

References and Suggested Readings Resources

Readers are strongly encouraged to refer/ consult the relevant regulatory agencies and Institutional Review Boards (IRB) websites for the most up-to-date information.

Regulations

Singapore Statutes Online	Home - Singapore Statutes Online (agc.gov.sg)
Health Products Act 2007	Health Products Act 2007 - Singapore Statutes Online (agc.gov.sg)
Health Products (Medical Devices) Regulations 2010	Health Products (Medical Devices) Regulations 2010 - Singapore Statutes Online (agc.gov.sg)
Health Products (Clinical Trials) Regulations 2016	Health Products (Clinical Trials) Regulations 2016 - Singapore Statutes Online (agc.gov.sg)
Health Products (Clinical Research Materials) Regulations 2016	Health Products (Clinical Research Materials) Regulations 2016 - Singapore Statutes Online (agc.gov.sg)
Human Biomedical Research Act	MOH Human Biomedical Research Act
Human Biomedical Research Act (HBRA) 2015	Human Biomedical Research Act 2015 - Singapore Statutes Online (agc.gov.sg)
Human Biomedical Research Regulations 2017	Human Biomedical Research Regulations 2017 - Singapore Statutes Online (agc.gov.sg)
Human Biomedical Research (Restricted Research) Regulations 2017	Human Biomedical Research (Restricted Research) Regulations 2017 - Singapore Statutes Online (agc.gov.sg)
Human Biomedical Research (Tissue Banking) Regulations 2019	Human Biomedical Research (Tissue Banking) Regulations 2019 - Singapore Statutes Online (agc.gov.sg)
Human Biomedical Research (Tissue Banking and Notification – Exemption) Regulations 2019	Human Biomedical Research (Tissue Banking and Notification – Exemption) Regulations 2019 - Singapore Statutes Online (agc.gov.sg)
Human Biomedical Research (Requirements for Appropriate Consent – Exemption) Regulations 2019	Human Biomedical Research (Requirements for Appropriate Consent – Exemption) Regulations 2019 - Singapore Statutes Online (agc.gov.sg)

Medicines Act 1975

[Medicines Act 1975 - Singapore Statutes Online \(agc.gov.sg\)](https://www.agc.gov.sg/act/1975)

Medicines (Clinical Trials) Regulations 2016

[Medicines \(Clinical Trials\) Regulations 2016 - Singapore Statutes Online \(agc.gov.sg\)](https://www.agc.gov.sg/regulation/2016)

Medicines (Medicinal Products as Clinical Research Materials) Regulations 2016

[Medicines \(Medicinal Products as Clinical Research Materials\) Regulations 2016 - Singapore Statutes Online \(agc.gov.sg\)](https://www.agc.gov.sg/regulation/2016)

Mental Capacity Act

[Mental Capacity Act 2008 - Singapore Statutes Online \(agc.gov.sg\)](https://www.agc.gov.sg/act/2008)

[NHG Intranet Access Required] NHG Research Data Policy

[Home \(nhg.com.sg\)](https://www.nhg.com.sg)

Guidelines

About NHG Standing Databases (SDB)

[About NHG Standing Databases \(SDB\)](#)

Belmont Report

[The Belmont Report | HHS.gov](https://www.hhs.gov/ohrt/belmont-report/)

Bioethics Advisory Committee Singapore, Ethics Guidelines For Human Biomedical Research (2021 Revised Edition) October 2021

[Publications \(bioethics-singapore.gov.sg\)](https://www.bioethics-singapore.gov.sg/publications)

- Data Governance
- Managing Research Data

[Data Governance \(nhg.com.sg\)](https://www.nhg.com.sg/data-governance)

Declaration of Helsinki

[WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects – WMA – The World Medical Association](https://www.wma.net/policy/declaration-of-helsinki)

DSRB Review Requirements & Process Guide

[DSRB Review Requirements & Process Guide \(nhg.com.sg\)](https://www.nhg.com.sg/dsrb-review-requirements)

HealthTech Instruction Manual (HIM)

[MOH | HealthTech Instruction Manual](#)

Human Biomedical Research Act (HBRA)

[Human Biomedical Research Act \(HBRA\) \(nhg.com.sg\)](https://www.nhg.com.sg/hbra)

Human Tissue Governance

[Human Tissue Governance \(nhg.com.sg\)](https://www.nhg.com.sg/human-tissue-governance)

ICH GCP E6(R2) Guidelines

[ICH Official web site : ICH](https://www.ich.org)

NHG Research Database Platform (REDCap)

[NHG REDCap Helpdesk Support for NHG Research Community](#)

[NHG Intranet Access Required] Tissue banking, NHG Institutional Tissue Bank Committee (ITBC) Contact

[Home \(nhg.com.sg\)](https://nhg.com.sg)

[NHG Intranet Access Required] NHG Proper Conduct of Tissue Bank SOPs & guidance documents

[Home \(nhg.com.sg\)](https://nhg.com.sg)

[NHG Intranet Access Required] NHG Incidental Findings Policy & Guidance Document on Management of Incidental Findings

[Home \(nhg.com.sg\)](https://nhg.com.sg)

NHG Review Not Required

[Reclassification of Studies involving Anonymised Data and or Human Biological Material \(nhg.com.sg\)](https://nhg.com.sg)

Personal Data Protection Commission Singapore, Data Protection Obligations

[Personal Data Protection Commission Singapore | PDPC](https://nhg.com.sg)

PDPC Guide to Basic Data Anonymisation Techniques

[PDPC | Help and Resources](https://nhg.com.sg)

[PDPC | Guide to Basic Anonymisation Now Available](https://nhg.com.sg)

Principal Investigator (PI) Self-Assessment Programme

NHG PI Self-Assessment Form (PISAF)

[Principal Investigator Self Assessment Programme \(nhg.com.sg\)](https://nhg.com.sg)

Research Monitoring

NHG proactive monitoring framework for HBR studies conducted in NHG

[Research Monitoring \(nhg.com.sg\)](https://nhg.com.sg)

Minimum Training Requirements

Overview of Minimum Training requirements

- CITI
- GCP
- FCOI Declaration Requirements
- FCOI Training Requirements
- NHG Human Biomedical Research (HBR) Essential Research Conduct Course
- HBRA – Human Tissue Framework Course

[Overview of Minimum Training Requirements \(nhg.com.sg\)](https://nhg.com.sg)
[Collaborative Institutional Training Initiative \(CITI\) Training \(nhg.com.sg\)](https://nhg.com.sg)
[Good Clinical Practice \(GCP\) Training \(nhg.com.sg\)](https://nhg.com.sg)
[Financial Conflict of Interest \(FCOI\) Part 1: Declarations \(nhg.com.sg\)](https://nhg.com.sg)
[Financial Conflict of Interest \(FCOI\) Part 2: Training \(nhg.com.sg\)](https://nhg.com.sg)
[HBR Essential Research Conduct \(ERC\) Course \(nhg.com.sg\)](https://nhg.com.sg)
[HBRA – Human Tissue Framework Course \(nhg.com.sg\)](https://nhg.com.sg)

Other Useful Information

NHG Research Ethics Framework	About the NHG Research Ethics Framework
NHG Ethics Review Meeting dates	DSRB Review Requirements & Process Guide (nhg.com.sg)
<ul style="list-style-type: none">• Cross Cluster Mutual Recognition / Collaborative Research• Collaborative Agreement between other IRBs and NHG DSRB	DSRB FAQs (nhg.com.sg) Mutual Recognition of IRB Reviews for Collaborative Studies
Minimum Training Requirements for Staff from SingHealth and Partner Institutions	https://www.singhealthdukenus.com.sg

Resources / SOPs / Templates

DSRB Templates for Study Documentation	DSRB Templates for Study Documentation (nhg.com.sg)
[NHG Intranet Access Required] NHG Proper Conduct of Research (PCR) Standard Operating Procedures (SOP) & Templates	NHG Proper Conduct of Research SOPs & Templates
NHG Guidance Document on Electronic Informed Consent Process	NHG Proper Conduct of Research SOPs & Templates
NHG Guidance Document on Electronic Filling of Essential Documents	NHG Proper Conduct of Research SOPs & Templates
[NHG Intranet Access Required] NHG Human Tissue Bank Policy, SOP & Templates	NHG Human Tissue Bank Policy, SOPs & Templates

Additional Readings

ECOS Guides	User Guides (nhg.com.sg)
Health Sciences Authority Guidance documents for clinical trials	HSA Guidance documents for clinical trials