

## The Human Biomedical Research Act: Prohibition Against Commercial Trading of Human Tissue

### Structure of the Human Biomedical Research Act (HBRA)

The HBRA was passed by Parliament on 18 Aug 2015 and enacted on 21st August 2015. It incorporates provisions for two separate but related regulatory frameworks, and is being brought into operation gradually in phases. The two frameworks are:

- The human biomedical research (HBR) regulatory framework; and
- The human tissue regulatory framework.

Purpose of HBR Regulatory Framework	Purpose of Human Tissue Regulatory Framework
<ul style="list-style-type: none"> <li>• Regulate the conduct of HBR in general;</li> <li>• Subject certain types of restricted HBR (e.g. research involving human eggs or embryos or human-animal combination embryos) to stricter controls; and</li> <li>• Prohibit certain types of HBR that are considered ethically unacceptable in Singapore.</li> </ul>	<ul style="list-style-type: none"> <li>• Regulate tissue banks and tissue banking activities for research; and</li> <li>• Prohibit commercial trading of human tissue (whether for research, therapy or any other purposes).</li> </ul>

The principal objectives of both frameworks seek to protect the interests of research subjects and tissue donors by:

- Protecting their safety and welfare ;
- Ensuring that their health and well-being are not compromised; and
- Ensuring respect for their privacy and autonomy.

### Provisions Relating to the Prohibition Against Commercial Trading of Human Tissue

The relevant provisions relating to the prohibition against commercial trading of human tissue, i.e. sections 32 and 33 of the HBRA came into effect on 1 January 2017. Other sections in the HBRA will be brought into operation gradually in stages.

Here are some notable points regarding the interpretation of the Act in relation to the prohibition against commercial trading of human tissue:

- The provisions in the human tissue regulatory framework largely apply only to dealings in human tissue. The considerations for what is, or is not, considered human tissue is specified in the Act.
- Reimbursement for “reasonable costs and expenses” incurred in the collection, preservation, assessment and transportation of human tissue is permitted under the Act. For the avoidance of doubt, when tissue is paid for in this manner, purchasers should obtain an itemised breakdown to show how the pricing was derived.

If you have previously made arrangements to obtain and/or supply human tissue, whether for use in therapy or research, please ensure that your arrangements are in compliance with the prohibitions in the HBRA. Any person convicted for commercial trading of human tissue under the HBRA may be liable for imprisonment for up to 10 years and/or a fine of up to \$100,000.

For more information, you may refer to the guideline issued by the Ministry of Health (MOH) on the prohibition against commercial trading of human tissue, available at the following link:

[https://www.moh.gov.sg/content/dam/moh\\_web/Legisla tion%20And%20Guidelines/Guidance%20on%20Prohibition%20Against%20Commercial%20Trading%20of%20Human%20Tissue%20under%20HBRA%20-%20February%202017.pdf](https://www.moh.gov.sg/content/dam/moh_web/Legisla tion%20And%20Guidelines/Guidance%20on%20Prohibition%20Against%20Commercial%20Trading%20of%20Human%20Tissue%20under%20HBRA%20-%20February%202017.pdf)

Should you have any enquiries relating to the above regulations, please contact MOH directly at [hbr\\_enquiries@moh.gov.sg](mailto:hbr_enquiries@moh.gov.sg).

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