Healthcare Services (Human Tissue Banking Service) Regulations FAQ

Table of Contents

General **3**

1. Who is required to hold a Human Tissue Banking Service licence under the Healthcare Services Act (HCSA)? 3
2. What human tissue types can I bank? 3
3. Do I need to apply for a Human Tissue Banking Service licence if the purpose of banking of human tissue is for research? 3
4. I already hold a Human Tissue Banking Service licence. Do I need to apply for a new licence if I intend to provide banking of a new human tissue type? 4

Clinical Governance Officer **4**

5. Who can be appointed as my Clinical Governance Officer (CGO)? 4
6. Is the CGO required to be physically present onsite at all times while the service is being provided? 5
7. How many CGOs need to be appointed? 5
8. Can a CGO delegate his/her duties? 6

Staff involved in provision of service **6**

9. What would constitute an adequate number of staff to provide the service? 6
10. Can a staff with less than 2 years of relevant experience perform tasks? What does “close supervision” of a staff member with less than 2 years of relevant experience entail? 6

Donor recruitment, counselling and consent **7**

11. When should donor consent be obtained? 7
12. How should donor consent be obtained? 7
13. Who can provide counselling to the donor or authorised person? 7

Evaluation and screening of donors **8**

14. What should the donor be screened for? 8

Processing, testing and quarantine of human tissue **8**

15. Am I expected to discard the human tissue if microorganisms are found to be present on the microbiological cultures of the human tissue? 8

Notification of abnormal or incidental findings **8**

16. What are incidental findings? 8
17. Am I expected to follow-up with a donor if there are abnormal or incidental findings from the tests conducted? 9

Outsourcing **9**

18. Can I outsource testing of the human tissue to other providers? What about other human tissue banking activities? 9

Price Transparency 10

19. Do I need to obtain donor's and/or recipient's express written agreement to the charges related to the conduct of human tissue banking activities? 10

General

1. Who is required to hold a Human Tissue Banking Service licence under the Healthcare Services Act (HCSA)?

- Any person or business who handle, process, test, store and distribute any human tissue intended for subsequent therapeutic use or transplant in the same or another individual is required to hold a Human Tissue Banking Service licence under the HCSA.
- Acute Hospital Service and/or Ambulatory Surgical Centre Service licensees, who only collect or retrieve human tissue from an individual and arranges with a Human Tissue Banking Service licensee to otherwise handle, process, test, store or distribute the tissue collected, do not need to hold a Human Tissue Banking Service licence under the HCSA. These licensees will be required to comply with the relevant requirements stipulated under the Acute Hospital Service Regulations and Ambulatory Surgical Centre Service Regulations for the surgical procedures associated with the collection of the human tissue.
- You will not require a Human Tissue Banking Service licence if the human tissue is to be transplanted within 48 hours upon retrieval from the human body. Otherwise, a Human Tissue Banking Service licence is required.

2. What human tissue types can I bank?

- The human tissue type banked should be supported by sufficient and appropriate scientific evidence for banking and for use to treat patients and accepted by the medical fraternity in Singapore as a therapeutic option.
- A Human Tissue Banking Service licence is required for all human tissues except any blood, blood component, therapeutic product that is derived from blood or blood component, cord blood, embryo, reproductive cell, hair, nail, naturally excreted or secreted bodily fluids or waste products, any human tissue intended for the manufacture of cell, tissue or gene therapy (CTGT) product, nucleic acids. For the avoidance of doubt, the storage of blood, cord blood, embryos and reproductive cells require a Blood Banking Service, Cord Blood Banking Service or Assisted Reproduction Service licences respectively.
- If you are not an existing Human Tissue Banking Service licensee and intend to apply for a human tissue banking licence, we strongly advise you to write to MOH at HCSA-enquiries@moh.gov.sg to seek MOH's advice prior to making an application in Healthcare Application Licensing Portal (HALP).

3. Do I need to apply for a Human Tissue Banking Service licence if the purpose of banking of human tissue is for research?

- Tissue banks that store or supply human tissue for the purpose of use in research, including human tissue to be transplanted into patients as part of the research (i.e. transplantation research tissue banks), are regulated under

the Human Biomedical Research Act (HBRA). They are not required to hold a Human Tissue Banking Service licence under the HCSA.

- However, if the intent at point of collection of the human tissue is to use the human tissue for clinical use eventually, a Human Tissue Banking Service licence is required.

4. I already hold a Human Tissue Banking Service licence. Do I need to apply for a new licence if I intend to provide banking of a new human tissue type?

- Licensees do not need to apply for a new licence to bank a new human tissue type.
- Instead, the licensee is required to make an application for approval in the Healthcare Application Licensing Portal (HALP) no later than two months before the date the licensee intends to provide banking of the new human tissue type listed under the First Schedule of the Healthcare Services (Human Tissue Banking Service) Regulations 2023.
- For addition of a new human tissue type not listed under the First Schedule of the Healthcare Services (Human Tissue Banking Service) Regulations 2023, the licensee is required to notify MOH for our review at HCSA-enquiries@moh.gov.sg no later than two months before the date the licensee intends to provide banking of the new human tissue type.
- Approval of the new human tissue type will only be granted if MOH is satisfied that there is sufficient clinical and medical evidence to support the storage and therapeutic use of the human tissue type.

Clinical Governance Officer

5. Who can be appointed as my Clinical Governance Officer (CGO)?

- The role of the CGO of a Human Tissue Banking Service should be held by a fully registered medical practitioner and specialist in any branch of medicine, and who have at least 5 years of work experience in human tissue or blood or cord blood banking.
- The 5 years of work experience should be relevant to the conduct of activities in the provision of the Human Tissue Banking Service. The activities include but are not limited to setting up of policies and procedures, assessing and setting out the suitability criteria for the human tissue, cord blood or blood for transplant or clinical use, supervision of personnel and review of quality assessment programmes.
- The role of the CGO is to provide clinical and technical oversight for the safe and ethical provision of the Human Tissue Banking Service. It is important that a suitably qualified and competent person be appointed as the CGO to

ensure that the roles and responsibilities of the CGO can be discharged effectively.

- As a matter of good practice, it is strongly encouraged for the CGO to have his/her specialty in the branch of medicine relevant to the type of the human tissue banked. For example, a cardiothoracic surgeon for cardiac homografts, an ophthalmologist for ocular tissue, a plastic surgeon for skin tissue, a haematologist for haematopoietic stem cell derived from bone marrow and peripheral blood.
- Notwithstanding, the licensee can appoint an advising specialist who is a specialist in the branch of medicine relevant to the type of the human tissue banked to support the CGO on the clinical aspects of the Human Tissue Banking Service. For avoidance of doubt, the CGO remains responsible for his/her stipulated duties and roles.

6. Is the CGO required to be physically present onsite at all times while the service is being provided?

- The CGO is required to be physically present onsite if the situation so warrants his/her presence in order to fulfil his/her obligations under the regulations. At all other times, the CGO is required to be accessible, which means being contactable at all times while the service is being provided, to oversee the service and provide directions/advice as appropriate.
- For period of his/her absence, there should be a covering arrangement and someone suitably qualified and competent appointed to act on his/her behalf. Notwithstanding the above, the CGO remains responsible for his/her stipulated duties and roles.

7. How many CGOs need to be appointed?

- Licensees can appoint one or more CGOs for the licensable healthcare service. There must be a sufficient number of CGOs to cover the types of human tissue banked.
- On top of fulfilling any stipulated requirements for CGOs, licensees are responsible for taking into consideration the competency, bandwidth and capacity of the appointed CGOs to discharge their duties for the Human Tissue Banking Service as part of assessing their suitability and ability for the role.
- Where multiple CGOs are appointed, the delineation in roles and responsibilities across multiple CGOs appointed for a licensable healthcare service should be formalised and clearly documented as part of good governance.

8. Can a CGO delegate his/her duties?

- A CGO may delegate certain duties to suitably qualified personnel, provided that the CGO has made a reasonable assessment on the rationale for delegating the duties and the personnel's competency in performing the delegated duty.
- Records of each delegated task tied to the appointed designee and the assessment of the competency of the suitably qualified personnel by the CGO must be retained and made available upon request by MOH.
- For avoidance of doubt, the duty to approve the Human Tissue Banking Service's policies and procedures cannot be delegated and must be retained by the CGO. In addition, the CGO remains responsible for his/her stipulated duties and roles, including ensuring compliance to the policies and procedures set out, regardless whether the duty has been delegated.

Staff involved in provision of service

9. What would constitute an adequate number of staff to provide the service?

- The appropriate number of staff required is not prescribed as that will depend on factors such as the scale of service provision, which may vary for different licensees. Licensees are expected to make a reasonable assessment of the appropriate number of staff and their competencies needed to meet the intended outcomes of the service.

10. Can a staff with less than 2 years of relevant experience perform tasks? What does "close supervision" of a staff member with less than 2 years of relevant experience entail?

- Yes, a staff with less than two years of relevant experience can perform tasks so long as the staff does so under the close supervision of the CGO, or a designated staff with at least of five years of work experience in performing the particular task of the Human Tissue Banking Service.
- There should be arrangements in place whereby the CGO or designated staff can effectively monitor and guide the less experienced staff member in performing human tissue banking activities as appropriate.
- The extent of supervision required (e.g. providing direct supervision on-site, or remaining contactable to give guidance when needed) should be determined by the CGO or designated staff based on an assessment of the less experienced staff's level of competency. Staff who has not been assessed competent should be under the direct supervision of the CGO or another competent staff.

Donor recruitment, counselling and consent

11. When should donor consent be obtained?

- Where the human tissue is to be collected from the body of a living person ("living donor"), written consent of the living donor must be obtained after counselling and before collection of the human tissue.
- The living donor should be given sufficient time after receiving counselling to decide whether or not to give consent.
- Where the human tissue is to be collected from the body of a deceased person ("deceased donor"), written consent of the authorised person must be obtained after counselling and before the collection of the human tissue, except where the human tissue is collected pursuant to section 3 or 4 of Medical (Therapy, Education and Research) Act (MTERA) 1972 and/or section 4(1) of Human Organ Transplant Act (HOTA) 1987.
- For gifts or donations made by the deceased donor under MTERA and/or HOTA, the Licensee should ensure that counselling of and consent-taking from the authorised person follow the workflows under MTERA and/or HOTA.

12. How should donor consent be obtained?

- The manner in which donor consent should be taken is set out in the Regulation 16(3) and (4) in the Healthcare Services (Human Tissue Banking Service) Regulations 2023.
- Donor recruitment may be outsourced. However, it is the obligation of the Human Tissue Banking Service licensee to ensure that the consent is not taken by harassment, coercion, intimidation, deception, misrepresentation, reward or remuneration by any person; and the consent taken is in compliance with the requirements set out in the tissue banking regulations.
- Where the Human Tissue Banking Service licence has any reason to suspect that the consent is obtained by any of the means mentioned, the licensee must not collect, handle, process, test, store, and distribute the human tissue.

13. Who can provide counselling to the donor or authorised person?

- The counselling should be conducted by either the transplant physician relevant to the human tissue intended for treatment or a transplant coordinator.
- A transplant coordinator should meet the following requisite requirements:
    a. Has at least a diploma or basic degree in nursing, science, social work or psychology;
    b. Has at least six months on-the-job training under supervision of the CGO or transplant physician or another designated transplant coordinator with at least 2 years of working experience; and

c. Assessed by the CGO or a suitably qualified personnel (refer to Qn 9 above on the delegation criteria) to have appropriate competency in providing donor counselling in relation to the provision of the Human Tissue Banking Service.

Evaluation and screening of donors

14. What should the donor be screened for?

- Screening of donors include whether there is risk to the donor in donating human tissue based on the donor's medical history and any potential high-risk behaviour, the medical history of the donor's immediate family, and the risk to the recipient in receiving the donated human tissue.
- The donor must be minimally screened for the following infectious diseases: Human Immunodeficiency Virus, Hepatitis B, Hepatitis C and Syphilis.
- The licensee should additionally test the donor for other transmissible diseases if assessed to be necessary.

Processing, testing and quarantine of human tissue

15. Am I expected to discard the human tissue if microorganisms are found to be present on the microbiological cultures of the human tissue?

- Where pathogenic or highly virulent bacteria or fungi are found, the licensee must either discard the human tissue or treat the human tissue with a sterilising procedure validated to eliminate the infectivity of the microorganism.
- Examples of pathogenic or highly virulent bacteria or fungi are:
    a. Fungi such as yeasts and moulds;
    b. Clostridium species; or
    c. Streptococcus pyogenes.

Notification of abnormal or incidental findings

16. What are incidental findings?

- Incidental findings are observations or other findings that may be picked up during a test which are beyond the primary objectives of the test and may have potential health or reproductive importance to the donor.
- Incidental findings differ from abnormal findings, which are observations or other findings that arise as a result from the primary objectives of the test.

17. Am I expected to follow-up with a donor if there are abnormal or incidental findings from the tests conducted?

- The notification of abnormal or incidental findings is only relevant for living donors.
- For licensees who have direct contact with the living donor, the licensee should first inform the living donor of all the necessary tests to be conducted and implement a process during counselling and consent taking to ascertain whether the living donor consents to:
    a. Being informed about any abnormal or incidental findings; and,
    b. Informing the medical practitioner overseeing or performing the collection of the human tissue, or any medical practitioner nominated by the donor, of any abnormal of incidental finding.
- The licensee should then follow up and inform the living donor or the relevant medical practitioner (where the living donor has consented), of any abnormal or incidental findings accordingly.
- For licensees who do not have direct contact with the living donor, the abnormal and incidental findings should be relayed to the healthcare institution which had performed the collection of the human tissue, for the healthcare institution to follow up with the living donor and relevant medical practitioner accordingly.

Outsourcing

18. Can I outsource testing of the human tissue to other providers? What about other human tissue banking activities?

- A licensee may outsource testing of the human tissue to another Human Tissue Banking Service licensee banking the same type of human tissue, or clinical laboratory services licensed under the HCSA, or overseas human tissue banks for the same type of human tissue or clinical laboratories which are accredited an accreditation body approved by Director-General of Health.
- A licensee may outsource donor recruitment as well. However, core human tissue banking activities, namely processing, storage and distribution, should not be outsourced, except for the purposes of business continuity planning.
- For any outsourced activity, the licensee is expected to retain oversight and remain ultimately responsible for compliance with the relevant Regulations and ensuring donor safety and welfare, as well as the safety and quality of the human tissue.

Price Transparency

19. Do I need to obtain donor's and/or recipient's express written agreement to the charges related to the conduct of human tissue banking activities?
• Express written agreement from the donor and/or recipient must be obtained only if charges are made directly to the donor and/or recipient by the Human Tissue Banking Service.