

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/legislation/medicines-act-1975)

Medicines (Clinical Trials) Regulations 2016

[Medicines \(Clinical Trials\) Regulations 2016 - Singapore Statutes Online \(agc.gov.sg\)](https://www.agc.gov.sg/legislation/medicines-clinical-trials-regulations-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/legislation/medicines-medicinal-products-as-clinical-research-materials-regulations-2016)

Mental Capacity Act

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

[NHG Health Intranet Access Required] NHG Health Research Data Policy

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

Guidelines

About NHG Health 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 \(nhg.com.sg\)](#)

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 \(nhg.com.sg\)](#)

HealthTech Instruction Manual (HIM)

[MOH | HealthTech Instruction Manual](#)

Human Biomedical Research Act (HBRA)

[Human Biomedical Research Act \(HBRA\) \(nhg.com.sg\)](#)

Human Tissue Governance

[Human Tissue Governance \(nhg.com.sg\)](#)

ICH GCP E6(R3) Guidelines

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

NHG Health Research Database Platform (REDCap)

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

[NHG Health Intranet Access Required]

Tissue banking, NHG Health Institutional Tissue Bank Committee (ITBC) Contact

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

[NHG Health Intranet Access Required]

NHG Health Proper Conduct of Tissue Bank SOPs & guidance documents

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

[NHG Health Intranet Access Required]

NHG Incidental Findings Policy & Guidance Document on Management of Incidental Findings

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

NHG Health 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 Health PI Self-Assessment Form (PISAF)

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

Research Monitoring

NHG Health proactive monitoring framework for HBR studies conducted in NHG Health

[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 Health 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 Health Research Ethics Framework

[About the NHG Research Ethics Framework](#)

NHG Health Ethics Review Meeting dates

[DSRB Review Requirements & Process Guide \(nhg.com.sg\)](#)

- Cross Cluster Mutual Recognition / Collaborative Research
- Collaborative Agreement between other IRBs and NHG Health 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 Health Intranet Access Required]

NHG Health Proper Conduct of Research (PCR) Standard Operating Procedures (SOP) & Templates

[NHG Proper Conduct of Research SOPs & Templates](#)

NHG Health Guidance Document on Electronic Informed Consent Process

[NHG Proper Conduct of Research SOPs & Templates](#)

NHG Health Guidance Document on Electronic Filling of Essential Documents

[NHG Proper Conduct of Research SOPs & Templates](#)

[NHG Health 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](#)