

# OFFICE OF HUMAN RESEARCH PROTECTION PROGRAMME (OHRPP) STUDIES EXCLUDED FROM THE HUMAN BIOMEDICAL RESEARCH ACT (HBRA)

**Office of Human Research Protection  
Programme (OHRPP)  
Group Research**

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Restricted, Sensitive - Normal  
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Adding years of healthy life

Please note that these slides are intended as a guide to provide an overview of the Human Biomedical Research Framework.

You are advised to read the following regulatory legislations in full to obtain a better understanding of its requirements:

- **Human Biomedical Research Act 2015**
- **Human Biomedical Research Regulations 2017**
- **Human Biomedical Research (Restricted Research) Regulations 2017**
- **Human Biomedical Research (Tissue Banking) Regulations 2019**
- **Human Biomedical Research (Tissue Banking and Notification – Exemption) Regulations 2019**
- **Human Biomedical Research (Requirements for Appropriate Consent – Exemption) Regulations 2019**

# OVERVIEW

1. Studies Excluded from HBRA
2. Information, Resources & References

# HBRA – EXCLUDED STUDIES

What studies are excluded under HBRA? (HBRA 2015, Second Schedule)

Normal human psychological responses and behaviours

- **NOT** designed or intended to study psychiatric or psychological disorders; and
- Involve no more than minimal risk to the research subject.

Measure human intelligence

- **NOT** designed or intended to study mental or intellectual disability; and
- which involve no more than minimal risk to the research subject.

Public Health Research for Infectious Diseases

- In accordance to Infectious Disease Act

Collection and compilation of health information

- For epidemiological or statistical purposes in accordance with the National Registry of Diseases Act
- For statistical purposes in accordance with the Statistics Act

Clinical Trials

- Of Health products conducted in accordance with the Health Products Act
- Of Medicinal products conducted in accordance with the Medicines Act

# OVERVIEW

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# INFORMATION, RESOURCES & REFERENCES

For more information on the Human Biomedical Research Act and its subsidiary legislation, refer to the following link: <https://www.moh.gov.sg/policies-and-legislation/human-biomedical-research-act>



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responsibilities of individuals and body corporates involved in human biomedical research and the handling of human tissue for use in research.

Through the legislation, the Ministry of Health (MOH) strives to ensure that human biomedical research and tissue banking activities carried out in Singapore follow the law and principles of good clinical practice relating to ethics and science to protect the safety and welfare of research subjects and tissue donors.

If you have any questions or concerns about your compliance with the HBRA, please write in to MOH at the following email address [hbr\\_enquiries@moh.gov.sg](mailto:hbr_enquiries@moh.gov.sg).

## Decision Trees

- > [Am I handling human tissue and conducting tissue banking activities regulated under the Human Tissue Framework?](#)
- > [Is my study human biomedical research?](#)

[Expand All](#) | [Collapse All](#)

### ⊖ About the Act

- [Human Biomedical Research Act 2015](#)
- [Human Biomedical Research Regulations 2017](#)
- [Human Biomedical Research \(Restricted Research\) Regulations 2017](#)
- [Human Biomedical Research \(Tissue Banking\) Regulations 2019](#)
- [Human Biomedical Research \(Tissue Banking and Notification — Exemption\) Regulations 2019](#)
- [Human Biomedical Research \(Requirements for Appropriate Consent — Exemption\) Regulations 2019](#)
- [Frequently Asked Questions](#)

# QUERIES TO HBRA?

Queries regarding HBRA?

Please write to the NHG Research Institution (RI) at [NHGRISecretariat@nhg.com.sg](mailto:NHGRISecretariat@nhg.com.sg)

To access the list of RI that notified MOH of their operations, go to <https://www.gov.sg> > Ministry of Health > About the Human Biomedical Research Framework > Research Institution that Notified MOH of their Operations

**THANK YOU FOR YOUR  
KIND ATTENTION**