SingHealth CIRB: Illuminaté
"To Énlighten... Ethics, above all"
Adapted version for researchers, investigator and study
SingHealth Defining Tomorrow's Medicine
Issue 10
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In this issue >>>

Research involving Human Biological Materials

1. Difference between Human Biological Materials and Human Tissue >>>

As defined in Human Biomedical Research Act 2015 (HBRA):

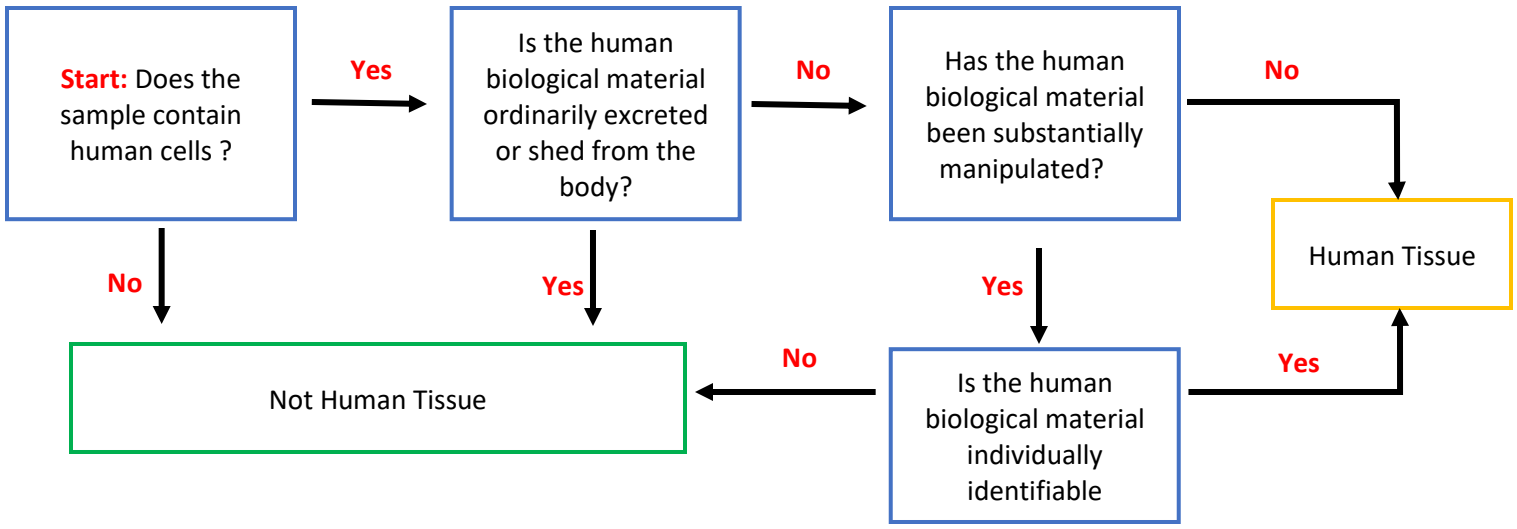
- Human Biological Materials (HBM) means any biological material obtained from the human body that consists of, or includes, human cells.
- Human Tissue (HT) means any human biological material but excludes human biological material specified in the HBRA, First Schedule.

First Schedule of HBRA: Human Biological Material excluded from definitions of Human Tissue

1. Hair Shaft, cut without dermal hair root or follicle.
2. Nail Plate, cut without underlying dermal tissue.
3. Naturally excreted bodily fluids and waste products such as saliva, sweat, urine and faeces.
4. Any other HBM that is not individually-identifiable and has been processed in a manner that its function structural and biological characteristics are substantially manipulated as compared to the time of collection.
   Note: Human Biological Material is not deemed to be substaintially manipulated merely because it has been processed by any of, or combination of, the following methods:

Cell separation, concentration or purification | Centrifugation | Cutting | Cryopreservation | Filtering | Freezing | Grinding | Low-level irradiation | Lypohilisation | Shaping | Soaking in antibiotic or antimicrobial solution | Sterilization | Vitrification

What is considered Human Tissue under the HBRA?



Reference: Overview of Human Tissue Framework. MOH Human Biomedical Research Act. (2021). Retrieved 22 April 2022, from https://www.moh.gov.sg/docs/librariesprovider5/legislation/overview-of-human-tissue-framework.pdf.

2. Introduction on Human Tissue Framework >>>

✓ Activated on 1 Nov 2019

Regulation of Research Tissue Banking

- Duties of Tissue Bank and other controls to be prescribed
- Restriction on activities relating to human tissue
- Compelling person to donate tissue
- Restriction on disclosure of information on tissue donor
- Saving & transitional provisions for legacy human biological material

As defined in HBRA:

- Tissue Bank means an individual or a body of person, whether corporate or unicorportate, or other organization, that carries on and conduct any tissue banking activity but exclude an individual, or a body of persons or an organization that conducts any tissue banking activities soley for the purposes of the person's or organization's own human biomedical research approved or exempted from review by an IRB.
- Tissue Banking Activties means a structured and an organized activity involving human tssue for the purposes of facilitating current or future research or for public health or epidemiological purposes or any combination of such purposes including any of the following activities:
  - The collection, storage, procurement or importation of human tissue
  - The supply, provision or export of human tissue

*Please refer to Section 34 to 39 and Section 64 of HBRA for more information on the Human Tissue Framework.

3. Role of IRB in reviewing research involving Human Tissue >>>

✓ CIRB will only review the human tissue required for the proposed research. Collection of additional or extra human tissue not for the proposed research should be excluded from the application submitted to CIRB. Such collection should be conducted under a Tissue Bank (TB) and using the TB's consent document.

✓ To ensure that the research is conducted in accordance to applicable regulations. Please refer to table below for the different scenaios and the consent requirements.

No.	Scenarios		Consent Requirement
1.	Involvement of HBM collection from participant.	HBM would be used in current research	HBRA S12 (1) and S12 (2) elements must be included in consent document
2.		Leftover HBM for future own research	Consent to use leftover HBM for future research should be captured in a separate section in the consent document.
3.		Leftover HBM to supply for other research	The supply of HBM to other research must be through a TB. CIRB Application Form S5(ii) should state: - The name of the TB where leftover HBM would be stored. - If the TB consent form will be used for obtaining consent to use leftover for future research.
4.	HBM will be obtained from Tissue Bank		Please state in CIRB Application Form Section S1b: - Name of Tissue Bank (registered with MOH) - The type of HBM that will be used.
5.	HBM from approved studies		Please state in CIRB Application Form: - Section Q: CIRB Reference and Protocol Title of approved studies - Section Q: Consent document (template) of the approved studies - Section S1b: The type of HBM that will be used. Note: PI must ensure that only HBM from individuals (who had consented for use of HBM for future research) will be used.

4. Involvement of Tissue Banks in Research >>>

- Before any tissue bank can supply individually-identifiable tissue for use in research, the tissue bank must ensure that:
  - An IRB has approved the proposed research that the tissue would be used for, and
  - Documentary evidence provided by the receiving party that the receiving party will ensure that the intended use of the tissue is in accordance with any restrictions/conditions of the donors' appropriate consent
- Before any tissue bank can supply non-identifiable tissue for use in research, the tissue bank must ensure that:
  - The tissue bank is satisfied that there is scientific merit for the proposed research

5. Changes to assent requirement >>>

	Table 1: Revised guidelines for assent requirements and documentation. (Applicable to new IRB applications submitted on and after 1 October 2022)	
	Child has sufficient understanding and intelligence	**Child does not have sufficient understanding and intelligence**
0 to 5 years	Written agreement of the child is not required	Written agreement of the child is not required
6 to 11 years	Assent Form	Assent Form (unless waived by the IRB)
12 to 20 years	Consent Form	Assent Form (unless waived by the IRB)

	Table 2: "Existing" guidelines for assent requirements and documentation. (Applicable to studies submitted and/or approved before 1 October 2022)
	Child has sufficient understanding and intelligence
0 to 5 years	Written agreement of the child is not required
6 to 12 years	Assent Form
13 to 20 years	Consent Form

1. All new IRB applications submitted on and after 1 October 2022, are required to implement the changes (revised guidelines).
2. Studies submitted and/or approved before 1 October 2022 may continue with the "existing" assent requirements and documentation, as outlined in Table 2 till study completion, unless the researchers make the voluntary determination to implement the changes.

Note: The term "submitted" refers to the date when the IRB application reaches CIRB via iSHaRe, upon completion of the institution endorsement process.

Takeaway message...

Whether human tissue would be obtained from participants, tissue bank or previously IRB-approved study, appropriate consent must be obtained before human tissue can be used in research.

If you have any questions, please contact CIRB at irb@singhealth.com.sg