

**OFFICE OF HUMAN RESEARCH
PROTECTION PROGRAMME (OHRPP)
PROHIBITED & RESTRICTED RESEARCH
ACCORDING TO 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. Prohibited Research
2. Restricted Research
3. Information, Resources & References

HBRA – PROHIBITED RESEARCH



NOT ALLOWED TO BE CONDUCTED

PROHIBITED RESEARCH (HBRA 2015, Third Schedule)

Human biomedical research involving the **development of human-animal combination embryos** beyond 14 days or the appearance of the primitive streak, whichever is the earlier.

Human biomedical research involving the implantation:

- of a **human-animal combination embryo** into the uterus of an **animal**;
or
- of a **human-animal combination embryo** into the uterus of a **human**

Human biomedical research involving the **introduction of human stem cells** (including induced pluripotent stem cells) or human neural cells **into the brain of living great apes** whether prenatal or postnatal

Human biomedical research involving the **breeding of animals which have had any kind of human pluripotent stem cells** (including induced pluripotent stem cells) introduced into them.

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HBRA – RESTRICTED RESEARCH



Requires MOH approval

RESTRICTED RESEARCH (HBRA 2015, Fourth Schedule)

Human eggs or human embryos

Human-animal combination embryos

- cytoplasmic hybrid embryos;
- human-animal combination embryos created by the incorporation of human stem cells (including induced pluripotent stem cells);
- human-animal combination embryos created in-vitro by using —(A) human gametes and animal gametes; or (B) one human pronucleus and one animal pronucleus;

Application to MOH will be done via TIARAS website, through the Research Institution after IRB approval has been obtained.

[Refer to HUMAN BIOMEDICAL RESEARCH (RESTRICTED RESEARCH) REGULATIONS 2017]

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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>



[For Public](#) [For Healthcare Professionals](#) [e-Services](#) [Who We Are](#)

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://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**