

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	Publications (bioethics-singapore.gov.sg)
<ul style="list-style-type: none"> • Data Governance • Managing Research Data 	Data Governance
Declaration of Helsinki	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 Health 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](#)