

# **Human Biomedical Research (Tissue Banking) Regulations 2019**

## **Table of Contents**

## **Enacting Formula**

## **Part 1 PRELIMINARY**

### **1 Citation and commencement**

### **2 Definitions**

## **Part 2 TISSUE BANKS GENERALLY**

### **3 Application of this Part**

### **4 Notification by tissue bank**

### **5 Notification of tissue banking activity started before 1 November 2019**

### **6 Principal person in charge designated by tissue bank**

### **7 Change of information and particulars**

### **8 Declaration of compliance**

### **9 Notification under section 35(3)(a) of Act**

### **10 Notification of serious adverse event**

### **11 Notification by tissue bank of serious adverse event**

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

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

**14 Notification of cessation of tissue bank's operations**

**15 Requirements before tissue is removed, supplied or exported**

**16 Protection of confidentiality of donor's information**

**17 Tracking of consent and integrity of records**

**18 Safety and welfare of donors**

**19 Policy on incidental findings**

### **Part 3 TISSUE FOR HUMAN TISSUE TRANSPLANTATION RESEARCH**

**20 Application of this Part**

**21 Documentation**

**22 Tracking of information relevant to safety and quality of tissue**

**23 Additional requirements before tissue is released, supplied or exported**

**24 Notification by recipient of human tissue**

**25 Management of tissue contamination**

**26 Quality and safety management systems**

### **Part 4 MISCELLANEOUS**

**27 Electronic system**

**28 False information**

**29 Fees**

## **FIRST SCHEDULE Declaration of compliance**

## **SECOND SCHEDULE Fees**

**No. S 702**

### **HUMAN BIOMEDICAL RESEARCH ACT 2015 (ACT 29 OF 2015)**

### **HUMAN BIOMEDICAL RESEARCH (TISSUE BANKING) REGULATIONS 2019**

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:

- (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,