

OFFICE OF HUMAN RESEARCH PROTECTION PROGRAMME (OHRPP)

INTRODUCTION TO THE HUMAN BIOMEDICAL RESEARCH ACT (HBRA) AND ITS IMPLICATIONS ON STUDIES

**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. Background & Framework of HBRA
2. Information & Resources

BACKGROUND

- ❖ Passed in Parliament on 18 August 2015
- ❖ Consists of two frameworks:

1. Human Biomedical Research Framework

Regulates conduct of Human Biomedical Research (HBR) studies

HBR Regulations 2017 (Subsidiary Legislation) gazetted on 30 October 2017

Activated on **01 November 2017**

2. Human Tissue Framework

Regulates Human Tissue* activities and Tissue Bank

Prohibits commercial trading of Human Tissue (Section 32 and 33) – in force since **01 January 2017**

Activated on **01 November 2019**

**Refer to First Schedule - Human biological materials that are excluded from definition of human tissue*

HBR FRAMEWORK

“Human biomedical research” covers 2 broad areas :

- 1) Human subject research that have certain intended purposes and involve certain methodologies, per section 3(2)

Any research that is intended to study –

- (a) the prevention, prognostication, diagnosis or alleviation of any disease, disorder or injury affecting the human body; or
- (b) the restoration, maintenance or promotion of the aesthetic appearance of human individuals through clinical procedures or techniques; or
- (c) the performance or endurance of human individuals,

where the research involves –

- (i) subjecting an individual to any intervention (including any wilful act or omission) that has a physical, mental or physiological effect (whether temporary or permanent) on the body of the individual; or
- (ii) the use of any individually-identifiable biological material obtained from the human body; or
- (iii) the use of any individually-identifiable health information.

HBR FRAMEWORK

[cont'd] “Human biomedical research” covers 2 broad areas :

2) Certain types of ‘sensitive’ embryological and stem cell research, as per section 3(3)

“Any research that involves –

- (a) human gametes or human embryos
- (b) cytoplasmic hybrid embryos
- (c) the introduction of any human-animal combination embryo into an animal or a human;
- (d) the introduction of human stem cells or human neural cells into an animal at any stage of development; or
- (e) any entity created as a result of any process referred to in paragraph (c) or (d).”

Note: Even if such tissues are non individually-identifiable, the research still falls within the scope of HBR Act.

OVERVIEW

1. Background & Framework of HBRA
2. Information, Resources & References

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.

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

To access the list of RI that notified MOH of their operations, go to <https://moh.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**