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HUMAN BIOMEDICAL RESEARCH ACT 2015 (ACT 29 OF 2015)

HUMAN BIOMEDICAL RESEARCH (TISSUE BANKING) REGULATIONS 2019

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In exercise of the powers conferred by section 63 of the Human Biomedical Research Act 2015, the Minister for Health makes the following Regulations:

PART 1

PRELIMINARY

Citation and commencement

1. These Regulations are the Human Biomedical Research (Tissue Banking) Regulations 2019 and come into operation on 1 November 2019.

Definitions

2. In these Regulations, unless the context otherwise requires —

“human tissue transplantation” means the transplantation or grafting of any tissue —

- (a) from one part to the same part of a body of an individual;
- (b) from one part to another part of the same body of an individual; or
- (c) from the body of one individual to the body of another individual or the bodies of other individuals;

“non-identifiable”, in relation to tissue, means tissue which has been rendered non-identifiable within the meaning of section 27(3) of the Act;

“principal person in charge designated”, for a tissue bank, means the individual designated by the tissue bank under section 35(2)(b) of the Act;

“recipient” means a person (including a researcher or research institution) who receives any human tissue directly or indirectly from a tissue bank but excludes the individual to whose body the tissue is transplanted or grafted;

“relevant website” means the website at <https://elis.moh.gov.sg/tiaras>;

“untoward occurrence” means an occurrence associated with the removal of human tissue primarily for research that —

- (a) results in, or contributes to, death;
- (b) is life-threatening;
- (c) requires in-patient hospitalisation or results in prolongation of existing hospitalisation;
- (d) results in or contributes to persistent or significant disability or incapacity;
- (e) results in the transmission of a communicable disease;

- (f) results in any misidentification or mix-up of any type of tissue, gametes or embryo; or
- (g) results in or contributes to a congenital anomaly or birth defect.

PART 2

TISSUE BANKS GENERALLY

Application of this Part

3. This Part applies to all tissue banks.

Notification by tissue bank

4.—(1) For the purposes of section 34(2) of the Act, the notification required to be submitted by a tissue bank must be in the applicable form set out at the relevant website and must contain all of the following information:

- (a) the name of the tissue bank and the address, telephone number and email address at which that tissue bank may be contacted;
- (b) such other information as may be required or specified in the form set out at that website.

(2) A tissue bank that has not started any tissue banking activity before 1 November 2019 must submit the notification required by section 34(2) of the Act no later than 30 days before the start of its first tissue banking activity.

Notification of tissue banking activity started before 1 November 2019

5.—(1) A tissue bank that has started any tissue banking activity before 1 November 2019 must submit a notification required by section 34(2) of the Act to the Director in the applicable form set out at the relevant website no later than 1 December 2019.

(2) The tissue bank must ensure that the notification mentioned in paragraph (1) must contain all of the following information:

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- (a) the name of the tissue bank and the address, telephone number and email address at which that tissue bank may be contacted;
 - (b) such other information as may be required or specified in the form set out at the relevant website.
- (3) A tissue bank who or which contravenes paragraph (1) or (2) shall be guilty of an offence and shall be liable on conviction —
- (a) in the case of an individual, to a fine not exceeding \$10,000 or to imprisonment for a term not exceeding 12 months or to both; or
 - (b) in any other case, to a fine not exceeding \$10,000.

Principal person in charge designated by tissue bank

6.—(1) Subject to paragraph (2), the principal person in charge designated by the tissue bank under section 35(2)(b) of the Act must be an individual who —

- (a) is ordinarily resident in Singapore;
 - (b) is in the direct employment of, or acting for or by arrangement with, the tissue bank;
 - (c) is principally responsible for the management and conduct of any type of business or tissue banking activities in Singapore of the tissue bank;
 - (d) has the authority to ensure that the tissue bank complies with the Act and these Regulations; and
 - (e) is suitably qualified to perform the duties of a principal person in charge.
- (2) In addition to paragraph (1), in the case of a tissue bank to whom Part 3 applies, the principal person in charge designated must be a medical practitioner.
- (3) The principal person in charge designated must at all reasonable times be contactable by the Director for the purposes of the duties and functions of the tissue bank under the Act and these Regulations.

(4) The tissue bank must notify the Director in the applicable form set out at the relevant website of all the following information:

- (a) the name and designation of the principal person in charge designated;
- (b) the address, telephone number and email address at which that person may be contacted;
- (c) such other information relating to that person as may be required or specified in that form.

(5) A tissue bank who or which contravenes paragraph (4) shall be guilty of an offence and shall be liable on conviction —

- (a) in the case of an individual, to a fine not exceeding \$10,000 or to imprisonment for a term not exceeding 12 months or to both; or
- (b) in any other case, to a fine not exceeding \$10,000.

Change of information and particulars

7.—(1) Every tissue bank must notify the Director in the applicable form set out at the relevant website of any change to the information and particulars notified under regulation 4, 5 or 6 no later than 30 days after the date the tissue bank or the principal person in charge designated first becomes aware of the change, whichever is the earlier.

(2) A tissue bank who or which contravenes paragraph (1) shall be guilty of an offence and shall be liable on conviction —

- (a) in the case of an individual, to a fine not exceeding \$10,000 or to imprisonment for a term not exceeding 12 months or to both; or
- (b) in any other case, to a fine not exceeding \$10,000.

Declaration of compliance

8.—(1) For the purposes of section 36(1) of the Act, the declaration of compliance that a tissue bank is required to submit to the Director under that section for all tissue banking activities conducted under the supervision and control of the tissue bank must be made in the form

set out in the First Schedule by the principal person in charge designated.

(2) The Director may modify or amend the form mentioned in paragraph (1) for the purpose of facilitating the submission of that form.

(3) The declaration of compliance must be made in writing and submitted to the Director at any time between 1 March and 18 April (both dates inclusive) of every year.

Notification under section 35(3)(a) of Act

9.—(1) For the purposes of section 35(3)(a) of the Act, a tissue bank must ensure that all relevant information (except for the information specified in paragraph (3)) required under that provision in relation to tissue banking activity conducted under the supervision and control of that tissue bank is —

- (a) recorded; and
- (b) submitted to the Director as soon as possible and in any event not later than 7 days after the tissue bank or the principal person in charge designated first becomes aware of the information, whichever is the earlier.

(2) The relevant information mentioned in paragraph (1) must be submitted to the Director in the applicable form set out at the relevant website.

(3) For the purposes of section 35(3)(a) of the Act, a tissue bank must ensure that relevant information relating to contraventions in relation to tissue banking activity conducted under the supervision and control of that tissue bank and that did not cause harm to and had no potential to cause harm to any tissue donor, is recorded and submitted to the Director —

- (a) at the same time the declaration of compliance is submitted in accordance with regulation 8(3); and
- (b) on an annual basis aggregating such information in the applicable form set out at the relevant website.

Notification of serious adverse event

10.—(1) A person conducting any tissue banking activity carried on or conducted under the supervision and control of a tissue bank must immediately report to that tissue bank any serious adverse event which is associated with that tissue banking activity.

(2) As soon as possible after making the report mentioned in paragraph (1), the person mentioned in that paragraph must submit to the tissue bank a detailed written report with all relevant information.

Notification by tissue bank of serious adverse event

11.—(1) For the purposes of section 35(3)(b) of the Act, a tissue bank must notify the Director of any serious adverse event which is associated with any tissue banking activity carried on or conducted under its supervision and control.

(2) Where the serious adverse event results in death or is life-threatening, the tissue bank must ensure that —

- (a) all relevant information about the serious adverse event is recorded;
- (b) the recorded information on the serious adverse event is submitted to the Director as soon as possible and in any event not later than 7 days after the tissue bank or the principal person in charge designated first becomes aware of the event, whichever is the earlier; and
- (c) any additional relevant information about the serious adverse event is recorded and submitted to the Director within 8 days after the record is made.

(3) Where the serious adverse event does not result in death and is not life-threatening, the tissue bank must ensure that all relevant information about that event is —

- (a) recorded; and
- (b) submitted to the Director as soon as possible and in any event not later than 15 days after the tissue bank or the principal person in charge designated first becomes aware of that event, whichever is the earlier.

(4) The notification of the serious adverse event must be submitted to the Director in the applicable form set out at the relevant website.

Notification of untoward occurrence arising from removal of tissue under section 35(3)(c) of Act

12.—(1) A person conducting any tissue banking activity carried on or conducted under the supervision and control of a tissue bank must immediately report to that tissue bank any untoward occurrence which is associated with that tissue banking activity.

(2) As soon as possible after making the report mentioned in paragraph (1), the person mentioned in that paragraph must submit to the tissue bank a detailed written report with all relevant information.

Notification by tissue bank of untoward occurrence arising from removal of tissue under section 35(3)(c) of Act

13.—(1) For the purposes of section 35(3)(c) of the Act, a tissue bank must notify the Director of any untoward occurrence which is associated with any tissue banking activity carried on or conducted under its supervision and control.

(2) Where the untoward occurrence results in death or is life-threatening, the tissue bank must ensure that —

- (a) all relevant information about the untoward occurrence is recorded;
- (b) the recorded information on the untoward occurrence is submitted to the Director as soon as possible and in any event not later than 7 days after the tissue bank or the principal person in charge designated first becomes aware of the occurrence, whichever is the earlier; and
- (c) any additional relevant information about the untoward occurrence is recorded and submitted to the Director within 8 days after the record is made.

(3) Where the untoward occurrence does not result in death and is not life-threatening, the tissue bank must ensure that all relevant information about that event is —

- (a) recorded; and

(b) submitted to the Director as soon as possible and in any event not later than 15 days after the tissue bank or the principal person in charge designated first becomes aware of that event, whichever is the earlier.

(4) A notification of an untoward occurrence must be submitted to the Director in the applicable form set out at the relevant website.

Notification of cessation of tissue bank's operations

14.—(1) A tissue bank must notify the Director of its intention to cease operating as a tissue bank as soon as possible and in any event not less than 30 days before the cessation of operation or such shorter period as the Director may allow in any particular case.

(2) The tissue bank must ensure that the notification required under paragraph (1) must be accompanied by —

- (a) a plan for the manner of disposal of the human tissues held by or in the possession of the tissue bank and information related to such tissues;
- (b) where the plan mentioned in sub-paragraph (a) involves the transfer of any human tissue or information related to such tissue to another tissue bank (called in this regulation the receiving bank) —
 - (i) the name, address and contact particulars of the receiving bank; and
 - (ii) documentary evidence provided by the receiving bank, such as but not limited to a letter of undertaking, to the effect that the receiving bank will ensure that the intended use of the tissue is in accordance with any conditions or restrictions specified as part of the appropriate consent of the donor;
- (c) the date of the cessation of operation of the tissue bank and the reason for the cessation; and
- (d) such other information as the Director may in any particular case require.

(3) The notification and the information mentioned in paragraphs (1) and (2) must be submitted to the Director in the applicable form set out at the relevant website.

(4) A tissue bank who or which contravenes paragraph (1) or (2) shall be guilty of an offence and shall be liable on conviction —

(a) in the case of an individual, to a fine not exceeding \$10,000 or to imprisonment for a term not exceeding 12 months or to both; or

(b) in any other case, to a fine not exceeding \$10,000.

Requirements before tissue is removed, supplied or exported

15.—(1) Before any tissue which is individually-identifiable may be removed from the supervision and control of, or supplied by, a tissue bank to any person for use in research carried out by that person in circumstances other than in paragraph (4), the tissue bank must ensure that —

(a) an institutional review board has approved or exempted from review the proposed research that the tissue would be used for; and

(b) there is documentary evidence provided by the recipient (such as but not limited to a letter of undertaking) to the effect that the recipient will ensure that the intended use of the tissue is in accordance with any conditions or restrictions specified as part of the appropriate consent of the donor.

(2) Before any non-identifiable tissue may be removed from the supervision and control of or supplied by a tissue bank to any person for use in research carried out by that person, the tissue bank must ensure that —

(a) either an institutional review board has approved or exempted from review the proposed research that the tissue would be used for or the tissue bank is satisfied that there is scientific merit for the proposed research; and

(b) there is documentary evidence provided by the recipient (such as but not limited to a letter of undertaking) to the

effect that the recipient will ensure that the intended use of the tissue is in accordance with any conditions or restrictions specified as part of the appropriate consent of the donor.

(3) Paragraph (2) does not apply where the non-identifiable tissue under a tissue bank's supervision and control is to be exported or otherwise removed from Singapore to a place outside Singapore for use in research.

(4) Before any individually-identifiable tissue under a tissue bank's supervision and control is to be exported or otherwise removed from Singapore to a place outside Singapore, the tissue bank must ensure that —

- (a) appropriate consent has been obtained from the donor for the export or removal, as the case may be; and
- (b) there is documentary evidence provided by the recipient (such as but not limited to a letter of undertaking) to the effect that the recipient will ensure that the intended use of the tissue is in accordance with any conditions or restrictions specified as part of the appropriate consent of the donor.

Protection of confidentiality of donor's information

16.—(1) Every tissue bank must establish a system comprising such reasonable measures as may be necessary to protect the confidentiality of information relating to the donor of each tissue under the supervision and control of the tissue bank and to maintain the donor's privacy.

(2) A tissue bank who or which contravenes paragraph (1) shall be guilty of an offence and shall be liable on conviction —

- (a) in the case of an individual, to a fine not exceeding \$10,000 or to imprisonment for a term not exceeding 12 months or to both; or
- (b) in any other case, to a fine not exceeding \$10,000.

Tracking of consent and integrity of records

17. Every tissue bank must establish a system to ensure —
- (a) that every donor's consent in relation to each tissue under the supervision and control of the tissue bank is accurately tracked; and
 - (b) the integrity of records of the consent and other information relating to the donor.

Safety and welfare of donors

18.—(1) Every tissue bank, who or which is involved in the removal of tissue from tissue donors for use in research, must establish a system to ensure the safety and welfare of the tissue donors.

(2) The tissue bank must ensure that the system mentioned in paragraph (1) must at the minimum take into consideration the following in relation to the tissue donors:

- (a) the qualifications of and training to be received by the personnel involved in the removal of tissue;
- (b) the measures to prevent or control the spread of any communicable disease which is or may be due to the contamination or infection of any tissue;
- (c) the management of quality control and maintenance of instruments and equipment used for the removal of tissue.

(3) A tissue bank who or which contravenes paragraph (1) or (2) shall be guilty of an offence and shall be liable on conviction —

- (a) in the case of an individual, to a fine not exceeding \$20,000 or to imprisonment for a term not exceeding 2 years or to both; or
- (b) in any other case, to a fine not exceeding \$20,000.

Policy on incidental findings

19. Every tissue bank must —

- (a) formulate a policy on whether or not the tissue donor should be re-identified and informed in the case of an incidental finding in relation to a tissue; and
- (b) inform all donors and recipients of every tissue received by the tissue bank on or after 1 November 2019 —
 - (i) of the details of the policy mentioned in paragraph (a); and
 - (ii) if the policy provides for the donor to be re-identified and informed in the case of an incidental finding, whether the donor has expressed a wish to be re-identified and informed.

PART 3**TISSUE FOR HUMAN TISSUE
TRANSPLANTATION RESEARCH****Application of this Part**

20. This Part applies only to a tissue bank that stores or supplies human tissue for the purpose of use in research involving human tissue transplantation (called in this Part a transplantational tissue bank).

Documentation

21.—(1) Every transplantational tissue bank must maintain a record containing a detailed description of the condition of each tissue under the supervision and control of the tissue bank, including any observed tissue abnormalities or imperfections.

(2) A transplantational tissue bank who or which contravenes paragraph (1) shall be guilty of an offence and shall be liable on conviction —

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- (a) in the case of an individual, to a fine not exceeding \$20,000 or to imprisonment for a term not exceeding 2 years or to both; or
 - (b) in any other case, to a fine not exceeding \$20,000.

Tracking of information relevant to safety and quality of tissue

22.—(1) Every transplantational tissue bank must establish a system to ensure that the information, relevant to the safety and quality of each tissue under the supervision and control of the tissue bank, is accurately tracked.

(2) A transplantational tissue bank who or which contravenes paragraph (1) shall be guilty of an offence and shall be liable on conviction —

- (a) in the case of an individual, to a fine not exceeding \$20,000 or to imprisonment for a term not exceeding 2 years or to both; or
- (b) in any other case, to a fine not exceeding \$20,000.

Additional requirements before tissue is released, supplied or exported

23.—(1) In addition to the requirements in regulation 15, the authorisation in writing of the principal person in charge designated by a transplantational tissue bank must be obtained before any tissue may be removed from the supervision and control of, or supplied by, that tissue bank or exported or otherwise removed from Singapore to a place outside Singapore.

(2) Every transplantational tissue bank must ensure that the following information must be provided to the recipient of the human tissue supplied by that tissue bank for the purpose of research involving human tissue transplantation:

- (a) the source of the tissue;
- (b) the donor screening process and necessary tests performed to ensure product safety and compatibility;

(c) any regulatory obligation imposed on the tissue bank as a result of the removal, supply or export of the tissue.

(3) A transplantational tissue bank who or which contravenes paragraph (1) or (2) shall be guilty of an offence and shall be liable on conviction —

(a) in the case of an individual, to a fine not exceeding \$20,000 or to imprisonment for a term not exceeding 2 years or to both; or

(b) in any other case, to a fine not exceeding \$20,000.

Notification by recipient of human tissue

24.—(1) Every transplantational tissue bank must ensure that the recipient of human tissue stored or supplied by that tissue bank is informed in writing of the responsibility to notify the tissue bank immediately of any suspected transmission of a communicable disease through transplanted tissue or a serious adverse event.

(2) On receipt of any notification mentioned in paragraph (1), the transplantational tissue bank must in turn make a notification under regulation 11 or 13, as may be appropriate.

(3) A transplantational tissue bank who or which contravenes paragraph (1) or (2) shall be guilty of an offence and shall be liable on conviction —

(a) in the case of an individual, to a fine not exceeding \$20,000 or to imprisonment for a term not exceeding 2 years or to both; or

(b) in any other case, to a fine not exceeding \$20,000.

Management of tissue contamination

25.—(1) Every transplantational tissue bank must establish a system to prevent or control the spread of any communicable disease which is or may be due to the contamination or infection of any tissue under the supervision and control of the tissue bank.

(2) The transplantational tissue bank must ensure that the system mentioned in paragraph (1) must at the minimum take into

consideration the following in relation to the tissue under the supervision and control of the tissue bank that is or may be contaminated or infected in any other way:

- (a) the traceability of the tissue;
- (b) the traceability of the equipment and material used in the processing of the tissue;
- (c) the processing and preservation of the tissue;
- (d) the recall procedure for the tissue.

(3) A transplantational tissue bank who or which contravenes paragraph (1) or (2) shall be guilty of an offence and shall be liable on conviction —

- (a) in the case of an individual, to a fine not exceeding \$20,000 or to imprisonment for a term not exceeding 2 years or to both; or
- (b) in any other case, to a fine not exceeding \$20,000.

Quality and safety management systems

26.—(1) Every transplantational tissue bank must establish a system to ensure the quality and safety of any tissue under the supervision and control of the tissue bank, which is intended for use in research involving human tissue transplantation.

(2) The transplantational tissue bank must ensure that the system mentioned in paragraph (1) must at the minimum take into consideration the following in relation to the tissue intended for use in research involving human tissue transplantation:

- (a) the qualifications of and training to be received by the personnel involved in the handling of tissue;
- (b) the method of processing and preservation to retain the biological function of tissue compatible with the intended use;
- (c) the appropriate labelling and conditions of storage of tissue;
- (d) the management of quality control and inventory;

(e) the suitability and testing of donors of tissue.

(3) Every transplantational tissue bank must establish an appropriate and effective system to ensure the recall of any tissue which had been unintentionally or otherwise erroneously supplied for use in research involving human tissue transplantation.

(4) A transplantational tissue bank who or which contravenes paragraph (3) shall be guilty of an offence and shall be liable on conviction —

(a) in the case of an individual, to a fine not exceeding \$20,000 or to imprisonment for a term not exceeding 2 years or to both; or

(b) in any other case, to a fine not exceeding \$20,000.

PART 4

MISCELLANEOUS

Electronic system

27.—(1) Every notification, form, document, declaration or other information that is required to be submitted to the Director under these Regulations must —

(a) be made using the electronic system of the Ministry of Health at the relevant website or by such other means as the Director may determine;

(b) be submitted to the Director in the form provided by that system; and

(c) be accompanied by the documents specified at the relevant website.

(2) The Director may modify or amend a form mentioned in paragraph (1) in order to facilitate the submission of that form.

False information

28. A person who, in submitting to the Director a notification, report, form, document, declaration or other information that is required to be submitted under these Regulations —

- (a) makes any statement or furnishes any information which that person knows to be false or does not believe to be true; or
- (b) by the intentional suppression of any material fact, furnishes information which is misleading,

shall be guilty of an offence and shall be liable on conviction to a fine not exceeding \$20,000 or to imprisonment for a term not exceeding 2 years or to both.

Fees

29.—(1) The fees specified in the Second Schedule are payable by the tissue bank concerned in respect of the matters set out in that Schedule.

(2) A fee specified in the Second Schedule must be paid when the notification or declaration (as the case may be) is submitted to the Director.

(3) The Director may, in any particular case, waive or refund the whole or any part of any fee payable or paid under paragraph (1).

FIRST SCHEDULE

Regulation 8(1)

DECLARATION OF COMPLIANCE

I declare, on behalf of _____ (name of tissue bank), all of the following:

1. I have read and understood the Human Biomedical Research Act 2015 (Act 29 of 2015), and all regulations and codes of practice or ethics issued under that Act (collectively called the Act).
2. Except for such offences and contraventions as may have been notified to the Director of Medical Services in accordance with section 35(3) of the Human Biomedical Research Act 2015 or regulation 9 of the Human Biomedical Research (Tissue Banking) Regulations 2019 (G.N. No. S 702/2019), all tissue banking activities conducted under the supervision and control of the tissue bank between _____ and _____ (insert dates) comply with the Act.

FIRST SCHEDULE — *continued*

3. The tissue bank —

- (a) has formulated and implemented appropriate standards, policies and procedures to supervise, review and monitor the conduct of the tissue banking activity conducted under its supervision and control;
- (b) supervises, reviews and proactively monitors the conduct of the tissue banking activity conducted under its supervision and control;
- (c) ensures that the tissue banking activity conducted under its supervision and control, including those that are conducted by a third party under a contractual agreement, complies with the Act, and is conducted in accordance with the standards, policies and procedures mentioned in sub-paragraph (a);
- (d) has formulated and implemented a policy on whether or not the donor should be re-identified and informed in the case of an incidental finding and has informed all donors and recipients of the details of the policy and if the policy provides for the donor to be re-identified and informed, whether the donor has expressed a wish to be re-identified and informed;
- (e) investigates any areas of concern and takes such remedial measures as appropriate;
- (f) performs such other functions and duties as may be prescribed in legislation; and
- (g) regularly reviews —
 - (i) the standards, policies and procedures formulated and implemented by the tissue bank to supervise, review and monitor the conduct of the tissue banking activity conducted under its supervision and control;
 - (ii) all serious adverse events and untoward occurrences; and
 - (iii) all safety lapses.

*Signature, name and
designation of principal
person in charge*

Date

 SECOND SCHEDULE

Regulation 29

FEES

- | | |
|--|---------|
| 1. Accepted notification made under regulation 4 or 5 | \$1,000 |
| 2. Accepted declaration of compliance made under regulation 8 where the tissue bank stores or supplies tissue for the purpose of use in research involving human tissue transplantation: | |
| (a) for the first tissue bank site; and | \$4,000 |
| (b) for each additional tissue bank site | \$500 |
| 3. Accepted declaration of compliance made under regulation 8 where tissue bank is not a tissue bank mentioned in item 2: | |
| (a) for the first tissue bank site; and | \$1,000 |
| (b) for each additional tissue bank site | \$500 |

Note:

Where tissue is stored at 2 or more premises located within the same building (bearing the same postal code in each premises' address) and under the supervision and control of a single tissue bank, these premises are counted as a single tissue bank site.

Made on 21 October 2019.

CHAN HENG KEE
*Permanent Secretary,
 Ministry of Health,
 Singapore.*

[MH 78:69; AG/LEGIS/SL/131C/2015/3 Vol. 2]