A Guide to the Prohibition Against Commercial Trading of Human Tissue

Human Biomedical Research Act

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1 The Human Biomedical Research Act 2015

1.1 The Human Biomedical Research Act (HBRA), which was passed by Parliament on 18 August 2015, incorporates provisions for two separate but related regulatory frameworks :

(a) the human biomedical research (HBR) regulatory framework; and

(b) the human tissue regulatory framework.

1.2 The principal objective of both these frameworks is to protect the safety and welfare of research subjects and tissue donors, ensuring that their health and well-being is not compromised, and their privacy and autonomy is respected.

1.3 For the HBR regulatory framework, the HBRA :

(a) regulates the conduct of HBR in general;

(b) subjects certain types of restricted HBR (e.g. research involving human eggs or embryos or human-animal combination embryos) to stricter controls; and

(c) prohibits certain types of HBR that are considered to be ethically unacceptable in Singapore.

1.4 For the human tissue regulatory framework, the HBRA :

(a) regulates tissue banks and tissue banking activities for research; and

(b) prohibits commercial trading of human tissue (whether for research, therapy or any other purpose).

1.5 The HBRA is being brought into operation gradually in stages. **The provisions relating to the prohibition against commercial trading of human tissue have come into force on 1 January 2017.** This will be followed by the provisions relating to the HBR regulatory framework, and thereafter, the remaining provisions relating to the regulation of tissue banks and tissue banking activities.

2 What Is (or Is Not) Considered "Human Tissue" in the HBRA

2.1 Many of the provisions in the HBRA, and in particular those relating to the human tissue regulatory framework, are applicable only to dealings in **human tissue**. Hence, it is important to define what is human tissue and what is not.

2.2 In this regard, there are two key, closely-related terms defined in the HBRA :

- "human biological material", means any biological material obtained from the human body that consists of, or includes, human cells;
- "human tissue", means any human biological material **but excludes** human biological material specified in the First Schedule (of the HBRA).

[*refer to definitions in section 2 of the HBRA*]

2.3 The human biological material specified in the First Schedule (and therefore **not** considered to be human tissue) can be viewed under two broad groups.

(a) The first group encompasses biological material that is considered 'mundane' and would ordinarily be excreted or shed from the body. Such biological material can be collected with little risk to the safety and welfare of the donor, and thus does not need to be regulated as human tissue.

The first group comprises the items currently listed in paragraphs 1, 2 and 3 of the First Schedule :

(i) hair, cut (or shaved or removed) from the body without the dermal hair root or follicle;

(ii) fingernail or toenail clippings, cut without the underlying dermal tissue; and

(iii) bodily fluids and waste products that are naturally excreted from the human body, such as saliva, sweat, urine and faeces.

[*Note : The placenta (or afterbirth) is currently not specified in the First Schedule, and is not considered a naturally excreted waste product. Thus, the placenta is considered human tissue.*]

(b) The second group encompasses biological material that is **not individually-identifiable**, and which might initially have been collected as human tissue, but has been processed such that its functional, structural and biological characteristics are **substantially manipulated** compared to when it was originally collected. Essentially, the biological material is considered to have been 'transformed' into material that is different from the original human tissue.

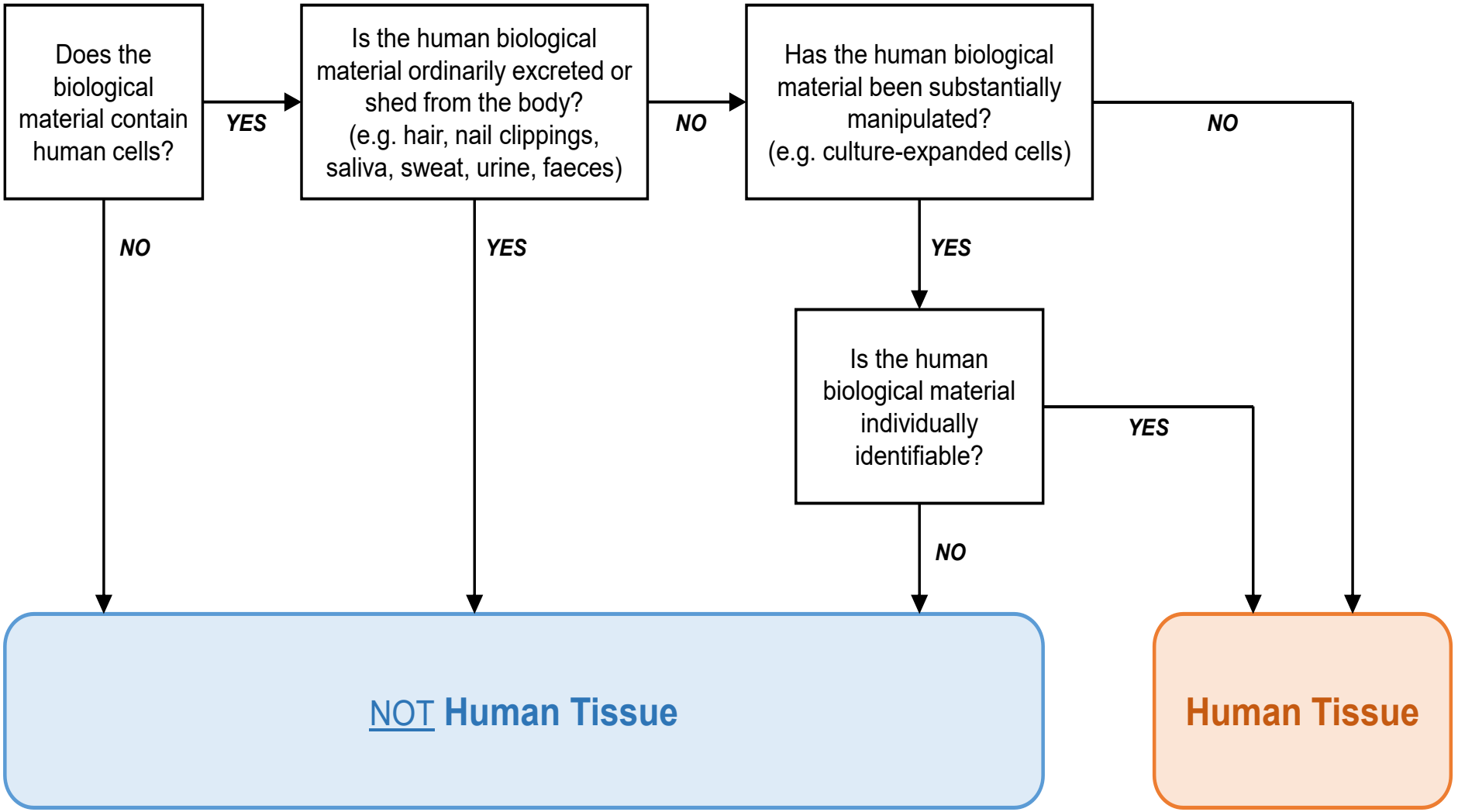
The second group is described in paragraph 4 of the First Schedule, and would generally include many of the tissue products and tissue derivatives made from human biological material.

2.4 When considering whether biological material that has undergone processing has been substantially manipulated, it is useful to consider the purpose of the processing and how it affects the original biological material. Some examples are as follows :

A tissue sample is plated to allow its constituent cells to undergo culture-expansion, resulting in a new generation of cells, and the creation of a cell line.	This would be considered substantial manipulation. The resulting culture-expanded cells and new cell lines would not be considered human tissue.
A tissue sample is subjected to a biological or chemical agent, resulting in the cells being genetically modified and/or irreversibly altered at the cellular level (e.g. immunolabelling, formalin-fixed paraffin-embedded tissue, tissue maintained in animal serum).	This would be considered substantial manipulation. The modified/altered cells would not be considered human tissue.
A tissue sample is subjected to enzymatic treatment to dissociate cell-cell contact and release the cells from the extracellular matrix.	This would be considered substantial manipulation. The cell suspension would not be considered human tissue.
A tissue sample is subjected to a buffer or chemical agent, to break open the cells and recover the subcellular components (e.g. tissue lysate, DNA, RNA, proteins, metabolites, organelles)	This would be considered substantial manipulation. The subcellular components would not be considered human tissue.
A tissue sample is subjected to high heat and fluid rinse, to destroy the constituent cells and recover the decellularised extracellular matrix.	This would be considered substantial manipulation. The extracellular matrix would not be considered human tissue.
A tissue sample undergoes freezing/ cryopreservation, to help preserve and prolong the viability of the tissue in its original state.	This would not be considered substantial manipulation. The frozen sample would continue to be human tissue.
A tissue sample is cut into several roughly equal segments, to allow the sample to be distributed and used by several different researchers.	This would not be considered substantial manipulation. The cut samples would continue to be human tissue.

2.5 An illustrative list of processes that would not be considered to be substantial manipulation is provided in paragraph 4(2) of the First Schedule of the HBRA. This list includes relatively simple processing methods (e.g. cutting, grinding, filtering and freezing), which, by themselves, would generally not result in substantial manipulation of the human biological material.

2.6 The properties that help distinguish between what is and what is not considered human tissue under the HBRA, are depicted in the following diagram.



3 Why is Commercial Trading of Human Tissue Prohibited?

3.1 Section 32 of the HBRA prohibits commercial trading of human tissue, making it an offence to buy or sell human tissue. Additionally, section 33 of the HBRA prohibits advertisements relating to the commercial trading of human tissue.

3.2 The prohibition against commercial trading of human tissue reflects the principle that **all human tissue, whether for use in research, therapy or any other purpose, should be obtained only through altruistic donations**. This prohibition is aligned with similar prohibitions against commercial trading of organs and blood (under the Human Organ Transplant Act), and of human eggs, sperm and embryos (under the Human Cloning and Other Prohibited Practices Act).

4 Dealing Lawfully with Human Tissue and Products and Derivatives of Human Tissue

4.1 The prohibition against commercial trading applies to human tissue, but not to other human biological material excluded from the definition of human tissue.

Tissue Products and Tissue Derivatives

4.2 In most instances, tissue products and tissue derivatives made from human biological material would have undergone substantial manipulation and processing. Where such tissue products and derivatives are not considered to be human tissue, they can be bought and sold on a commercial basis.

Obtaining and Supplying Human Tissue Lawfully

4.3 While the HBRA prohibits commercial trading of human tissue, it allows for payment to reimburse the reasonable costs and expenses incurred in the process of collecting and supplying human tissue – including the removal of tissue from the donor, and the subsequent transportation, preparation, preservation, quality control and storage of the tissue. The payment must not be for the purchase or sale of the tissue itself.

4.4 In this regard, obtaining tissue from sources that are part of a tissue sharing network or exchange programme, whether local or international, and paying only reasonable costs and expenses in relation to such sourcing, would generally be permitted. In contrast, sourcing for tissue from foreign commercial suppliers or tissue banks that routinely charge a price for selling the tissue itself, should be done cautiously, and any proposed transaction should be considered carefully beforehand to ensure that it does not contravene the prohibition.

4.5 When making arrangements to obtain human tissue, it is advisable to clarify the arrangements with the supplier providing the human tissue to ensure that the supply of the tissue is on a cost-recovery basis. These arrangements and transactions with the supplier should be documented accordingly, preferably with a breakdown of the supplier's costs and expenses that the payment is for. All documents should be kept readily available for inspection when requested.

4.6 To minimise potential complications when obtaining human tissue from foreign sources, it is advisable to obtain human tissue from suppliers in countries or jurisdictions that similarly prohibit the commercial trading of human tissue and only allow payment of reasonable costs and expenses, for example, Australia and New Zealand. Legitimate tissue banks and tissue suppliers in such places would be familiar with the need for documentation, and the manner in which to document such supply, in order to demonstrate compliance with the prohibition.

5 Penalties for Commercial Trading of Human Tissue

5.1 Commercial trading of human tissue is a serious offence under the HBRA. Any person who is convicted in Court for any of the offences under sections 32 or 33 of the HBRA, is liable to a fine of up to $100,000 and/or imprisonment for up to 10 years.

6 Contact Information

6.1 If you have any information on unlawful dealings in human tissue in Singapore, or would like to seek further clarification or information on this prohibition against commercial trading of human tissue, please contact HSA at HSA_HBR_Enquiries@hsa.gov.sg.

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