CASE EXAMPLES – HBR?

S/N	Study Description	HBR?	Reasons
1	Surveys are conducted with paediatric patients and their parents to get feedback on a post-operative pain management program and how the institution's care team could improve when administering the program.	No	Service evaluation. (However, if for example, the survey was to collect data to develop a novel pain management program, then it is research)
2	To identify strategies aimed at encouraging healthier food consumption (eg labelling foods as 'lower in calories'), an experimental web-based grocery store is set up and participants are recruited to do e-shopping. Data collected is used to quantify which strategy has the greatest positive effect on calories purchased.	No	Non-HBR. Both purposive and method elements are not satisfied as the research studies social behavior, has no specific clinical care or physiological purpose and does not involve health information, human biological material or intervention with the subjects.

Notes:- Brown text denotes purposive element (Section 3(2)(a), (b) or (c) of HBRA)

Purple text denotes method element (Section 3(2)(i), (ii) or (iii) of HBRA)



CASE EXAMPLES – HBR?

S/N	Study Description	HBR?	Reasons
3	A qualitative study was conducted using structured interviews on hospital patients, to find out psychosocial, behavioral and environmental factors impacting patients' frequent admissions to the hospital, with the objective of supporting policy-making on managing healthcare costs.	No	Non-HBR. Purposive element not satisfied as the research studies social and environmental behavior and factors.
4	To study ingestion of certain quantities of ice-slurries to improve endurance performance .	Yes	HBR. Both purposive and method elements satisfied
5	Retrospective analysis of stroke patients' medical records to evaluate trends in survivability outcomes for this patient group following inpatient hospitalization.	Yes	HBR. Both purposive and method elements satisfied.

Notes:- Brown text denotes purposive element (Section 3(2)(a), (b) or (c) of HBRA)

Purple text denotes method element (Section 3(2)(i), (ii) or (iii) of HBRA)



Extract of 12 June 2018 MOH-POC Meeting slides

**The IRB reviewing your study will, in the course of its review and approval process, confirm whether your study has been correctly classified as HBR or non-HBR.

FAQs – What is HBR?

Types of research and studies out of the scope of HBR:

Under the Human Biomedical Research Act (HBRA), any form of human biomedical research (HBR) that falls within the scope specified in section 3 of the Act and not excluded in the Second Schedule is regulated and the HBR protocol will need to be reviewed and approved by an institutional review board (IRB) appointed by the research institution (RI)

The HBRA is <u>not</u> intended to regulate 'research studies' presented in the form:







Clinical audit



Surveillance



Outbreak investigation

A table with more information on HBR and other HBR-like activities can be accessed from the MOH HBR website by clicking here



TISSUE?

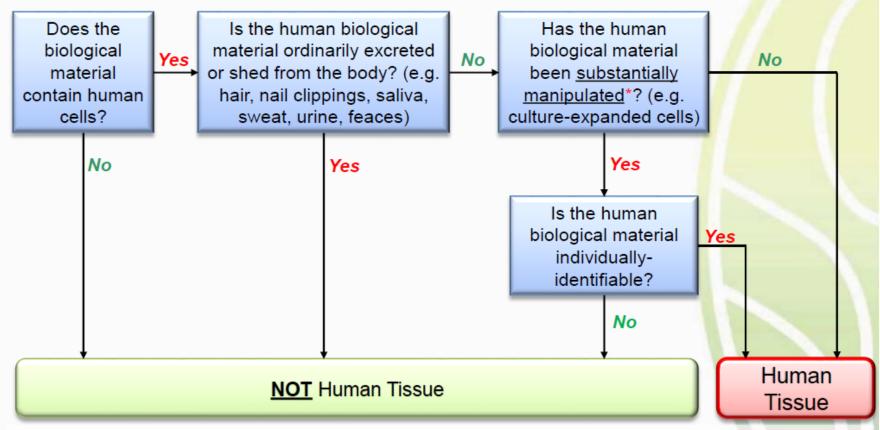
- Page 4 of MOH's Guide To Prohibition Against Commercial Trading in Human Tissue

To access the statement on Prohibition Against Commercial Trading of Human Tissue Under Human Biomedical Research Act click here



Definition of Human Tissue under the HBRA

What is considered human tissue under the HBRA?



*N.B. Processes that would not be considered to be substantial manipulation include cutting, grinding, shaping, centrifugation, soaking in antibiotic or antimicrobial solutions, sterilization, low-level irradiation, cell separation, concentration or purification, filtering, lyophilisation, freezing, cryopreservation, vitrification.