

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 \(agc.gov.sg\)](#)

Medicines (Clinical Trials) Regulations 2016

[Medicines \(Clinical Trials\) Regulations 2016 - Singapore Statutes Online \(agc.gov.sg\)](#)

Medicines (Medicinal Products as Clinical Research Materials) Regulations 2016

[Medicines \(Medicinal Products as Clinical Research Materials\) Regulations 2016 - Singapore Statutes Online \(agc.gov.sg\)](#)

Mental Capacity Act

[Mental Capacity Act 2008 - Singapore Statutes Online \(agc.gov.sg\)](#)

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

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

Guidelines

About NHG Health Standing Databases (SDB)

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

Belmont Report

[The Belmont Report | HHS.gov](#)

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

- Data Governance
- Managing Research Data

[Publications \(bioethics-singapore.gov.sg\)](#)

Declaration of Helsinki

[Data Governance](#)

[WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects – WMA – The World Medical Association](#)

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](#)

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

[NHG Health Intranet Access Required]

NHG Health Proper Conduct of Tissue Bank
SOPs & guidance documents

[NHG Health Intranet Access Required]

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

NHG Health Review Not Required

Personal Data Protection Commission
Singapore, Data Protection Obligations

PDPC Guide to Basic Data Anonymisation
Techniques

[Research Compliance Unit - Home](#)

[Updated link](#)

[Research Compliance Unit - Home](#)

[Updated link](#)

[Research Compliance Unit - Home](#)

[Updated link](#)

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

[Personal Data Protection Commission
Singapore | PDPC](#)

[PDPC | Help and Resources](#)

[PDPC | Guide to Basic Anonymisation
Now Available](#)

Principal Investigator (PI) Self-Assessment Programme

NHG Health PI Self-Assessment Form
(PISAF)

[Principal Investigator Self Assessment
Programme \(nhg.com.sg\)](#)

Research Monitoring

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

[Research Monitoring \(nhg.com.sg\)](#)

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

[Collaborative Institutional Training
Initiative \(CITI\) Training \(nhg.com.sg\)](#)

[Good Clinical Practice \(GCP\) Training
\(nhg.com.sg\)](#)

[Financial Conflict of Interest \(FCOI\) Part
1: Declarations \(nhg.com.sg\)](#)

[Financial Conflict of Interest \(FCOI\) Part
2: Training \(nhg.com.sg\)](#)

[HBR Essential Research Conduct \(ERC\)
Course \(nhg.com.sg\)](#)

[HBRA – Human Tissue Framework
Course \(nhg.com.sg\)](#)

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](#)

Minimum Training Requirements for Staff from SingHealth and Partner Institutions

[DSRB FAQs](#)

<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

[OHRPP - Research Quality Management \(RQM\) - Home](#)

[Updated link](#)

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

[Research Compliance Unit - Home](#)

[Updated link](#)

Additional Readings

ECOS Guides

[User Guides \(nhg.com.sg\)](#)

Health Sciences Authority Guidance documents for clinical trials

[HSA | Guidance documents for clinical trials](#)