No. S

HUMAN BIOMEDICAL RESEARCH ACT 2015
(ACT 29 OF 2015)

HUMAN BIOMEDICAL RESEARCH (TISSUE BANKING) REGULATIONS 2018

ARRANGEMENT OF REGULATIONS

PART 1

PRELIMINARY

Regulation

PART 2

ALL TISSUE BANKS

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 2018 and come into operation on [date to be inserted].

Definitions

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

"human tissue transplantation" means the transplantation or grafting of any tissue from one part to another part of the same body of an individual or from the body of one individual to another individual or 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;

"relevant website" means the Internet website at https://elis.moh.gov.sg/tiaras.

PART 2

ALL TISSUE BANKS

Application of Part 2

3. This Part applies to all tissue banks.

Notification by tissue bank

4.—(1) For the purposes of section 34(3) 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 on that website.

(2) A tissue bank that has not started any tissue banking activity before [date to be inserted], 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 [date to be inserted]

5.—(1) A tissue bank that has started any tissue banking activity before [date to be inserted], 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 [30 days after operational date].

(2) The notification mentioned in paragraph (1) 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 the relevant website.

(3) A tissue bank who 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

6.—(1) Subject to paragraph (2), the principal person in charge designated by a 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 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 by the tissue bank must be a medical practitioner.

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

(5) A tissue bank who 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 by the tissue bank first becomes aware of the change, whichever is the earlier.

(2) A tissue bank who 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 by the

principal person in charge designated by the tissue bank in the form specified in the First Schedule.

(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 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 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 by the tissue bank 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.

Notification of serious adverse event

10.—(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 occurred when the tissue banking activity was 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 by the tissue bank 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 by the tissue bank 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 under section 35(3)(*c*) of Act

11.—(1) For the purposes of section 35(3)(*c*) of the Act, a tissue bank must notify the Director of any untoward occurrence which occurred when the tissue banking activity was 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 by the tissue bank 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 by the tissue bank 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 on the relevant website.

(5) In this regulation, an "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; or

(*f*) results in any misidentification or mix-up of any type of tissue, gametes, or embryo.

Notification by recipient of human tissue

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

(2) On receipt of any notification mentioned in paragraph (1), the tissue bank must in turn make a notification under regulation 10 or 11, as may be appropriate.

Notification of cessation of tissue bank's operations

13.—(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 and the notification must be accompanied by —

(*a*) a plan for the manner of disposal of the human tissues held or in the possession of the tissue bank and health information related to such tissues;

(*b*) where the plan mentioned in paragraph (*a*) involves the transfer of the human tissues or health information related to the tissues 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; and

(*c*) such other information as may be specified on the relevant website.

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

Requirements before tissue is removed, supplied or exported

14.—(1) Before any tissue which is individually-identifiable may be removed from the supervision and control of or supplied by a tissue bank for use in research in circumstances other than in paragraph (3), the tissue bank must ensure that —

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

(*b*) there is documentary evidence provided by the receiving party, such as but not limited to a letter of undertaking, to the effect that the receiving party 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 for use in research in circumstances other than in paragraph (3), the tissue bank must ensure that —

(*a*) either an institutional review board has approved 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 receiving party, such as but not limited to a letter of undertaking, to the effect that the receiving party 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) Before any tissue (whether or not it is individually-identifiable) 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 receiving party, such as but not limited to a letter of undertaking, to the effect that the receiving party 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.

Documentation

15. A 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.

Tracking of consent and integrity of records

16. A tissue bank must establish a system to ensure that the donor's consent and health information relevant to the safety and quality of each tissue under the supervision and control of the tissue bank are accurately tracked and to ensure the integrity of records of the consent and other information relating to the donor.

Protection of confidentiality of donor's information

17. A 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.

Safety and welfare of donors

18.—(1) A tissue bank, who 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 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 tissues;

(*c*) the management of quality control and maintenance of instruments and equipment used for the removal of tissues.

PART 3

TISSUES FOR HUMAN TISSUE TRANSPLANTATION RESEARCH

Application of Part 3

19. This Part applies only to a tissue bank that stores or supplies tissues for the purpose of use in research involving human tissue transplantation.

Additional requirements before tissue is released, supplied or exported

20.—(1) In addition to the requirements in regulation 14, the authorisation in writing of the principal person in charge of a 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) A tissue bank must ensure that the following information must be provided to the researcher to whom the tissue is supplied 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; and

(*c*) any regulatory obligation of the tissue bank and the regulatory agencies involved as a result of the removal, supply or export of the tissue.

Management of tissue contamination

21.—(1) A 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 tissues under the supervision and control of the tissue bank.

(2) 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.

Quality and safety management systems

22.—(1) A tissue bank must establish a system to ensure the quality and safety of the tissues,under the supervision and control of the tissue bank, which are intended for use in research involving human tissue transplantation.

(2) 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 the tissue compatible with the intended use;

(*c*) the appropriate labelling and conditions of storage of the tissues;

(*d*) the management of quality control and inventory;

(*e*) the suitability and testing of donors of the tissues.

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

PART 4

MISCELLANEOUS

Electronic system

23.—(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

24. Any 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

25.—(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, all tissue banking activities conducted under the supervision and control of the tissue bank between _____ and _____ (insert dates) comply with the Act.

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 contractual agreement, complies with the Act, and is conducted in accordance with the standards, policies and procedures mentioned in sub-paragraph (*a*);

(*d*) investigates any areas of concern and takes such remedial measures as appropriate;

(*e*) ensures that if any human tissue under its supervision and control is to be exported or otherwise removed from Singapore to a place outside Singapore, the appropriate consent has been obtained from the donor

and documentary evidence such as but not limited to a letter of undertaking is provided by the receiving party.

(*f*) ensures that if any individually-identifiable human tissue is to be removed or supplied for use in research, documentary evidence such as but not limited to a letter of undertaking is provided by the receiving party and the research that the tissue would be used for is approved by an institutional review board (IRB);

(*g*) ensures that if any human tissue rendered non-identifiable is to be removed or supplied for use in research, documentary evidence such as but not limited to a letter of undertaking is provided by the receiving party and the research that tissue would be used for is approved by an IRB or scientifically endorsed by experts on the merits of the research;

(*h*) ensures that if any human tissue is to be removed or supplied for transplantation research, appropriate safeguards in the conduct of the tissue banking activity are in place in accordance with the Act to ensure the safety of the recipient;

(*i*) performs such other functions and duties as may be prescribed in legislation; and

(*j*) 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

(iii) all safety lapses.

Signature, name and

designation of principal

person in charge

Date

SECOND SCHEDULE

Regulation 25

FEES

[TO BE INSERTED LATER]

Made on 2018.

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

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