frequently Asked Questions

With effect from 1 April 2020, Duke-NUS Medical School ("Duke-NUS") researchers may submit their collaborative research with SingHealth institutions to SingHealth CIRB for ethics review.

1. What type of collaborative research is eligible for CIRB review?

ALL the following conditions must be met for a collaborative research study to be eligible for CIRB review:

a) Duke-NUS and SingHealth institution sites must be involved in research. Examples of research studies reviewed by CIRB can be found in "Step 1: Do you need to submit for IRB review?" of the *Centralised Institutional Review Board (CIRB) Research Handbook* on CIRB website Forms & Resources Page.

b) The site Principal Investigators are from Duke-NUS and SingHealth institutions.

c) This is a new collaborative study submitted to CIRB on and after 1 April 2020.

2. Who should be the Overall Principal Investigator (PI) for collaborative research?

For collaborative research, **SingHealth Institutions and Duke-NUS need to be listed as study sites in Section B1(i) of CIRB application**. The SingHealth and Duke-NUS Principal Investigators shall discuss and agree on who should be the Overall PI and Site PI. The Overall PI will be the contact person for CIRB and shall be responsible for the overall conduct of the research.

3. What type of studies are not eligible for CIRB review?

All existing studies approved by CIRB prior to 1 Apr 2020 will continue to be reviewed by CIRB. In such studies, only SingHealth institutions are under the purview of CIRB.

Note: The SingHealth Principal Investigator should not submit study amendment to add Duke-NUS as a new study site.

In addition, the following examples seek to illustrate Duke-NUS or SingHealth studies that are not collaborative research and hence not eligible for CIRB review:

CIRB review for collaborative research studies between Duke-NUS and SingHealth Institutions

Frequently Asked Questions

Example 1:
SingHealth physicians refer patients for recruitment by Duke-NUS study team. All the research activities including informed consent will be carried out by Duke-NUS researchers, whether remotely, at the community, or Duke-NUS site.

Note:
For purposes of CIRB review, this is not a collaborative research. SingHealth is not considered to be engaged in research. SingHealth is only a referral site, not a study site. Duke-NUS researchers should submit such studies to NUS-IRB for review.

Example 2:
SingHealth physicians contribute domain expertise in design of the research study, refer patients for recruitment by Duke-NUS study team and provide input/advice to the research data. Duke-NUS recruitment posters will be placed within SingHealth institutions. All other research activities including informed consent will be carried out by Duke-NUS researchers, whether remotely, at the community, or Duke-NUS site.

Note:
For purposes of CIRB review, this is not a collaborative research. While SingHealth physicians may be part of the study team of this Duke-NUS research, this type of research study will not be reviewed by CIRB as SingHealth is only a referral site and not a study site. For advertisement at SingHealth, the Duke-NUS researchers should go through the SingHealth Group Communications. Duke-NUS researchers should submit such studies to NUS-IRB for review.

Example 3:
A Duke-NUS researcher has appointments in both Duke-NUS and SingHealth. This researcher under his/her SingHealth appointment conducts research activities such as obtaining informed consent, administering questionnaire, performing data collection, under the supervision of a SingHealth PI.

Note:
For purposes of CIRB review, this is not a collaborative research. As this Duke-NUS researcher carries out the research study solely under his/her SingHealth's appointment, Duke-NUS is not considered to be engaged in research as it is not a study site. The researcher's involvement in the SingHealth research and his/her SingHealth appointment should be reflected on Section B2 of CIRB application.

Example 4:
Duke-NUS personnel without SingHealth appointments (e.g. researchers, medical students) on voluntary basis (for personal interest, partnership, shared expertise) or as part of clinical attachment to SingHealth institutions, conduct research activities at SingHealth such as obtaining informed consent, administering questionnaire, performing data collection, under the supervision of a SingHealth PI.

Note:
For purposes of CIRB review, this is not a collaborative research. While Duke-NUS personnel may be part of the study team of this SingHealth research, Duke-NUS is not considered to be engaged in research as it is not a study site. The SingHealth PI should ensure the institution has granted permission to Duke-NUS personnel to access its facilities and/or carry out the research activities under the supervision of the SingHealth PI.

Example 5:
A Duke-NUS researcher uses anonymised data or de-identified data, which has been obtained from SingHealth, for his/her own research analysis.

Note:
For purposes of CIRB review, this is not a collaborative research. SingHealth is not considered to be engaged in research. SingHealth only acts as contributor of data to a study, not a study site. Duke-NUS researchers should submit such studies to NUS-IRB for review. Where required, data sharing arrangement or agreement between Duke-NUS and SingHealth should be in place.

Example 6:
A Duke-NUS researcher uses anonymised or de-identified biological material, which has been obtained from SingHealth, for his/her own research analysis.

Note:
For purposes of CIRB review, this is not a collaborative research. SingHealth is not considered to be engaged in research. SingHealth only acts as contributor of biological material to a study, not a study site. Duke-NUS researchers should submit such studies to NUS-IRB for review. Where applicable, material transfer arrangement or agreement between Duke-NUS and SingHealth should also be in place.

4. How the CIRB application should be submitted?

CIRB application should be submitted online via the iSHaRe e-CIRB portal.

Refer to "e-CIRB User Guidebook: New Application" available on CIRB website Forms & Resources Page.

Duke-NUS researchers are encouraged to visit the CIRB website for the submission requirements and reporting timeline.

5. Does the study team need to create an account to access iSHaRe e-CIRB?

Please refer to CIRB website FAQs Page on

- Who should be listed as study team members?
- Who should not be listed as study team members?

Where Duke-NUS is listed as study site in Section B1(i) of CIRB application, Duke-NUS researchers who meet the definition of study team are required to set up an iSHaRe account via the iSHaRe homepage and be listed on Section B2 of the CIRB application using their registered iSHaRe accounts. This will allow them to view their CIRB applications, download study-related documents such as approval letters and receive communications from SingHealth CIRB.

Refer to User Guidebook: iSHaRe Account Registration - *Section 2.2 iSHaRe Account Set-up- External Use* for step-by-step guide.

Note:
For SingHealth research that comprises Duke-NUS researchers as part of the study team, where Duke-NUS is not engaged in research and not a study site, these Duke-NUS researchers who meet the definition of study team should be listed using "Changes to External Study Team Members Form" and attached it under "Other Attachments" section of the CIRB application, unless the Duke-NUS researchers already have an existing and active iSHaRe accounts. The form is available for download on CIRB website Forms & Resources Page.

CIRB review for collaborative research studies between Duke-NUS and SingHealth Institutions

Frequently Asked Questions

6. What are the training requirements for SingHealth study team?

Principal Investigator, Site Principal Investigator, Co-Investigator and Study Team Member from SingHealth are required to complete the CITI Program for Biomedical Research Investigators and Key Personnel programme or minimally the 11 CITI core modules (see Table 1).

Principal Investigator and Site Principal Investigator conducting clinical trials from SingHealth are required to complete local Good Clinical Practice Program (offered by SingHealth Academy, National Healthcare Group, or National University Health System) in addition to the required CITI Program.

Table 1: Minimum CITI training requirement for SingHealth study team

Study Roles	Training
Everyone in the study team, including: ● Principal Investigator ● Site Principal Investigator ● Co-Investigator ● Study Team Member	Collaborative Institutional Training Initiative (CITI) – ➢ **Biomedical Research Investigators and Key Personnel program**; OR ➢ **CITI program with these 11 core modules:** 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

7. What are the training requirements for Duke-NUS study team?

Principal Investigator, Site Principal Investigator, Co-Investigator and Study Team Member from Duke-NUS are required to complete the CITI Program according to NUS requirement – 'Biomedical Research' (Basic and/or Refresher course). See Table 2 for a list of the modules.

Principal Investigator and Site Principal Investigator from Duke-NUS conducting clinical trials are required to complete local Good Clinical Practice Program (offered by SingHealth Academy, National Healthcare Group, or National University Health System) in addition to the required CITI Program.

Table 2: Minimum CITI training requirement for Duke-NUS study team

Study Roles	Training
Everyone in the study team, including: ● Principal Investigator ● Site Principal Investigator ● Co-Investigator ● Study Team Member	Collaborative Institutional Training Initiative (CITI) – ➢ **Biomedical Research:** 1. Belmont Report and Its Principles 2. Avoiding Group Harms-U.S. Research Perspectives 3. Populations in Research Requiring Additional Considerations and/or Protections 4. History and Ethics of Human Research 5. Basic Institutional Review Board (IRB) regulations and Review Process 6. Informed Consent 7. Social and Behavioral Research (SBR) for Biomedical Researchers 8. Records-Based Research 9. Genetic Research in Human Populations 10. Research Involving Prisoners 11. Research Involving Children 12. Research Involving Pregnant Women, Human Fetuses, and Neonates 13. International Studies 14. FDA-Regulated Research 15. Research and HIPAA Privacy Protections 16. Vulnerable Subjects-research involving workers/employees 17. Conflict of interest in Human Subjects Research

8. How should the researcher and/or the institution's research development office (RDO) check for completeness of the CIRB application?

Refer to *CIRB Initial Application Checklist* on CIRB website Forms & Resources Page. This document serves to facilitate the study team and the RDO in preparing the CIRB application.

9. The Informed Consent templates from SingHealth CIRB and NUS are different. Which templates should be used?

For collaborative research, where SingHealth institutions and Duke-NUS are listed as study site in Section B1(i) of CIRB application, and involves participants recruitment at respective sites, each recruiting study site should use its own Informed Consent templates.

The SingHealth CIRB Informed Consent Form template (available on CIRB website) should be used for SingHealth site.

The NUS Informed Consent Form template (available on NUS-IRB website) should be used for Duke-NUS site.

10. Researchers are required to report Serious Adverse Events (SAEs) to CIRB. Is there any difference in reporting timeline for SingHealth and Duke-NUS study sites?

Any SAEs occurred at the study sites should be reported to CIRB via iSHaRe, according to the *Reporting Requirement and Timeline for SAE* on CIRB website Forms & Resources Page.

Additionally, Duke-NUS PI or Site PI should report to NUS RCIO, any SAEs occurred at the study site as soon as possible and within 1 working day. Refer to Reportable Events section of the NUS-IRB website for guidelines and forms.

11. Researchers are required to report Protocol Deviation/Non-Compliance (PD/NC) to CIRB. Is there any difference in reporting timeline for SingHealth and Duke-NUS study sites?

Any PD/NC occurred at the study sites should be reported to CIRB via iSHaRe immediately once the Principal Investigator/ Site Principal Investigator is aware of the incident.

Additionally, Duke-NUS PI or Site PI should report to NUS RCIO, any PD/NC occurred at the study site, as soon as possible and within 1 working day. Refer to RCIO Policy Appendix 2C SAE and SOC Reporting Guidelines (accessible via NUS network only).

If the respective Research Institutions (RIs) assess that the reported PD/NC is a suspected offence of contravention (SOC), the RI will submit SOC reporting to MOH accordingly.

12. How long should research data be kept?

SingHealth study site

- Research data should be retained in accordance to the SHS-ODDG-04 Information Classification & Document Management (accessible via SingHealth intranet only).

Duke-NUS study site

- Research data should be retained for a minimum period of 10 years after study completion or for 3 years after publication, whichever is later.