

HBRA specifies restrictions to participation and the persons authorized to give consent for minors and adults who lack sufficient intelligence or mental capacity

Subjects who lack sufficient intelligence or mental capacity

- Cannot participate in restricted research
- Research of comparable effectiveness cannot be carried out without the participation of this class of persons
- If tissue is removed, primary purpose of removal must be for treatment

Who can take consent for these vulnerable subjects

- Adults who lack mental capacity (in this order of priority) => Donee/Deputy → Spouse → Adult son/daughter → Parent/guardian → Adult brother/sister → Named person
- Minor => Minor and at least one adult parent/guardian (If IRB waives requirement for parent/guardian consent, only Minor's consent required)
- Minor without mental capacity / sufficient intelligence => Deputy / At least one adult parent/guardian

HBRA has specific restrictions where tissues are removed from minors and adults who lack sufficient intelligence or mental capacity





See extract of MOH's 2 Mar 2018 Draft Human Tissue Framework Pre-Regulation Consultation presentation

Appropriate consent requirement for dealings in human tissue in research

Section 37 -For removal, storage, supply and use of tissues-

General Rules :

1. **There must be appropriate consent.**
2. The activity must be conducted in accordance with any conditions specified as part of the consent.



Setting	Specific Controlling Provisions for Removal of Tissue
<p>Diagnosis & Therapy</p> 	<ol style="list-style-type: none"> 1. Where tissue is removed for a therapeutic or diagnostic purpose but <i>will also be used for research purposes</i>, appropriate consent must be obtained for the research purposes <i>in addition to</i> the consent obtained for the therapeutic or diagnostic procedure. 2. Cannot store, supply or use the tissue for research or any other purpose <u>unless</u> the medical practitioner or the healthcare institution has <u>completed</u> all the necessary therapeutic or diagnostic procedures.
<p>Research</p> 	<p>Where the tissue is to be removed for a research purpose, appropriate consent must be obtained for the tissue to be removed from the donor.</p> <ul style="list-style-type: none"> • Where the donor is an adult, consent is obtained from the donor. • Where the donor is a minor with sufficient understanding and intelligence, consent is obtained from <u>both</u> the minor and at least one adult parent or guardian.

Extract of MOH's 2 Mar 2018 Draft Human Tissue Framework Pre-Regulation Consultation presentation – cont'd



Appropriate consent for minor & adult donors who lack mental capacity

Section 37

Group	Consent	Additional Restriction
Minors who (i) lack sufficient understanding and intelligence, or (ii) lack mental capacity 	Consent is obtained from at least one adult parent or guardian. <div style="border: 1px solid red; border-radius: 10px; padding: 5px; display: inline-block;"> Not allowed to be used in restricted research </div>	The tissue is removed <u>primarily for a therapeutic or diagnostic purpose.</u>
Adults who lack mental capacity 	Donee/deputy → Spouse → adult son/daughter → either parent/ guardian → adult bro/sis → named person <div style="border: 1px solid red; border-radius: 10px; padding: 5px; display: inline-block;"> Not allowed to be used in restricted research </div>	The tissue is removed <u>primarily for a therapeutic or diagnostic purpose.</u>

IRB may waive the additional restriction if the board is satisfied that :

- a) the removal of tissue involves no more than minimal risk to the donor; **AND**
- b) there are reasonable grounds for believing that the proposed area of research cannot be carried out without the use of the tissue from such class of persons.