OFFICE OF HUMAN RESEARCH PROTECTION PROGRAMME (OHRPP)

1. INTRODUCTION TO NHG'S OFFICE OF HUMAN RESEARCH PROTECTION PROGRAMME (OHRPP)

Reference:

NHG Investigator Manual

NHG Group Research

Version November 2022

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1. Introduction to NHG's Office of Human Subject Research Protection Programme (OHRPP)

1.1 OHRPP Research Ethics Governance

1.2 Orgnisational Structure

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OFFICE OF HUMAN RESEARCH PROTECTION PROGRAMME (OHRPP)

Office of Human Research Protection Programme (OHRPP)

- Mirrors internationally recognised Offices of Human Research Protection
- A reflection of the growth and maturity of the NHG Human Research Protection Programme
- Focused with consolidated key strength on human research

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OFFICE OF HUMAN RESEARCH PROTECTION PROGRAMME (OHRPP)

To ensure the safety and well-being of human research participants, and to advocate their rights through:

- Efficient, and high quality ethics review
- Education on human research protection
- Quality assurance and continuous improvement
- Engagement of public and research partners

OHRPP RESEARCH ETHICS GOVERNANCE

National Healthcare Group Member Institutions

▪ Tan Tock Seng Hospital	▪ Primary Care Academy
▪ Institute of Mental Health	▪ Khoo Teck Puat Hospital
▪ National Healthcare Group Polyclinics	▪ Yishun Community Hospital
▪ National Skin Centre	▪ Geriatrics Education and Research Institute
▪ NHG College	▪ Admiralty Medical Centre
▪ NHG Diagnostics	▪ Woodlands Integrated Health Campus
▪ NHG Pharmacy	

OHRPP RESEARCH ETHICS GOVERNANCE

Partner Institutions

Institutions and organisations with ethics governance under the NHG DSRB

▪ National University Health System	▪ Agency for Integrated Care ▪ Ang Mo Kio Thye Hua Kwan Hospital ▪ Dover Park Hospice ▪ Health Sciences Authority ▪ Health Promotion Board ▪ Lilly Centre for Clinical Pharmacology ▪ Singapore Institute for Clinical Sciences, A*STAR ▪ Singapore Institute of Food and Biotechnology Innovation (SIFBI), A*Star ▪ Skin Research Institute of Singapore (SRIS), A*Star

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IRB JURISDICTION

- **NHG Domain Specific Review Board (DSRB)**: Any research conducted within NHG or Partner Institutions' premises and/or utilizing NHG or Partner Institutions' facilities and/or conducted by or under the direction of an NHG or Partner Institutions' employee, or involving NHG or Partner Institutions' patients must be reviewed and approved by the DSRB prior to initiation of the research activity.

- **SingHealth Centralised Institutional Review Board (CIRB)**: Similar requirements, SingHealth premises, facilities, employees and patients

- **NTU-IRB:** Nanyang Technological University IRB (NTU-IRB) will conduct ethical reviews on all research proposals involving human research participants or human biological materials.

For more information on the above, go to https://www.research.nhg.sg > Ethics & Quality > DSRB Announcements

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CIRB – DSRB MUTUAL RECOGNITION

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/Partner 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).

For the latest CIRB-DSRB Mutual recognition information, go to www.research.nhg.com.sg > Ethics & Quality > DSRB Announcements

Under the Oversight of SingHealth CIRB

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

Under the Oversight of NHG DSRB
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 (WH **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)

WHICH IRB DO I SUBMIT TO?
(CIRB – DSRB MUTUAL RECOGNITION)

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.

CO-OPERATIVE AGREEMENT FOR RESEARCH ETHICS REVIEW BETWEEN NHG DSRB & NTU

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 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.

For the latest Co-operative Agreement for Research Ethics Review between NHG DSRB and NTU IRB information, go to www.research.nhg.com.sg > Ethics & Quality > Research Ethics Framework > DSRB Announcements

Reminder: To check with respective IRBs if need to submit to 1 or multiple IRBs for a collaborative study.

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WHICH IRB DO I SUBMIT TO?
(CO-OPERATIVE AGREEMENT BETWEEN NHG DSRB) & NTU

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.

Note: 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 HBRA).

- 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 to TIARAS.
- The respective RIs will still be responsible for the reporting of contraventions and SAE to MOH.

OHRPP Organisational Structure

NHG Research Ethics Committee

NHG Group Research

Office of Human Research Protection Programme (OHRPP)

DSRB Management & Operations

- Comprises 8 peer-review boards based on scientific domains.
- Provides comprehensive ethics review of research protocols to protect well-being of human subjects in NHG institutions and our partner institutions.
- Develops IRB review policies
- Conducts IRB Training & Education

Research Quality Management

(A)Quality Assurance

- Ensure research protocols approved by the IRB(s) are carried out in accordance to applicable SOPs and regulations (ICH-GCP, NHG SOPs)

(B) Quality Improvement & Process Innovation

- Ensure and improve efficiency of research review applications

(C) Quality Control

Monitor quality of conduct in all NHG PI-Initiated Human Biomedical Research studies conducted in NHG institutions

Research Education

(A)Develop Researcher Training Programmes

(B)Execute Researcher Education Initiatives

(C)Researcher and Study Team Outreach

Research Compliance

(A)Compliance with Human Biomedical Research Act & other applicable regulation

- Research Institution Compliance
- Human Tissue Compliance
- Research Data Compliance
- Proactive Monitoring

(B) Responsible Conduct of Research

- Oversees the propagation of RCR culture and education within the research community.

Partnerships & Outreach

(A)Public Outreach

- Coordinates public education efforts to create a better-informed population on their participation in clinical trials or clinical research.

(B) Partnerships & Cooperative Reviews

- Establishes and strengthens partnerships with external Research Institutions.

Questions?

Refer to www.research.nhg.com.sg

Or contact the NHG Research Education Unit @ researchcoord@nhg.com.sg

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