

Human Biomedical Research Bill

Bill No. /2014.

Read the first time on 2014.

HUMAN BIOMEDICAL RESEARCH ACT 2014

(No. of 2014)

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A BILL

i n t i t u l e d

An Act to regulate the conduct of human biomedical research, to further regulate certain restricted human biomedical research, to prohibit certain types of human biomedical research, to regulate tissue banks and tissue banking activities and to provide for matters connected therewith.

Be it enacted by the President with the advice and consent of the Parliament of Singapore, as follows:

PART 1

PRELIMINARY

Short title and commencement

- 5 **1.** This Act may be cited as the Human Biomedical Research Act 2014 and shall come into operation on such date as the Minister may, by notification in the *Gazette*, appoint.

Interpretation

2. In this Act, unless the context otherwise requires —
- “adult” means a person who is of 21 years of age or older;
- 10 “appointed day” means the date of commencement of this Act;
- “appropriate consent” means the consent given by a person or, where applicable, by another person on his behalf, in accordance with Part 3;
- “authorised officer” means —
- 15 (a) any public officer or any officer of any statutory body appointed by the Director under section 4(2) to perform the duties and exercise the powers of the Director under this Act; or
- 20 (b) any person authorised by the Director under section 4(6) to assist in the administration of this Act;
- “declaration of compliance” means a declaration by a research institution or a tissue bank of its compliance with the requirements of this Act;
- 25 “Director” means the Director of Medical Services and includes a Deputy Director of Medical Services;
- “donor” means a natural person, whether living or dead, from whose body the human tissue is obtained;
- “health information” means information pertaining to an individual —

(a) obtained in the course of or in connection with providing healthcare services; or

(b) relating to the study, prevention, prognostication, diagnosis, or alleviation of a disease, disorder, or injury;

“human biological material” or “biological material” means any biological material obtained from the human body that consists of, or includes, human cells;

“human biomedical research” has the meaning assigned to it in section 3;

“human tissue” means any human biological material but excludes —

(a) hair shaft, cut without dermal hair root or follicle;

(b) nail plate, cut without underlying dermal tissue;

(c) naturally excreted bodily fluids and waste products such as saliva, sweat, urine and faeces;

(d) human biological material that has been processed in such a manner that their functional, structural and biological characteristics are altered, from the time of such;

“individually-identifiable”, in relation to information or human biological material pertaining to an individual, means that the identity of that individual can be readily discovered or ascertained from that information or the human biological material;

“institutional review board” means a board or committee appointed by a research institution under section 14 or 15 to conduct ethics review of proposed human biomedical research;

“minor” means a person who is below 21 years of age;

“prohibited human biomedical research” means any human biomedical research specified in the First Schedule;

“research institution” means a body of persons, whether corporate or unincorporate or other organisation, or ministry or department of the Government who or which —

- 5 (a) engages (either through contractual or other arrangements) one or more researchers to conduct human biomedical research in Singapore; and
- (b) exercises supervision and control over human biomedical research conducted in Singapore by the researchers the institution has engaged;

10 “research subject” means a natural person —

- (a) whom a researcher involves in human biomedical research; or
- (b) from whom human biological material or health information is obtained for use in the human biomedical research;

“researcher” means any natural person who conducts human biomedical research under the supervision or control of a research institution;

20 “restricted human biomedical research” means any human biomedical research specified in the Second Schedule;

“reviewing authority”, in relation to human biomedical research, means the institutional review board responsible for the initial or continuing review of the research;

“serious adverse event” —

- 25 (a) in relation to human biomedical research, means any untoward medical occurrence as a result of any human biomedical research which —
 - (i) results in or contributes to death;
 - (ii) is life-threatening;
 - 30 (iii) requires inpatient hospitalisation or prolongation of existing hospitalisation;

- (iv) results in or contributes to persistent or significant disability or incapacity;
- (v) results in or contributes to a congenital anomaly or birth defect;
- 5 (vi) results in surgery performed on the wrong body part;
- (vii) results in surgery performed on the wrong patient;
- 10 (viii) results in wrong surgical procedure performed on a patient; or
- (ix) such other event as may be prescribed;
- (b) in relation to tissue banking, means any untoward occurrence associated with the procurement, testing, processing, storage or distribution of human tissues (including gametes or embryos) intended for human application which —
- 15 (i) results in or contributes to death;
- (ii) is life-threatening;
- 20 (iii) requires inpatient hospitalisation or prolongation of existing hospitalisation;
- (iv) results in or contributes to persistent or significant disability or incapacity;
- (v) results in transmission of a communicable disease;
- 25 (vi) results in any misidentification or mix-up of any type of tissue, gametes or embryo; or
- (vii) such other event as may be prescribed;
- “tissue bank” means an individual person or a body of persons, whether corporate or unincorporate or other organisation,
- 30 that carries on or conducts any tissue banking activity;
- “tissue banking activity” means a structured and organised collection, by one or more individuals or a body of persons,

whether corporate or unincorporate or other organisation, of tissues as a resource for the purposes of facilitating biomedical research or for public health or epidemiological purposes or any combination of such purposes.

5 **Meaning of “human biomedical research”**

3.—(1) In this Act, “human biomedical research” means the research specified in subsection (2) or (3).

(2) Any research that is intended to study —

- 10 (a) the prevention, prognostication, diagnosis or alleviation of any disease, disorder or injury affecting the human body;
- (b) the restoration, maintenance or promotion of the aesthetic appearance of human individuals through clinical procedures or techniques; or
- (c) the performance or endurance of human individuals,

15 where the research involves —

- (i) subjecting an individual to any intervention (including any wilful act or omission) that has a physical, mental or physiological effect (whether temporary or permanent) on the body of the individual;
- 20 (ii) the use of any individually-identifiable human biological material; or
- (iii) the use of any individually-identifiable health information.

(3) Any research that involves —

- (a) human embryos or human gametes;
- 25 (b) human-animal combination embryos created by the incorporation of human genetic materials or human cells; or
- (c) the introduction of human genetic materials or human cells into animals, including prenatal animals.

30 (4) For the purposes of this Act, human biomedical research shall be treated as conducted under the supervision and control of a research institution if the research institution is identified as the

research institution for that research and that research has been reviewed by an institutional review board appointed by that research institution.

PART 2

5 ADMINISTRATION OF ACT

Administration of Act

4.—(1) The Director shall be responsible for the administration and enforcement of this Act, subject to the general and special directions of the Minister.

10 (2) The Director may in writing appoint any public officer or any officer of any statutory body to be an authorised officer for the purposes of this Act.

(3) Every authorised officer, when exercising his powers and carrying out his duties under this Act, shall comply with such
15 general or special directions as may, from time to time, be given to him by the Director.

(4) Every authorised officer when exercising any of his powers under this Act shall, if not in uniform, declare his office and shall, on demand, produce to any person affected by the exercise of that
20 power such identification card as the Director may direct to be carried by the authorised officer when exercising such power.

(5) The Director may, in writing, delegate all or any of the powers conferred on him by this Act to any authorised officer subject to such conditions or restrictions as he thinks fit, except the power of
25 delegation conferred by this subsection.

(6) The Director may, in writing, authorise any other person to assist the Director or an authorised officer in the administration and enforcement of the Act.

(7) Every authorised officer and a person authorised under
30 subsection (5) shall be deemed to be a public servant for the purposes of the Penal Code (Cap. 224).

Advisory Committees

5 **5.**—(1) The Minister may establish one or more advisory committees consisting of such persons as he thinks fit to appoint for the purpose of advising him on any matter arising out of the administration of this Act.

(2) The Director may establish one or more advisory committees consisting of such persons as he thinks fit to appoint for the purpose of advising him on any matter arising out of the administration, functions and enforcement of this Act.

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PART 3

CONSENT

Taking of appropriate consent

6. Any appropriate consent shall for the purposes of this Act be obtained —

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(a) in writing;

(b) from the research subject personally in the presence of a prescribed witness or otherwise in accordance with section 7, 8, 9 or 10, as the case may be;

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(c) after the information referred to in section 11 has been provided; and

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(d) before the body of the research subject is subjected to any intervention or before any human tissue is obtained or removed from the body of a donor or before any individually-identifiable biological material obtained from his body or any of his individually-identifiable health information is used, as the case may be.

Consent in the case of adults

7.—(1) The appropriate consent shall be obtained from the following persons in the following circumstances:

- (a) in the case of a married or an unmarried adult, with the exception of a person referred to in paragraphs (b) and (c), the adult gives consent;
- 5 (b) in the case of an adult who lacks capacity within the meaning of section 4 of the Mental Capacity Act (Cap. 177A) to consent to the research, if the donee of the adult's lasting power of attorney or a deputy appointed by the court under that Act who is authorised to give consent to the research, gives consent and there are reasonable grounds for believing that research of comparable effectiveness cannot be carried out without the participation of such class of persons;
- 10 (c) in the case referred to in paragraph (b) but where there is no donee of the adult's lasting power of attorney or a deputy, appointed by the court under the Mental Capacity Act, who is authorised to give consent to the research, consent is given by any of the following persons in the order of priority stated, when persons in prior classes are not available, and in the absence of actual notice of contrary indications by the adult, or actual notice of opposition of a member of the same class or a prior class:
 - 15 (i) the spouse;
 - (ii) an adult son or daughter;
 - (iii) either parent or a guardian;
 - 20 (iv) an adult brother or sister;
 - 25 (v) any other person named by the adult as someone to be consulted on the matter in question or on matters of that kind.

(2) For the purposes of subsection (1) —

- 30 (a) an adult person shall be assumed to have capacity to give consent unless it is established that he lacks capacity;
- (b) “research” means human biomedical research.

Consent for research involving minors

8.—(1) The appropriate consent shall be obtained from the following persons in the following circumstances:

- 5 (a) in the case of a minor who has sufficient understanding and intelligence to enable the minor to understand fully what is proposed in the research or procedure, if the minor and at least one parent or guardian of the minor, both give consent;
 - 10 (b) in the case of a minor who has sufficient understanding and intelligence to enable the minor to understand fully what is proposed in the research, if the minor gives consent and an institutional review board has, in accordance with section 12, waived the requirement to obtain the consent of at least one parent or guardian of the minor;
 - 15 (c) in the case of a minor who does not have sufficient understanding and intelligence to enable the minor to understand fully what is proposed in the research, if at least one parent or guardian of the minor gives consent and there are reasonable grounds for believing that research of comparable effectiveness cannot be carried out without the participation of such class of minors.
 - 20
- (2) In this section, “research” means human biomedical research.

Consent for use or removal of tissues involving minors

9. The appropriate consent for the removal or use of human tissues shall be obtained from the following persons in the following circumstances:

- 25 (a) in the case of a minor who has sufficient understanding and intelligence to enable the minor to understand fully what is proposed in the procedure, if the minor and at least one parent or guardian of the person, both give consent;
- 30 (b) in the case of a minor who does not have sufficient understanding and intelligence to enable the minor to understand fully what is proposed in the procedure, if at least one parent or guardian of the person gives consent and

the removal of the tissue is primarily for a therapeutic or diagnostic purpose for the medical treatment of the donor.

Consent in case of dead persons

5 **10.** In the case of a deceased person and the research involves the use of individually-identifiable biological material or health information of the deceased person, the appropriate consent shall be obtained from any of the following persons in the order of priority stated, when persons in prior classes are not available at the time of death, and in the absence of actual notice of contrary indications by
10 the person, or actual notice of opposition of a member of the same class or a prior class:

- (a) the spouse;
- (b) an adult son or daughter;
- (c) either parent or a guardian of the deceased person at the
15 time of his death;
- (d) an adult brother or sister;
- (e) the administrator or executor of the estate of the deceased person;
- (f) any person authorised or under obligation to dispose of the
20 body of the deceased person.

Information to be provided before taking appropriate consent

11.—(1) In the case of human biomedical research, the appropriate consent shall be obtained after the research subject or, where applicable, the person authorised to give consent under this
25 Part, has been informed of all of the following:

- (a) the investigational nature of the research;
- (b) the purpose of the research;
- (c) the reasonably foreseeable risks, discomforts or
30 inconveniences to a living research subject arising from this research;

- (d) the benefits which research subjects may reasonably expect from the research;
 - (e) where applicable, whether there are any alternative procedures or treatments available to the research subject, and the potential benefits and risks of such alternatives;
 - (f) any compensation and treatment available to the subject in the event of injury arising from participation in the research;
 - (g) any anticipated expenses the subject is likely to incur as a consequence of participating in the research;
 - (h) the extent to which information identifying the subject will be kept confidential;
 - (i) whether individually-identifiable information obtained from the research subject will be used for future research;
 - (j) where applicable, whether biological material taken from the research subject will be destroyed, discarded or stored for future research;
 - (k) whether the participation of the subject involves data in individually-identifiable form;
 - (l) the circumstances, if any, under which, the research subject or the person authorised to give consent under this Part will be contacted for further consent;
 - (m) whether the research subject would wish to be re-identified in the case of an incidental finding;
 - (n) such other information as the institutional review board may require;
 - (o) such other information as may be prescribed.
- (2) In the case of the removal, donation or use of human tissues, the appropriate consent shall be obtained after the tissue donor or, where applicable, the person authorised to give consent under this Part, has been informed of all of the following:
- (a) the specific purpose for which the tissue is intended to be used, if this information is available but if not available, the

purpose for which the tissue is intended to be used may be stated as for general research;

- 5 (b) the reasonably foreseeable risks, discomforts or inconveniences to a living donor arising from the removal of the tissue;
- (c) the donation of the tissue is voluntary and the renunciation of the donor's rights to the tissue and any intellectual property rights that may be derived from the use of the tissue;
- 10 (d) the donor's right to withdraw his consent in the circumstances specified in section 13 and the limitations of such withdrawal as specified in that section;
- 15 (e) any compensation and treatment available to the donor in the event of injury arising from participation in the process of tissue donation;
- (f) any anticipated expenses the donor is likely to incur as a consequence of donating tissue;
- (g) the extent to which records identifying the donor will be kept confidential;
- 20 (h) whether individually-identifiable information obtained from the tissue donor will be used for future research;
- (i) where applicable, whether biological material taken from the tissue donor will be destroyed, discarded or stored and used for future research;
- 25 (j) whether, and the circumstances under which, the donor or the person authorised to give consent under this Part, as the case may be, will be contacted for further consent;
- (k) whether the tissue donation would result in the use of the donor's tissue in an individually-identifiable form;
- 30 (l) whether the donor or the person authorised to give consent under this Part, as the case may be, would wish to be re-identified in the case of an incidental finding;

- (m) such other information as the institutional review board may require;
- (n) such other information as may be prescribed.

Waiver of appropriate consent by institutional review board

- 5 **12.**—(1) Notwithstanding anything in this Part, an institutional review board which is the reviewing authority of a human biomedical research proposal may waive the requirement —
- 10 (a) for the appropriate consent obtained for the participation of a person as a research subject or for the use of human tissues, as the case may be, to be in writing, in such circumstances as are specified in Part 1 of the Third Schedule;
 - 15 (b) to obtain appropriate consent for the use of human biological material or health information, as the case may be, in such circumstances as are specified in Part 2 of the Third Schedule; or
 - 20 (c) to obtain appropriate consent for the participation of a person as a research subject for emergency research in such circumstances as are specified in Part 3 of the Third Schedule.
- 25 (2) Notwithstanding sections 8 and 9, an institutional review board which is the reviewing authority of a human biomedical research proposal may waive the requirement to obtain the appropriate consent of at least one parent or guardian for the participation of a minor as a research subject if the board is satisfied that —
- 30 (a) the proposed research involves no more than minimal risk to the research subjects;
 - (b) the waiver of parental consent will not adversely affect the rights and welfare of the research subjects;
 - (c) the proposed research may not practicably be carried out unless there is such a waiver, and the research proposal —

- 5 (i) is designed for conditions or for a subject population for which parental or guardian consent is not a reasonable requirement to protect the subjects (such as neglected or abused minors), and an appropriate mechanism for protecting the minors is substituted;
- (ii) is of such a private and sensitive nature that it is not reasonable to require permission, (such as adolescents in studies concerning treatment of sexually transmitted diseases); or
- 10 (iii) is within the description of such circumstances as may be prescribed.

(3) For the avoidance of doubt —

- (a) subsection (1) shall not apply to the waiver of consent for the removal of human tissue from a person;
- 15 (b) a waiver under subsection (1) or (2) shall not affect a person's duty to protect individually-identifiable information from unauthorised disclosure under sections 28 and 38 or imposed by law;
- 20 (c) nothing in this section will provide immunity to the custodian of any individually-identifiable information for such information to be disclosed, unless it was done in accordance with this Act.

(4) A waiver under subsection (1) or (2) shall have effect notwithstanding any obligation as to confidentiality or other
25 restriction upon the disclosure or use of information imposed by law, contract or rules of professional conduct.

(5) A researcher who conducts human biomedical research pursuant to a waiver under subsection (1) or (2) shall not be treated as being in breach of any obligation as to confidentiality or other
30 restriction upon the disclosure or use of information or material imposed by law, contract or rules of professional conduct.

Withdrawal of consent

13.—(1) A research subject or any person who gives consent on his behalf may, at any time, withdraw such consent to human biomedical research.

5 (2) A donor of human tissue or any person, who gives consent on his behalf, may, at any time, withdraw his consent to the use of his tissue for human biomedical research if —

(a) the tissue is individually-identifiable and has not been used for the research; or

10 (b) the tissue is individually-identifiable and has been used for the research but it is practicable to discontinue further use of the tissue for the research.

(3) The withdrawal of consent in the circumstances specified in subsection (1) or (2)(b) shall not affect the research information
15 obtained before the consent is withdrawn and such information may be retained and used for the human biomedical research.

(4) Any penalty or damages imposed on a research subject solely by reason of the withdrawal of his consent to human biomedical research shall be void and unenforceable.

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PART 4

INSTITUTIONAL REVIEW BOARDS

Appointment of institutional review boards

14.—(1) A research institution shall appoint one or more institutional review boards for the purpose of reviewing human
25 biomedical research conducted under the control or supervision of that research institution and in accordance with such requirements as may be prescribed.

(2) For the avoidance of doubt, a person may be appointed as a member concurrently of 2 or more institutional review boards
30 appointed by the same research institution or different research institutions.

(3) A person who is appointed as a member concurrently of 2 or more institutional review boards shall not be disqualified from sitting on the different boards which are reviewing proposals for human biomedical research that are part of the same research or are otherwise connected or related.

(4) A research institution shall notify the Director of —

(a) any institutional review board which it has appointed under this section or section 15; or

(b) any institutional review board which appointment it has revoked,

as the case may be.

(5) A notification for the purposes of subsection (4) shall be submitted to the Director in such form and manner and within such time as the Director may require, and shall be accompanied by such fee as may be prescribed.

(6) Any person who contravenes subsection (4)(a) or (b) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding \$10,000 or to imprisonment for a term not exceeding 6 months or to both.

(7) Any person who, in submitting a notification for the purposes of subsection (4) —

(a) makes any statement or furnishes any document which he 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.

Appointment of institutional review boards by multiple research institutions

15.—(1) This section shall apply where human biomedical research is conducted jointly or in collaboration with more than one research institution and there is an agreement amongst the research

institutions for one research institution to be appointed as the lead research institution for the purpose of coordinating the research (referred to in this section as the lead research institution).

(2) For the purpose of their common human biomedical research, the research institutions may, instead of appointing the institutional review boards appointed by them under section 14, appoint a common institutional review board which may be the institutional review board appointed by the lead research institution or such other institutional review board as may be agreed amongst the institutions.

(3) The provisions of this Act shall, with necessary modifications, apply to the institutional review board designated by the research institution under subsection (2) in the same manner as it applies to the institutional review board appointed by the board under section 14.

Functions and duties of institutional review boards

16.—(1) The functions of an institutional review board are —

- (a) to carry out a review (referred to in this Act as an initial review) of any proposed human biomedical research (referred to in this section as the proposed research) on ethical grounds;
- (b) to carry out a review of the progress of the proposed research on ethical grounds at such times as may be prescribed;
- (c) to assess the suitability and the qualifications of the researcher for the proposed research;
- (d) to assess whether the minors or the class of minors, if any, who are research subjects in the proposed research are capable of giving consent to the proposed research having regard to the ages, psychological states and maturity of the minors or class of minors involved;
- (e) to assess whether there are adequate provisions for taking the consent of the minors or the class of minors, if any, who are research subjects in the proposed research;

- (f) to assess if a data and safety monitoring board is necessary for the purposes of the proposed research;
 - (g) to assess the suitability and adequacy of the system of oversight of the research institution conducting the particular research proposal;
 - (h) to assess the suitability of the premises for the proposed research; and
 - (i) if the board considers appropriate —
 - (i) to grant its approval for the research to be conducted or continued, as the case may be;
 - (ii) to require modifications to be made to the research proposal before granting its approval or allowing the proposed research to continue, as the case may be;
 - (iii) to disallow the conduct or continuation of the proposed research, as the case may be, with written justifications.
- (2) Notwithstanding subsection (1), if the chairman of an institutional review board that is responsible for reviewing a proposed human biomedical research or another member authorised by the board is satisfied that the proposed research falls within such criteria as may be prescribed, including but not limited to the risk of harm to research subjects, the chairman or the authorised member may, if he considers appropriate —
- (a) exempt the proposed research from the requirement to be approved by an institutional review board; or
 - (b) review the proposed research proposal through an expedited process by the chairman alone or by a single member authorised by the institutional review board,
- subject to such conditions as may be imposed by the board or prescribed.

Composition, quorum and proceedings of institutional review board

5 **17.**—(1) The composition, quorum and proceedings of an institutional review board shall be in accordance with regulations made under section 60.

(2) The office of a member of an institutional review board shall become vacant if the member —

- (a) dies;
- (b) resigns his office;
- 10 (c) becomes subject to any of the disqualifications specified in the regulations;
- (d) becomes subject to a disqualification order made under the regulations; or
- 15 (e) has his appointment revoked before the expiry of the term for which he has been appointed.

(3) If any vacancy arises in the institutional review board, the research institution may appoint any person who is eligible under the regulations to fill the vacancy.

20 (4) An institutional review board may act notwithstanding any vacancy in the board, except that where the number of members of the board becomes less than 5, the board shall be dissolved.

(5) The validity of any proceedings of an institutional review board shall not be affected —

- 25 (a) by any defect in the appointment or qualification of any member of the board;
- (b) by any contravention of section 18(1) by any member of the board; or
- 30 (c) by any contravention of the regulations relating to the procedures of institutional review boards except for requirements relating to the quorum for meetings of the board.

Conflicts of interest

18.—(1) A member of an institutional review board shall declare at every meeting of the board the nature and extent of all conflicts of interest or potential conflicts of interest in relation to a matter under
5 consideration by the board at that meeting, including such circumstances as may be prescribed in regulations.

(2) A person who is a member concurrently of 2 or more institutional review boards which are reviewing proposals for human biomedical research that are part of the same research or are
10 otherwise connected or related —

(a) shall not be disqualified from participating in the proceedings of the boards on the ground of conflicts of interests; but

(b) shall disclose his participation in each board's proceedings
15 to the other boards.

Application to institutional review board for review

19. Every application to an institutional review board for the review of human biomedical research shall be made by one or more researchers responsible for the conduct and supervision of the
20 research in accordance with such requirements as may be prescribed.

Appeal against decision of institutional review board

20.—(1) Any researcher who, having submitted an application to an institutional review board for initial review, is aggrieved by the
25 decision of the institutional review board (referred to in this section as the first board) not to grant for the research to be conducted or continued, as the case may be, within 30 days of the decision of the first board, submit an appeal to the research institution which appointed the first board.

(2) The research institution receiving an appeal under
30 subsection (1) may —

(a) dismiss the appeal;

(b) direct the first board to reconsider and review its decision;
or

(c) direct the researcher to submit the research to another
institutional review board appointed by the research
5 institution (referred to in this section as the second board)
for a second initial review.

(3) No appeal under subsection (1) shall be allowed unless the
first board has confirmed in writing that it has disallowed the
conduct or continuation of the research and provided reasons for the
10 decision.

(4) There shall be no appeal against the decision of the research
institution or the second board referred to in subsection (2).

PART 5

REGULATION OF HUMAN BIOMEDICAL RESEARCH

15 **Conduct of human biomedical research and duties of researcher**

21.—(1) No human biomedical research shall be conducted
except under the supervision and control of a research institution.

(2) No person shall conduct any human biomedical research
unless he has first complied with all the following requirements:

20 (a) he has made the necessary contractual or other
arrangements with a research institution for the proposed
research to be conducted under the supervision and control
of the research institution;

(b) he has ensured that the proposed research has been —
25 (i) reviewed and approved by an institutional review
board appointed by the research institution referred
to in paragraph (a); or
(ii) exempted from review by an institutional review
board in accordance with the manner prescribed
30 under section 16(2);

5 (c) he has ensured that, except in such circumstances as may be prescribed, appropriate consent has been obtained in accordance with Part 3 for the participation of the research subject or the use of individually-identifiable biological material or health information of the research subject in the proposed research.

(3) A researcher shall ensure that —

10 (a) the research does not deviate from the research proposal that has been reviewed and approved or exempted from review by an institutional review board unless the deviation —

(i) has been reviewed and approved, or otherwise exempted from review, by the institutional review board; or

15 (ii) is necessary to mitigate an immediate risk of harm to a research subject and the researcher without unreasonable delay informs the institutional review board of the deviation;

20 (b) any research is without unreasonable delay discontinued if the institutional review board has withdrawn its approval for the research;

25 (c) the further participation of the research subject or further use of the individually-identifiable biological material or health information of the research subject is without unreasonable delay discontinued if the consent has been withdrawn or is otherwise invalid.

30 (4) For the avoidance of doubt, the delegation of any obligation or duty under this Act to another person or service provider under a contract or other arrangement shall not absolve or relieve the person of any of his obligations under this Act.

(5) Any person who contravenes subsection (1), (2) or (3) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding \$50,000 or to imprisonment for a term not exceeding 5 years or to both.

Functions and duties of research institutions

22.—(1) Every research institution shall, in respect of any human biomedical research to be conducted under its supervision and control —

- 5 (a) submit a notification in such form and manner, and within such time as may be prescribed, before the commencement of the first human biomedical research conducted under that research institution's supervision and control;
 - 10 (b) submit, in accordance with section 23(1), a declaration of compliance in respect of all human biomedical research conducted under its supervision and control in the preceding 12 months, or by such time as the Director may require; and
 - 15 (c) ensure there is in force an approval for the human biomedical research under section 16(1) issued by an institutional review board which it had appointed or a waiver under section 16(2) of the requirement for that research to be approved by the institutional review board appointed by the research institution.
- 20 (2) Every research institution shall, in respect of any human biomedical research which is carried out under its supervision and control —
- (a) supervise, review and proactively monitor the conduct of the research;
 - 25 (b) designate a principal person-in-charge to be responsible for ensuring that the research institution complies with this Act;
 - (c) formulate and implement appropriate standards, policies and procedures to monitor, supervise and review the conduct of the research;
 - 30 (d) establish a data and safety monitoring board if the research institution considers that it is necessary for the purposes of any particular research proposal;
 - (e) investigate any areas of concern and take such remedial measures as appropriate;

(f) ensure that the research —

(i) is in compliance with the requirements of this Act;
and

5 (ii) is conducted in accordance with its standards,
policies and procedures referred to in paragraph (c);
and

10 (g) ensure that, where the human biomedical research is
conducted jointly or in collaboration with more than one
research institution, there is an agreement amongst the
research institutions for one research institution to be
appointed as the lead research institution for the purpose of
coordinating the research;

(h) perform such other functions and duties as may be
prescribed by the Minister.

15 (3) Every research institution shall notify the Director, in such
form and manner as may be prescribed, of —

(a) the commission of any suspected offence or contravention
under this Act or the regulations;

(b) the occurrence of any serious adverse event; and

20 (c) such other matters as may be prescribed.

(4) The designation of a principal person-in-charge by a research
institution under subsection (2)(b) shall not absolve or relieve the
institution of any of its obligations or duties under this Act.

25 (5) For the avoidance of doubt, the delegation of any obligation or
duty under this Act to another person or service provider under a
contract or other arrangement shall not absolve or relieve the
research institution of any of its obligations under this Act.

30 (6) Any person who contravenes subsection (1)(a) or (b) shall be
guilty of an offence and shall be liable on conviction to a fine not
exceeding \$10,000 or to imprisonment for a term not exceeding
12 months or to both.

(7) Any person who contravenes subsection (1)(c), shall be guilty
of an offence and shall be liable on conviction to a fine not

exceeding \$50,000 or to imprisonment for a term not exceeding 5 years or to both.

- (8) Any person who contravenes subsection (3) 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.

Declaration of compliance by research institution

23.—(1) Every research institution shall submit a declaration of compliance for the purposes of section 22(1) for all research conducted under the supervision and control of the research institution to the Director in such form and manner and within such time as the Director may prescribe and shall be accompanied by —

- (a) such particulars, information and documents as the Director may require;
- (b) if required by the Director, a statutory declaration by the research institution verifying any information contained in or related to the declaration of compliance; and
- (c) such fee as may be prescribed.

(2) A research institution shall notify the Director —

- (a) of any change in the information submitted under subsection (1)(a), within 30 days after the occurrence of the change or such longer period as the Director may allow in any particular case; and
- (b) of its intention to cease operating as a research institution not less than 30 days before the cessation of operation or such shorter period as the Director may allow in any particular case.

(3) Any person who, in submitting a declaration of compliance referred to in subsection (1) or any notification referred to in subsection (2) —

- (a) makes any statement or furnishes any document which he 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.

(4) Any person who contravenes subsection (2) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding \$10,000 or to imprisonment for a term not exceeding 12 months or to both.

Appropriate consent from research subjects

24. No human biomedical research shall be conducted if the appropriate consent of a person for participation as a research subject, including the use of his biological material or individually-identifiable health information, has not been obtained in accordance with Part 3.

Compelling person to participate in research

25.—(1) Any person who —

(a) by means of coercion or intimidation, compels another person against that person's will to participate or continue to participate as a research subject in any human biomedical research;

(b) by means of coercion or intimidation, compels another person against that person's will to give his consent or to refrain from withdrawing his consent for the participation of another person as a research subject in any human biomedical research;

(c) by means of deception or misrepresentation, causes another person to participate or continue to participate as a research subject in any human biomedical research; or

(d) by means of deception or misrepresentation, causes another person to give his consent or to refrain from withdrawing his consent for the participation of another person as a research subject in any human biomedical research,

shall be guilty of an offence and shall be liable on conviction to a fine not exceeding \$100,000 or to imprisonment for a term not exceeding 10 years or to both.

5 (2) It shall be a defence to a prosecution under subsection (1)(c) if the defendant proves all of the following:

- (a) the deception or misrepresentation was a necessary requirement of the human biomedical research;
- (b) the possibility of the deception or misrepresentation was disclosed to the research subject;
- 10 (c) the research was conducted in accordance with the research proposal approved by the reviewing authority.

Duty to protect health information and human biological material against loss, unauthorised disclosure, etc.

15 **26.**—(1) Every person who has obtained individually-identifiable information or human biological material for the purposes of human biomedical research shall take all reasonable steps and safeguards as may be necessary, including rendering information or material non-identifiable, to protect such information or material against accidental or unlawful loss, modification or destruction, or
20 unauthorised access, disclosure, copying, use or modification.

(2) Any person who contravenes subsection (1) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding \$10,000 or to imprisonment for a term not exceeding 12 months or to both.

25 (3) In this section and section 27, the act of rendering information or material non-identifiable means the removal of identifying details from the information or material so that the identity of the research subject from whom the information or material was obtained cannot be readily discovered or ascertained by a person who subsequently
30 accesses or receives the information or material.

No re-identification of anonymised information or biological material without consent

27.—(1) This section shall apply to any information or human biological material —

- 5 (a) relating to human biomedical research; and
- (b) which was individually-identifiable but which has been rendered non-identifiable within the meaning of section 26(3).
- (2) No person who is in possession of or in contact with any
- 10 information or human biological material referred to in subsection (1) shall take any action to identify the person from whom such information or material was obtained except —
- (a) with the consent of the research subject or the person authorised under Part 3 to give consent on his behalf, as the
- 15 case may be;
- (b) when it is necessary to do so in connection with the administration or execution of anything under this Act;
- (c) when ordered to do so by a court;
- (d) where the information on the identity is publicly available;
- 20 (e) for the purpose of providing the identity to any person or class of persons to whom, in the opinion of the Director, it is in the public interest that the information be disclosed; and
- (f) where it is permitted or provided for under this Act or any
- 25 other written law or rule of law.

(3) Any person who contravenes subsection (2) 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.

Restrictions on disclosure of information

28.—(1) No person shall disclose any individually-identifiable information of any research subject which has come to his

knowledge in the course of discharging his functions or duties under this Act, or by virtue of his conduct or review of the human biomedical research, as the case may be, except —

- 5 (a) with the consent of the research subject or the person authorised under Part 3 to give consent on his behalf, as the case may be;
- (b) when it is necessary to do so in connection with the administration or execution of anything under this Act;
- (c) when ordered to do so by a court;
- 10 (d) where the information is publicly available;
- (e) to any person or class of persons to whom, in the opinion of the Director, it is in the public interest that the information be disclosed; and
- 15 (f) where any other right of disclosure arises under this Act or any other written law or rule of law.

(2) No person receiving any individually-identifiable information or human biomedical material of a research subject, shall disclose any individually-identifiable information of the research subject, if at the time when he received the information or material, he knew or
20 had reasonable grounds to believe that it had been communicated or supplied to him in contravention of this Act or any other written law or rule of law.

(3) Any person who contravenes subsection (1) or (2) shall be guilty of an offence and shall be liable on conviction to a fine not
25 exceeding \$20,000 or to imprisonment for a term not exceeding 2 years or to both.

Prohibited human biomedical research

29.—(1) Notwithstanding anything in this Act, no research institution or person shall conduct, supervise or control any
30 prohibited human biomedical research specified in the First Schedule.

(2) Any person who contravenes subsection (1) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding

\$100,000 or to imprisonment for a term not exceeding 10 years or to both.

Restricted human biomedical research

5 **30.**—(1) Without prejudice to the other provisions in this Act, no research institution or person shall conduct, supervise or control any restricted human biomedical research specified in the Second Schedule except in accordance with such additional requirements as the Minister may prescribe.

10 (2) Without prejudice to the generality of subsection (1), the additional requirements which may be prescribed for the purposes of subsection (1) may include the following:

- (a) that the Director should be notified of the conduct of such restricted human biomedical research;
- 15 (b) that the restricted human biomedical research should be carried out only under, and in accordance with the conditions of approval obtained from the Director or a public officer authorised by the Minister;
- 20 (c) that the restricted human biomedical research should be reviewed by an institutional review board, or such other committee as may be prescribed, comprising members with certain specified qualifications;
- (d) that the restricted human biomedical research should be conducted only by certain specified persons;
- 25 (e) that the appropriate consent in a restricted human biomedical research be obtained from the research subject who has capacity to give consent in person and not from a person authorised under Part 3 to give consent on the subject's behalf;
- 30 (f) that the restricted human biomedical research should be carried out only at certain specified premises;
- (g) that the restricted human biomedical research should or should not be conducted in any specified manner.

(3) Any person who contravenes subsection (1) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding \$100,000 or to imprisonment for a term not exceeding 10 years or to both.

5

PART 6

REGULATION OF HUMAN TISSUES AND TISSUE BANKS

Commercial trading of human tissues prohibited

31.—(1) Subject to subsections (4) and (5), a contract or an arrangement under which a person agrees, for valuable consideration, whether given or to be given to himself or to another person, to the sale or supply of any human tissue from his body or from the body of another person, whether before or after his death or the death of the other person, as the case may be, shall be void.

(2) A person who enters into a contract or an arrangement of the kind referred to in subsection (1) and to which that subsection applies shall be guilty of an offence and shall be liable on conviction to a fine not exceeding \$100,000 or to imprisonment for a term not exceeding 10 years or to both.

(3) Any person who —

- (a) gives or offers to give valuable consideration for the sale or supply of, or for an offer to sell or supply, any human tissue from the body of another person other than for the purpose of transplantation to his body;
- (b) receives valuable consideration for the sale or supply of, or for an offer to sell or supply, any human tissue from the body of another person;
- (c) offers to sell or supply any human tissue from the body of another person for valuable consideration;
- (d) initiates or negotiates any contract or arrangement for the sale or supply of, or for an offer to sell or supply, any human tissue from the body of another person for valuable consideration other than for the purpose of transplantation to his body; or

(e) takes part in the management or control of a body corporate or body unincorporate whose activities consist of or include the initiation or negotiation of any contract or arrangement referred to in paragraph (d),

5 shall be guilty of an offence and shall be liable on conviction to a fine not exceeding \$100,000 or to imprisonment for a term not exceeding 10 years or to both.

(4) Subsections (1) and (3) shall not apply to or in relation to —

10 (a) a contract or an arrangement providing only for the reimbursement of any expenses necessarily incurred by a person in relation to the removal of blood in accordance with the provisions of any other written law;

15 (b) any scheme introduced or approved by the Government granting medical benefits or privileges to any organ or blood donor and any member of the donor's family or any person nominated by the donor; and

20 (c) any contract, arrangement or valuable consideration providing only for the defraying or reimbursing, in money or money's worth, of such costs or expenses that may be reasonably incurred by a living person in relation to —

(i) the removal, transportation, preparation, preservation, quality control or storage of any human tissue;

25 (ii) the costs or expenses (including the costs of travel, accommodation, domestic help or child care) or loss of earnings so far as are reasonably or directly attributable to that person supplying any human tissue from his body; and

30 (iii) any short-term or long-term medical care or insurance protection of that person which is or may reasonably be necessary as a consequence of his supplying any human tissue from his body.

(5) The Minister may, by notification in the *Gazette*, declare that subsection (1) or (3) shall not apply to the sale or supply of a

specified class or classes of product derived from any human tissue that has been subjected to processing or treatment.

(6) A person who as vendor or supplier enters into a contract or an arrangement for the sale or supply of a product derived from any human tissue that has been subjected to processing or treatment, other than such a product which is of a class declared under subsection (5), shall be guilty of an offence if the human tissue from which the product was derived was obtained under a contract or an arrangement that is void by reason of subsection (1), and shall be liable on conviction to a fine not exceeding \$10,000 or to imprisonment for a term not exceeding 12 months or to both.

(7) Nothing in this section shall render inoperative a consent or an authority given or purporting to have been given under this Act in relation to any human tissue from the body of a person or in relation to the body of a person if a person acting in pursuance of the consent or authority did not know and had no reason to know that the human tissue or the body was the subject-matter of a contract or an arrangement referred to in subsection (1) or (3).

(8) This section and section 32 shall not apply to any human tissue where any of the following provisions applies to that tissue:

- (a) section 14 or 15 of the Human Organ Transplant Act (Cap. 131A) (Prohibition of trading in organs and blood); or
- (b) section 13 of the Human Cloning and Other Prohibited Practices Act (Cap. 131B) (Prohibition against commercial trading in human eggs, human sperm and human embryos).

Advertisements relating to commercial trading of human tissues prohibited

32.—(1) No person shall issue or cause to be issued any advertisement relating to the buying or selling in Singapore of any human tissue or of the right to take any human tissue or blood from the body of a person.

(2) In this section, “advertisement” includes every form of advertising, whether in a publication, or by the display of any notice or signboard, or by means of any catalogue, price list, letter

(whether circulated or addressed to a particular person) or other documents, or by words inscribed on any article, or by the exhibition of a photograph or a cinematograph film, or by way of sound recording, sound broadcasting or television, or in any other way, and any reference to the issue of an advertisement shall be construed accordingly.

(3) Any person who contravenes subsection (1) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding \$100,000 or to imprisonment for a term not exceeding 10 years or to both.

Notification of tissue bank

33.—(1) A research institution shall notify the Director of any tissue bank which the research institution is directly or indirectly operating or which is part of the research institution.

(2) A tissue bank shall notify the Director of its particulars unless a research institution has made a notification of that tissue bank in accordance with subsection (1).

(3) A notification for the purposes of subsection (1) or (2) shall be submitted to the Director in such form and manner, with such particulars and within such time as may be prescribed, and shall be accompanied by such fee as may be prescribed.

(4) Any person who contravenes subsection (1) or (2) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding \$10,000 or to imprisonment for a term not exceeding 6 months or to both.

(5) Any person who, in submitting a notification for the purposes of subsection (1) or (2) —

(a) makes any statement or furnishes any document which he 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.

Duties of tissue bank

5 **34.**—(1) Every tissue bank shall, in respect of any tissue banking activity to be conducted under its supervision and control —

10 (a) submit a notification in such form and manner, and within such time as may be prescribed, before the commencement of any tissue banking activity conducted under that tissue bank's supervision and control;

 (b) submit, in accordance with section 35, a declaration of compliance in respect of all tissue banking activity conducted under its supervision and control in the preceding 12 months, or by such time as the Director may require.

15 (2) Every tissue bank shall, in respect of any tissue banking activity which is carried out under its supervision and control —

 (a) supervise, review and proactively monitor the conduct of the tissue banking activity;

20 (b) designate a principal person-in-charge to be responsible for ensuring that the tissue bank complies with this Act;

 (c) formulate and implement appropriate standards, policies and procedures to monitor, supervise and review the conduct of the tissue banking activity;

25 (d) investigate any areas of concern and take such remedial measures as appropriate;

 (e) ensure that the tissue banking activity —

 (i) is in compliance with the requirements of this Act; and

30 (ii) is conducted in accordance with its standards, policies and procedures referred to in paragraph (c); and

(f) perform such other functions and duties as may be prescribed by the Minister.

(3) Every tissue bank shall notify the Director, in such form and manner as may be prescribed, of —

- 5 (a) the commission of any suspected offence or contravention under this Act or the regulations;
- (b) the occurrence of any serious adverse event; and
- (c) such other matters as may be prescribed.

10 (4) The designation of a principal person-in-charge by a tissue bank under subsection (2)(b) shall not absolve or relieve the tissue bank of any of its obligations under this Act.

15 (5) For the avoidance of doubt, the delegation of any obligation or duty under this Act to another person or service provider under a contract or other arrangement shall not absolve or relieve the tissue bank of its obligations under this Act.

 (6) Any person who contravenes subsection (1) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding \$10,000 or to imprisonment for a term not exceeding 12 months or to both.

20 (7) Any person who contravenes subsection (3) 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.

Declaration of compliance by tissue bank

25 **35.**—(1) Every tissue bank shall submit a declaration of compliance for the purposes of section 34(1) for all tissue banking activities conducted under the supervision and control of the tissue bank to the Director in such form and manner and within such time as the Director may require and shall be accompanied by —

- 30 (a) such particulars, information and documents as the Director may require;

(b) if required by the Director, a statutory declaration by the tissue bank verifying any information contained in or related to the declaration of compliance; and

(c) such fee as may be prescribed.

5 (2) A tissue bank shall notify the Director —

(a) of any change in the information submitted under subsection (1)(a), within 30 days after the occurrence of the change or such longer period as the Director may allow in any particular case; and

10 (b) of its intention to cease operating as a tissue bank not less than 30 days before the cessation of operation or such shorter period as the Director may allow in any particular case.

(3) Any person who, in submitting a declaration of compliance referred to in subsection (1) or any notification referred to in subsection (2) —

(a) makes any statement or furnishes any document which he knows to be false or does not believe to be true; or

20 (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.

25 (4) Any person who contravenes subsection (1) or (2) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding \$10,000 or to imprisonment for a term not exceeding 12 months or to both.

Restrictions on activities relating to human tissues

30 **36.—**(1) No person shall remove any human tissue from a donor unless —

(a) where the tissue is to be removed for a therapeutic or diagnostic purpose as part of the medical treatment of the donor and solely used for that therapeutic or diagnostic

purpose, consent has been obtained for the necessary procedures to be carried out in the course of the treatment;

5 (b) where the tissue is to be removed for a therapeutic or diagnostic purpose as part of the medical treatment of the donor but will also be or is likely to be used for other purposes, appropriate consent has been obtained for the tissue to be removed from the donor;

(c) where the tissue is to be removed for a purpose other than a therapeutic or diagnostic purpose —

10 (i) the potential risks to the donor is negligible and clearly outweighed by the likely benefits; and

(ii) appropriate consent has been obtained for the tissue to be removed from the donor.

15 (2) No person shall store any human tissue for subsequent use in research unless —

(a) appropriate consent has been obtained for the tissue to be stored for subsequent use; and

(b) the storage is in accordance with any conditions or restrictions specified as part of the appropriate consent.

20 (3) No person shall supply any human tissue to another person for use in research unless —

(a) appropriate consent has been obtained for the tissue to be used in research; and

25 (b) the intended use is in accordance with any conditions or restrictions specified as part of the appropriate consent.

(4) No person shall use any human tissue in research unless —

(a) appropriate consent has been obtained for the tissue to be used in research; and

30 (b) the use is in accordance with any conditions or restrictions specified as part of the appropriate consent.

(5) Where the tissue was removed from a donor for a therapeutic or diagnostic purpose, no person shall —

- (a) store the tissue for use other than the intended therapeutic or diagnostic purpose;
 - (b) supply the tissue for use in research; or
 - (c) use the tissue in research,
- 5 unless the doctor responsible for the medical treatment of the donor had completed all the necessary therapeutic or diagnostic procedures and no longer requires the tissue or part thereof for the treatment.
- (6) This section shall not apply to —
- 10 (a) the removal, storage or supply of any human tissue in the course of a post-mortem examination conducted pursuant to and in accordance with the Coroner's Act (Cap. 63A) or carried out pursuant to the order of a Coroner made under that Act;
 - 15 (b) the removal, storage or supply of any organ as defined in the Human Organ Transplant Act (Cap. 131A) and carried out in accordance with that Act;
 - 20 (c) the removal, storage or supply of all or any part of a human body or a post-mortem examination carried out in accordance with the Medical (Therapy, Education and Research) Act (Cap. 175).
- (7) Any person who contravenes this section shall be guilty of an offence and shall be liable on conviction to a fine not exceeding \$50,000 or to imprisonment for a term not exceeding 5 years or to both.

Compelling person to donate tissue

37. Any person who —

- 30 (a) by means of coercion or intimidation, compels another person against that person's will to allow his tissue to be removed from his body;
- (b) by means of coercion or intimidation, compels another person against that person's will to give his consent or to

refrain from withdrawing his consent for the removal of tissue from his body;

(c) by means of deception or misrepresentation, causes another person to allow or continue to allow his tissue to be removed from his body; or

(d) by means of deception or misrepresentation, causes another person to give his consent or to refrain from withdrawing his consent for the removal of tissue from his body,

shall be guilty of an offence and shall be liable on conviction to a fine not exceeding \$100,000 or to imprisonment for a term not exceeding 10 years or to both.

Restrictions on disclosure of information on tissue donor

38.—(1) No person shall disclose any individually-identifiable information on any donor of human tissue which has come to his knowledge except —

(a) with the consent of the donor or his legal representative, as the case may be;

(b) when it is necessary to do so in connection with the administration or execution of anything under this Act;

(c) when ordered to do so by a court;

(d) where the information is publicly available;

(e) to any person or class of persons to whom, in the opinion of the Director, it is in the public interest that the information be disclosed; and

(f) where any other right of disclosure arises under this Act or any other written law or rule of law.

(2) No person receiving any individually-identifiable information of a donor shall disclose any individually-identifiable information of the donor, if at the time when he received the information or material, he knew or had reasonable grounds to believe that it had been communicated or supplied to him in contravention of this Act or any other written law or rule of law.

(3) Any person who contravenes subsection (1) or (2) 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.

5

PART 7

CODES OF PRACTICE AND ETHICS

Codes of practice or ethics

39.—(1) The Director may, from time to time —

- 10 (a) issue one or more codes of practice for the purpose of providing guidance with respect to the requirements of this Act relating to safety and research practices and for standards;
- (b) issue one or more codes of ethics for the ethical conduct of human biomedical research or tissue banking activity;
- 15 (c) approve as a code of practice or a code of ethics any document prepared by another person or body of persons other than the Director, if the Director considers the document as suitable for this purpose;
- 20 (d) amend or revoke the whole or part of any code of practice or code of ethics issued under paragraph (a) or (b) or approved under paragraph (c).

(2) The Director shall publish any code of practice or code of ethics issued or approved under subsection (1), including any amendment or revocation thereto, in such manner [accessible to
25 research institutions, tissue banks and researchers] as he thinks fit.

(3) Any code of practice or ethics issued under this section shall not have legislative effect and need not be published in the *Gazette*.

Use of codes of practice or ethics

30 **40.**—(1) A person shall not be liable to any criminal proceedings by reason only that he has failed to observe any code of practice or code of ethics issued or approved under section 39.

(2) In any proceedings for an offence under this Act, a code of practice or code of ethics issued or approved under section 39 that is relevant to any matter which it is necessary for the prosecution to prove in order to establish the commission of the offence shall be admissible in evidence in the proceedings.

(3) In determining for the purpose of any provision of this Act as to whether any activity or practice in or in relation to the conduct of human biomedical research or tissue banking activity is reasonable and in accordance with the generally accepted practices and principles of ethical conduct, regard shall be had to any relevant code of practice or code of ethics issued or approved under section 39.

PART 8

ENFORCEMENT POWERS

Immediate stoppage of human biomedical research or tissue banking activity, etc.

41.—(1) Where the Director is of the opinion that any human biomedical research or tissue banking activity —

(a) has given rise or is likely to give rise to a serious adverse event or to such other matter as may be prescribed;

(b) is in contravention of —

(i) any provision of this Act;

(ii) any relevant code of practice or code of ethics issued or approved under section 39;

(c) is not being properly reviewed by an institutional review board appointed by the research institution; or

(d) is contrary to the public interest,

the Director may, in writing, order the researcher and other persons conducting the human biomedical research or tissue banking activity to immediately stop all activities, or any part thereof, relating to the human biomedical research or tissue bank, and direct the research institution, institutional review board, tissue bank or

researcher, as the case may be, to take such precautionary, remedial or other measures as the Director may specify.

(2) Where the Director is of the opinion that an institutional review board is not discharging its duties in a proper or satisfactory manner, the Director may do one or more of the following:

- (a) direct the research institution to suspend any human biomedical research for which the institutional review board was the reviewing authority;
- (b) direct the research institution to assign another appointed institutional review board to review any human biomedical research for which the institutional review board was the reviewing authority;
- (c) direct the research institution which appointed the institutional review board to —
 - (i) remove or replace any member of the institutional review board; or
 - (ii) dissolve the institutional review board.

(3) Where the Director is of the opinion that a research institution or tissue bank is not discharging its duties under this Act, or as prescribed in regulations made under this Act, in a proper or satisfactory manner, the Director may, by notification published in the *Gazette*, prohibit the further conduct of any, all or specified types of human biomedical research or tissue banking activity, as the case may be, under the supervision and control of that research institution or tissue bank.

(4) Any person who contravenes an order given to him under subsection (1), (2) or (3) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding \$100,000 or to imprisonment for a term not exceeding 10 years or to both and, in the case of a continuing offence, to a further fine not exceeding \$2,000 for every day or part thereof during which the offence continues after conviction.

Prohibiting person from conducting research or tissue banking activities

5 **42.**—(1) The Director may, by order published in the *Gazette*, prohibit any person from conducting any, all or specified types of human biomedical research or tissue banking activities, as the case may be, if —

- (a) the person has been convicted of an offence under this Act;
- (b) the person has been convicted in Singapore or elsewhere of any offence involving fraud, dishonesty or moral turpitude;
- 10 (c) the Director is satisfied that the person is not of good reputation or character, or is otherwise unfit to conduct human biomedical research or tissue banking activities, as the case may be; or
- (d) for medical reasons, the person is unable to perform his
15 duties as a researcher, as assessed by a medical practitioner.

(2) Any person who conducts human biomedical research or tissue banking activity in contravention of a prohibition order made under subsection (1) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding \$100,000 or to imprisonment
20 for a term not exceeding 10 years or to both.

Review of prohibition order

43.—(1) A person who is the subject of a prohibition order under section 42(1) may, on the payment of such fee as may be prescribed, apply to the Director for the order to be reviewed.

25 (2) On receipt of an application under subsection (1), the Director may revoke the prohibition order where he is satisfied that the grounds on which the order was made no longer apply or have substantially changed, subject to such terms and conditions as he thinks fit to impose.

30 (3) In determining the terms and conditions to be imposed upon the revocation of a prohibition order, the Director shall have regard to —

(a) the character and fitness of the applicant to conduct human biomedical research or tissue banking activity; and

(b) any other matter which the Director considers relevant.

5 (4) No application to review a prohibition order under subsection (1) shall be made to the Director —

(a) before the expiration of 12 months after the date on which the prohibition order was published in the *Gazette*; and

(b) more than once in any continuous period of 3 years.

Powers of entry, inspection and search, etc.

10 **44.**—(1) An authorised officer may, at any time and without warrant, enter, inspect and search any premises and the facilities in the premises that are being used, or that he has reasonable cause to believe are being used, for the conduct of any human biomedical research or tissue banking activity, for the purpose of —

15 (a) investigating whether any provision of this Act has been or is being contravened;

(b) investigating any complaint or matter in respect of which the Director may take action under section 41;

20 (c) assessing whether the practices and procedures of a research institution, a researcher or an institutional review board in relation to any human biomedical research are in compliance with this Act and the regulations made under this Act;

25 (d) assessing whether the practices and procedures of a tissue bank in relation to any tissue banking activity are in compliance with this Act and the regulations made under this Act.

(2) For the purposes of subsection (1), an authorised officer may —

30 (a) inspect and make copies of and take extracts from, or require the occupier or any person having the management or control of, the premises to provide copies of or extracts from, any book, document, record or electronic material;

- 5 (b) inspect and make copies of and take extracts from, or require the occupier or any person having the management or control of, the premises to provide copies of or extracts from, any medical record of any person who has been or who is being treated or examined at the premises, notwithstanding that the prior consent of such person has not been obtained;
 - (c) inspect any apparatus, appliance, equipment or instrument used or found in the premises;
 - 10 (d) inspect any test or procedure relating to any human biomedical research that has been or is being conducted in the premises;
 - 15 (e) inspect, test, examine, remove and detain any biological material or organism or any product of human biomedical research found in the premises;
 - 20 (f) inspect, test, examine and remove any container, article and other thing that the authorised officer reasonably believes to contain or to have contained any biological material or organism or any product of human biomedical research that has been or is being conducted in the premises.
- (3) An authorised officer may seize, remove and detain from any premises or place —
- (a) any biological material or organism or any product of human biomedical research;
 - 25 (b) any book, document, or record, apparatus, appliance, equipment or instrument which the authorised officer reasonably believes to be the subject matter of, or to be connected with the commission of, an offence under this Act.
- 30 (4) Any person who is present in any premises referred to in subsection (1) shall render all necessary assistance and co-operation to the authorised officer as are necessary for an entry, inspection, investigation or otherwise for the exercise of his powers under this Act in relation to those premises.

(5) An authorised officer may —

(a) require any person —

(i) to furnish any information within his knowledge; or

5 (ii) to produce any book, document, record, electronic material, article or thing within his possession for inspection by the authorised officer and the making of copies thereof, or to provide the authorised officer with copies of such book, document or other record;

10 (b) examine orally any person supposed to be acquainted with the facts and circumstances of any serious adverse event, contravention or suspected contravention, or related safety issues with respect to any matter under this Act, and shall —

15 (i) reduce to writing any statement made by the person so examined who shall be bound to state truly the facts and circumstances with which he is acquainted;

(ii) read the statement over to him; and

(iii) require the person so examined to sign the statement, after correction (if any); and

20 (c) require, by order in writing, the attendance before himself of any person, being within the limits of Singapore, who, from information given or otherwise, appears to be acquainted with the facts and circumstances of matters under this Act and that person shall attend as so required.

25 (6) Any person who, without reasonable excuse —

(a) obstructs, hinders or impedes an authorised officer in the exercise of his power under this section; or

30 (b) fails to comply with any order or requirement of an authorised officer under this section or to produce any book, document, record, electronic material, article or thing which he is required by or under this Act to produce to an authorised officer,

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.

(7) For the purposes of subsection (6), it is a reasonable excuse for a person to refuse or fail to furnish any information, produce any book, document or record or answer any question if doing so might tend to incriminate him.

Disposal of documents or articles

45.—(1) Any document or article produced, detained or seized under section 44 shall —

(a) where the document or article is produced in any criminal trial, be dealt with in accordance with section 364(1) of the Criminal Procedure Code (Cap. 68); or

(b) in any other case —

(i) be returned to the owner; or

(ii) if the owner is not known, be reported to a Magistrate's Court.

(2) Where the report of any document or article produced, detained or seized under section 44 is made to a Magistrate's Court under subsection (1)(b)(ii), the Magistrate's Court may order the document or article —

(a) to be forfeited; or

(b) to be disposed of in such manner as the Magistrate's Court thinks fit.

(3) Nothing in this section shall be taken to prejudice any right to retain or dispose of property which may exist in law apart from this section.

Minister may appoint committee of inquiry under Inquiries Act

46. In addition to the matters on which the Minister may appoint a committee of inquiry under section 9(1) of the Inquiries Act (Cap. 139A), the Minister may appoint a committee of inquiry under that section and direct the committee to inquire into —

- (a) any actual or suspected serious adverse event that has occurred; or
- (b) any contravention or suspected contravention of the requirements of the Act or any relevant code of practice or code of ethics issued under section 39 by a research institution, institutional review board, tissue bank or researcher, as the case may be.

Protected information

47.—(1) If a person exercising any function under this Act obtains protected information relating to the research being conducted or to be conducted, he shall not disclose that protected information to any other person unless the disclosure —

- (a) is made with the written consent of the research institution responsible for the supervision and control of the research;
- (b) is for the purpose of the administration or enforcement of this Act; or
- (c) is in compliance with the requirement of any court, tribunal, authority or person having lawful authority to require the production of documents or the answering of questions.

(2) Any person who contravenes subsection (1) 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.

(3) For the purposes of this section —

- (a) the reference to a person disclosing any protected information includes his permitting any other person to have any access to any record, document or other thing containing that information which is in his possession or under his control; and
- (b) “protected information” means information the disclosure of which would, or could reasonably be expected to disclose confidential information or to adversely affect a person or a

research institution in relation to the research being conducted or to be conducted.

Enhanced penalty for corporations

5 **48.** Where a body corporate is convicted of an offence under this Act, the penalty that the court may impose shall be a fine not exceeding 2 times the maximum amount that the court could, but for this section, impose as a fine for that offence.

Liability of employers for acts of employees

10 **49.**—(1) Any act done or conduct engaged in by a person in the course of his employment (referred to in this section as the employee) shall be treated for the purposes of this Act as done or engaged in by his employer as well as by him, whether or not it was done or engaged in with the employer's knowledge or approval.

15 (2) In any proceedings for an offence under this Act brought against any person in respect of an act or conduct alleged to have been done or engaged in, as the case may be, by an employee of that person, it is a defence for that person to prove that he took such steps as were practicable to prevent the employee from doing the act or engaging in the conduct, or from doing or engaging in, in the course of his employment, acts or conduct, as the case may be, of that description.

(3) This section shall not apply to an employer which is the Government or a ministry or department of the Government.

Offences by bodies corporate, etc.

25 **50.**—(1) Where an offence under this Act committed by a body corporate is proved —

(a) to have been committed with the consent or connivance of an officer; or

(b) to be attributable to any neglect on his part,

30 the officer as well as the body corporate shall be guilty of the offence and shall be liable to be proceeded against and punished accordingly.

(2) Where the affairs of a body corporate are managed by its members, subsection (1) shall apply in relation to the acts and defaults of a member in connection with his functions of management as if he were a director of the body corporate.

5 (3) Where an offence under this Act committed by a partnership is proved —

(a) to have been committed with the consent or connivance of a partner; or

(b) to be attributable to any neglect on his part,

10 the partner as well as the partnership shall be guilty of the offence and shall be liable to be proceeded against and punished accordingly.

(4) Where an offence under this Act committed by an unincorporated association (other than a partnership) is proved —

15 (a) to have been committed with the consent or connivance of an officer of the unincorporated association or a member of its governing body; or

(b) to be attributable to any neglect on the part of such an officer or member,

20 the officer or member as well as the unincorporated association shall be guilty of the offence and shall be liable to be proceeded against and punished accordingly.

(5) In this section —

“body corporate” includes a limited liability partnership;

25 “officer” —

(a) in relation to a body corporate, means any director, partner, member of the committee of management, chief executive, manager, secretary or other similar officer of the body corporate and includes any person purporting to act in any such capacity; or

30

(b) in relation to an unincorporated association (other than a partnership), means the president, the secretary, or any member of the committee of the unincorporated

association, or any person holding a position analogous to that of president, secretary or member of a committee and includes any person purporting to act in any such capacity;

5 “partner” includes a person purporting to act as a partner.

(6) Regulations may provide for the application of any provision of this section, with such modifications as the Minister considers appropriate, to any body corporate or unincorporated association formed or recognised under the law of a territory outside Singapore.

10 **Composition of offences**

51.—(1) The Director or any authorised officer authorised by the Director may, in his discretion, compound any offence under this Act which is prescribed as a compoundable offence by collecting from a person reasonably suspected of having committed the
15 offence a sum not exceeding the lower of the following sums:

(a) one half of the amount of the maximum fine that is prescribed for the offence;

(b) a sum of \$5,000.

(2) On payment of such sum of money, no further proceedings
20 shall be taken against that person in respect of the offence.

(3) The Minister may make regulations to prescribe the offences which may be compounded.

(4) All sums collected under this section shall be paid into the Consolidated Fund.

25 **PART 9**

APPEALS

Appeal to Minister

52.—(1) Any person who is aggrieved by —

(a) any decision of the Director in the exercise of any discretion
30 vested in him by or under this Act other than section 42;

- (b) any order made or direction given by the Director under this Act other than section 42; or
 - (c) anything contained in any code of practice or code of ethics issued or approved by the Director under section 39,
- 5 may, within 14 days after being notified of the decision, notice or direction, or the issue or approval of the code of practice or standard of performance, as the case may be, (or such longer period as the Minister may allow), appeal to the Minister in the prescribed manner.
- 10 (2) Any person who is aggrieved by any prohibition order made by the Director under section 42 may, within 90 days after the date on which the order was published in the *Gazette* (or such longer period as the Minister may allow), appeal to the Minister in the prescribed manner.
- 15 (3) Any person who makes an appeal to the Minister under subsection (1) or (2) shall, within the period specified therein —
 - (a) state as concisely as possible the circumstances under which the appeal arises, the issues and grounds for the appeal; and
 - (b) submit to the Minister all relevant facts, evidence and arguments for or against the appeal, as the case may be.
- 20 (4) Where an appeal has been made to the Minister under subsection (1) or (2), the Minister may require —
 - (a) any party to the appeal; and
 - (b) any person who is not a party to the appeal but appears to the Minister to have information that is relevant to the matters mentioned in that subsection,
- 25 to provide the Minister with all such information as he may require (whether for the purpose of deciding if an Appeals Advisory Panel should be established or for determining the appeal), and any person so required to provide such information must provide it in such manner and within such period as may be specified by the Minister.
- 30 (5) The Minister may reject any appeal of an appellant who fails to comply with subsection (3) or (4).

(6) Unless otherwise provided by this Act or the Minister, where an appeal is lodged under this section, the decision, order, direction or other thing appealed against shall be complied with until the determination of the appeal.

5 (7) The Minister may determine an appeal under this section —

(a) by confirming, varying or reversing any decision, order or direction of, or code of practice or code of ethics issued or approved by, the Director; or

10 (b) by directing the Director to reconsider its decision, order, direction, code of practice or code of ethics, as the case may be.

(8) Before determining an appeal under subsection (7) and for the purpose of forming an opinion on which to base such determination, the Minister may consult such Appeals Advisory Panel established for the purpose of advising the Minister in respect of the appeal but, in making such determination, shall not be bound by such consultation.

(9) The decision of the Minister in any appeal shall be final.

20 (10) The Minister may make rules in respect of the manner in which an appeal may be made to, and the procedure to be adopted in the hearing of any appeal by, the Minister under this section.

Appeals Advisory Panel

25 **53.**—(1) Where the Minister considers that an appeal lodged under section 52(1) or (2) involves issues of such nature or complexity that it ought to be considered and determined by persons with particular medical, scientific or other specialised knowledge, he may establish an Appeals Advisory Panel, comprising one or more of such persons with particular medical, scientific or other specialised knowledge and such other persons as the Minister considers appropriate, to provide advice to the Minister with regard to the discharge of his functions under section 52 in respect of any appeal that has been made to the Minister under section 52(1) or (2).

30 (2) For the purposes of establishing an Appeals Advisory Panel, the Minister may do all or any of the following:

- (a) determine or vary the terms of reference of the Appeals Advisory Panel;
 - (b) appoint persons to be the chairperson and other members of an Appeals Advisory Panel;
 - 5 (c) at any time remove the chairperson or other member of an Appeals Advisory Panel from such office;
 - (d) determine the procedure to be adopted by the Appeals Advisory Panel in considering any matter referred to it;
 - 10 (e) determine any other matters which the Minister considers incidental or expedient for the proper and efficient conduct of business by the Appeals Advisory Panel.
- (3) An Appeals Advisory Panel may regulate its proceedings as it considers appropriate, subject to the following:
- 15 (a) the quorum for a meeting of the Appeals Advisory Panel shall be a majority of its members;
 - (b) a decision supported by a majority of the votes cast at a meeting of the Appeals Advisory Panel at which a quorum is present shall be the decision of that Panel.
- (4) An Appeals Advisory Panel shall be independent in the performance of its functions.
- 20

PART 10

MISCELLANEOUS

Application of Act to Government

25 **54.**—(1) Except as otherwise provided in subsection (2), this Act shall bind the Government and shall apply to the Government including any human biomedical research conducted under the supervision and control of the Government.

(2) Nothing in this Act shall render the Government liable to prosecution for an offence.

30 (3) For the avoidance of doubt, no person shall be immune from prosecution for any offence under this Act by reason that the person

is employed by, seconded to or engaged to provide services to the Government.

Power to exempt

5 **55.** The Minister may, either permanently or for such period as the Minister may think fit and subject to such conditions as the Minister may impose, exempt from all or any of the provisions of this Act —

- (a) any person, research institution or tissue bank;
- (b) any class of persons, research institutions or tissue banks;
- (c) any ministry or department of the Government;
- 10 (d) any human biomedical research or tissue banking activity;
or
- (e) any class of human biomedical research or human biological material.

Service of documents, etc.

15 **56.—**(1) Subject to subsection (3), any document required or authorised to be served under this Act may be served —

- (a) in the case of an individual —
 - (i) by delivering it to the individual personally;
 - (ii) by leaving it with an adult person apparently resident
20 at, or by sending it by pre-paid registered post to, the
usual or last known address of the place of residence
of the individual;
 - (iii) by leaving it with an adult person apparently
25 employed at, or by sending it by pre-paid registered
post to, the usual or last known address of the place
of business of the individual;
 - (iv) by affixing a copy of the notice in a conspicuous
place at the usual or last known address of residence
or business of the individual;
 - 30 (v) by sending it by facsimile transmission to the fax
transmission number operated at the usual or last

5 known address of the place of residence or business of the individual, or the last fax number given to the Director or an authorised officer by the individual as the facsimile transmission number for the service of documents on the individual; or

10 (vi) by electronic communication, by sending an electronic communication of the document to the last email address given to the Director or an authorised officer by the individual as the email address for the service of documents on the individual;

(b) in the case of a partnership other than a limited liability partnership —

15 (i) by delivering it to any one of the partners or the secretary or other like officer of the partnership;

(ii) by leaving it at, or by sending it by pre-paid registered post to, the principal or last known place of business of the partnership in Singapore;

20 (iii) by sending it by facsimile transmission to the fax transmission number operated at the principal or last known place of business of the partnership in Singapore; or

25 (iv) by electronic communication, by sending an electronic communication of the document to the last email address given to the Director or an authorised officer by the partnership as the email address for the service of documents on the partnership; and

(c) in the case of any limited liability partnership or any other body corporate —

30 (i) by delivering it to the secretary or other like officer of the body corporate or, in the case of a limited liability partnership, the manager thereof;

(ii) by leaving it at, or by sending it by pre-paid registered post to, the registered office or principal

office of the limited liability partnership or body corporate in Singapore;

(iii) by sending it by facsimile transmission to the fax transmission number operated at the registered office or principal office of the limited liability partnership or body corporate in Singapore; or

(iv) by electronic communication, by sending an electronic communication of the document to the last email address given to the Director or an authorised officer by the limited liability partnership or body corporate as the email address for the service of documents on the limited liability partnership or body corporate.

(2) Where any notice or other document to be served by the Director or the Minister is —

(a) sent by a facsimile transmission to the fax transmission number operated at the last known place of residence or business or registered office or principal office in accordance with subsection (1), it shall be deemed to have been duly served on the person to whom it is addressed on the day of transmission, subject to receipt on the sending facsimile machine of a notification (by electronic or other means) of a successful transmission to the place of residence or business or registered office or principal office, as the case may be;

(b) sent by electronic communication to an email address in accordance with subsection (1), it shall be deemed to have been duly served on the person to whom it is addressed at the time of entering the information system addressed to the email address; and

(c) sent by pre-paid registered post, it shall be deemed to have been duly served on the person to whom it is addressed 2 days after the day the notice or document was posted, whether or not it is returned undelivered.

(3) Service of any document under this Act on a person by electronic communication may be effected only if the person gives as part of his or its address for service an email address.

5 (4) This section shall not apply to notices and documents to be served in proceedings in court.

Jurisdiction of court

10 **57.** Notwithstanding any provision to the contrary in the Criminal Procedure Code (Cap. 68), a District Court shall have jurisdiction to try any offence under this Act and shall have power to impose the full penalty or punishment in respect of the offence.

Protection from personal liability

58. No liability shall be incurred by the Director or any authorised officer for anything which is done or intended to be done in good faith and with reasonable care in —

- 15 (a) the exercise or purported exercise of any power under this Act; or
- (b) the performance or purported performance of any function or duty under this Act.

Amendment of Schedules

20 **59.—**(1) The Minister may at any time, by order published in the *Gazette*, amend the First, Second and Third Schedules.

(2) The Minister may, in any order made under subsection (1), make such incidental, consequential or supplementary provision as may be necessary or expedient.

Regulations

25 **60.—**(1) The Minister may make regulations for carrying out the purposes and provisions of this Act and for prescribing anything that is required to be prescribed.

30 (2) Without prejudice to the generality of subsection (1), the Minister may make regulations with respect to any or all of the following matters:

- (a) the duties of research institutions, appointing bodies of institutional review boards, and researchers;
- (b) the qualifications of researchers;
- 5 (c) the composition, duties, procedures, responsibilities and powers of institutional review boards;
- (d) the duties and responsibilities, qualifications of and training to be received by members of institutional review boards;
- 10 (e) the practices, procedures and other requirements for the conduct of human biomedical research or tissue banking activity, including —
 - (i) the standards to be adhered to in the conduct of any human biomedical research or tissue banking activity;
 - 15 (ii) the procedures for the selection of research subjects for any biomedical research and for obtaining the appropriate consent for their participation as donors or subjects in such human biomedical research;
 - (iii) the appropriate consent required for the participation of vulnerable persons as research subjects in human biomedical research;
 - 20 (iv) the records and documents to be maintained by researchers or tissue banks and the information to be contained in such records and documents;
 - 25 (v) the furnishing to the Director of such information, returns and reports as the Director may require or as may be prescribed in connection with the administration and enforcement of this Act; and
 - 30 (vi) the requirements pertaining to specific types of human biomedical research or tissue banking activity;
- (f) the procedures and requirements in relation to obtaining appropriate consent and the form of consent;

- (g) the requirements in relation to reporting of and investigations into any serious adverse event;
- (h) the duties, procedures, responsibilities and powers of Inquiries Committees;
- 5 (i) the establishment of a scheme of accreditation for research institutions, researchers or institutional review boards, as the case may be, in relation to their compliance with the requirements of this Act;
- (j) the licensing of tissue banks and tissue banking activities;
- 10 (k) the forms necessary for the administration of this Act; and
- (l) the fees and charges payable under or for the purposes of this Act.

(3) The Minister may, in making any regulations, provide that any contravention of or failure to comply with any regulation shall be an offence punishable with a fine not exceeding \$50,000 or with imprisonment for a term not exceeding 12 months or with both.

Savings and transitional provisions for legacy human biological materials

61.—(1) This Act, with the exception of sections 29 (prohibited human biomedical research), 30 (restricted human biomedical research), 31 (commercial trading of human tissues prohibited) and 32 (advertisements relating to commercial trading of human tissues prohibited), shall not apply to any legacy human biological material or any information derived from such material.

(2) Notwithstanding subsection (1), regulations made under section 60 may provide for requirements and conditions in relation to the use of legacy human biological material for human biomedical research that are different from the provisions of this Act.

(3) In this section, “legacy human biological material” means —

- (a) any human biological material which has been removed from a human body, whether living or dead, at any time

before the date of commencement of this section (referred to in this section as the appointed day);

- (b) any biological material from the body of a dead person which has been stored for the purposes of human biomedical research at any time before the appointed day, and which has been rendered non-identifiable within the meaning of section 26(3) at any time before the appointed day.

Savings and transitional provisions

- 62.**—(1) Every research institution which immediately before the appointed day was supervising or controlling the conduct of human biomedical research may continue supervising or controlling the conduct of human biomedical research as if this Act had not been enacted for a period of 12 months after that day or for such other longer period as the Director may in any particular case allow.
- (2) Every person who immediately before the appointed day was conducting any human biomedical research may continue conducting the research as if this Act had not been enacted for a period of 12 months after that day or for such other longer period as the Director may in any particular case allow.
- (3) For a period of 2 years after the appointed day, the Minister may, by regulations, prescribe such additional provisions of a savings or transitional nature consequent on the enactment of this Act as he may consider necessary or expedient.

FIRST SCHEDULE

25

Sections 2, 29 and 59(1)

PROHIBITED HUMAN BIOMEDICAL RESEARCH

1. Human biomedical research involving the development of human-animal combination embryos beyond 14 days or the appearance of the primitive streak, whichever is the earlier.
2. Human biomedical research involving the insertion of brain-specific human cells or human stem cells into the brains of great apes.

SECOND SCHEDULE

Sections 2, 30 and 59(1)

RESTRICTED HUMAN BIOMEDICAL RESEARCH

1. Human biomedical research involving human eggs or human embryos.
- 5 2. Human biomedical research involving human-animal combination embryos created by the incorporation of human genetic material or cells.
3. Human biomedical research involving entities created as a result of —
 - (a) the introduction of human cells into animal foetus;
 - (b) the introduction of human pluripotent stem cells (including induced pluripotent stem cells) or human neural cells (and their precursor cells)

10 into the postnatal animal; or
 - (c) the introduction of human cells into the brain of a living postnatal animal.
- 15 4. In this Schedule, a “cytoplasmic hybrid” means an embryo created by replacing the nucleus of an animal egg or an animal cell or 2 animal pronuclei, with 2 human pronuclei, one nucleus of a human gamete or of any other human cell.

THIRD SCHEDULE

Sections 12 and 59(1)

20 WAIVER OF REQUIREMENTS FOR APPROPRIATE CONSENT BY INSTITUTIONAL REVIEW BOARD

PART 1

WAIVER OF REQUIREMENTS FOR APPROPRIATE CONSENT TO BE IN WRITING

- 25 1. Where the institutional review board is satisfied that the human biomedical research or use of the human tissue, as the case may be, involves no more than minimal risk to the research subject or donor and involves no procedures for which written consent is ordinarily required outside of a research context (for therapeutic or diagnostic purposes).
- 30 2. Where the institutional review board is satisfied that the only record linking the research subject and the human biomedical research or use of the human tissue, as the case may be, is or will be the consent form and the principal risk to

the research subject or donor is the potential harm resulting from unauthorised disclosure of confidential information such as the research subject's identity and the fact of his participation in the research.

PART 2

5 WAIVER OF REQUIREMENT FOR APPROPRIATE CONSENT FOR HUMAN BIOMEDICAL RESEARCH INVOLVING HUMAN BIOLOGICAL MATERIAL OR HEALTH INFORMATION

3. Where the institutional review board is satisfied that —
 - 10 (a) the individually-identifiable human biological material or health information research, as the case may be, may not practicably be carried out unless there is a waiver;
 - (b) the use of the individually-identifiable human biological material or health information, as the case may be, involves no more than minimal risk to the research subject or donor;
 - 15 (c) the waiver concerned will not otherwise adversely affect the rights and welfare of the research subject or donor; and
 - (d) the human biomedical research or health information research would reasonably be considered to contribute to the greater public good.

PART 3

20 WAIVER OF REQUIREMENT FOR APPROPRIATE CONSENT FOR EMERGENCY RESEARCH

4. Where the institutional review board is satisfied that the human biomedical research is emergency research and where —
 - (a) the research subjects are in a life-threatening situation;
 - 25 (b) there is no professionally accepted standard of treatment or the available treatments are unproven;
 - (c) the collection of valid scientific evidence is necessary to determine the safety and effectiveness of a particular intervention or treatment;
 - (d) participation in the proposed research holds out the prospect of direct benefit to the research subjects;
 - 30 (e) obtaining informed consent is not feasible because the subjects will not have capacity within the time available to give their informed consent as a result of their medical condition or situation;
 - (f) the human biomedical research may not practicably be carried out unless there is a waiver; and
 - 35

- (g) whenever appropriate, the research subject will be provided with additional pertinent information after his participation.

5 5. In paragraph 4, “emergency research” means human biomedical research where life-threatening emergency situations may arise such that appropriate consent may not be obtained before the research subject is subjected to any intervention or after any individually-identifiable biological material obtained from his body, or any of his individually-identifiable health information is used.

EXPLANATORY STATEMENT

This Bill seeks to —

- (a) regulate the conduct of human biomedical research and to further regulate certain restricted human biomedical research;
- (b) prohibit certain types of human biomedical research;
- (c) regulate tissue banking; and
- (d) prohibit the commercial trading of human tissues.

PART 1

PRELIMINARY

Part 1 sets out the preliminary provisions of the Bill.

Clause 1 relates to the short title and commencement.

Clause 2 sets out the various definitions of terms used in the Bill.

Clause 3 defines “human biomedical research”.

PART 2

ADMINISTRATION OF ACT

Part 2 deals with the administration of the Bill.

Clause 4 provides that the Director of Medical Services (the Director) will be responsible for the administration and enforcement of the Bill subject to the general and special directions of the Minister. The clause provides for the appointment of authorised officers and empowers the Director to delegate the powers conferred under this Bill to any authorised officer. The Director may also authorise other persons to assist in the administration and enforcement of the Bill.

Clause 5 empowers the Minister to establish advisory committees for the purpose of advising him on any matter arising out of the administration of this Bill. The Director is also empowered to establish advisory committees for the

purpose of advising him on any matter arising out of the administration, functions and enforcement of the Bill.

PART 3

CONSENT

Part 3 deals with appropriate consent.

Clause 6 provides for how appropriate consent must be taken.

Clause 7 provides for consent may be given in the case of adults.

Clause 8 provides for consent for research involving minors.

Clause 9 provides for consent for use or removal of tissues involving minors.

Clause 10 provides for how consent may be obtained in the case of dead persons.

Clause 11 specifies the information that has to be provided before taking appropriate consent.

Clause 12 empowers an institutional review board to waive in circumstances specified in the Third Schedule.

Clause 13 provides that a research subject or tissue donor or any person who gives consent on their behalf may, at any time, withdraw such consent. The withdrawal of consent however will not affect the research information obtained before the consent is withdrawn and such information may be retained and used for the research.

PART 4

INSTITUTIONAL REVIEW BOARDS

Part 4 deals with the establishment and conduct of institutional review boards.

Clause 14 imposes the duty on every research institution to appoint one or more institutional review boards for the purpose of reviewing human biomedical research conducted under the control or supervision of that research institution. A research institution is also under a duty to inform the Director of the appointment or revocation of appointment of its institutional review board.

Clause 15 provides that in a multi-research institutions common human biomedical research project, the research institutions may, instead of appointing the institutional review boards appointed by them, appoint a common institutional review board which may be either a board appointed by the lead research institution or another institutional review board as agreed amongst the institutions.

Clause 16 sets out the functions of an institutional review board and provides for expedited reviews performed solely by the chairman or other authorised member.

Clause 17 relates to the composition, quorum and proceedings of institutional review boards.

Clause 18 provides that a member of an institutional review board will declare at every meeting of the board the nature and extent of all conflicts of interest or potential conflicts of interest in relation to a matter under consideration by the board at that meeting.

Clause 19 provides that every application to an institutional review board for the review of human biomedical research will be made by one or more researchers responsible for the conduct and supervision of the research in accordance with prescribed requirements.

Clause 20 provides for appeals against the decision of an institutional review board to the research institution. The research institution may —

- (a) dismiss the appeal;
- (b) direct the board to reconsider and review its decision; or
- (c) direct the researcher to submit the research to another institutional review board for a second initial review.

PART 5

REGULATION OF HUMAN BIOMEDICAL RESEARCH

Part 5 deals with the regulation of human biomedical research.

Clause 21 deals with the conduct of human biomedical research and sets out the duties of a researcher.

Clause 22 deals with the functions and duties of research institutions.

Clause 23 imposes a duty on every research institution to submit a declaration of compliance.

Clause 24 provides that no human biomedical research can be conducted without the appropriate consent of a person for participation as a research subject, including the use of his biological material or individually-identifiable health information. The appropriate consent must be obtained in accordance with the requirements of Part 3.

Clause 25 prohibits the coercion, intimidation or deception of another person against that person's will to participate or continue to participate as a research subject in any human biomedical research.

Clause 26 imposes a duty on every person who has obtained individually-identifiable information or human biological material for the

purposes of human biomedical research to take all reasonable steps and safeguards as may be necessary, including rendering information or material non-identifiable, to protect the confidentiality of such information or material.

Clause 27 prohibits the re-identification of individually-identifiable information or human biological material relating to human biomedical research that has been rendered non-identifiable.

Clause 28 imposes restrictions on the disclosure of any individually-identifiable information of any research subject which has come to a person's knowledge in the course of discharging his functions or duties under this Bill, or by virtue of his conduct or review of the human biomedical research.

Clause 29 prohibits any research institution or person from conducting, supervising or controlling any prohibited human biomedical research specified in the First Schedule.

Clause 30 imposes additional requirements on any research institution or person conducting, supervising or controlling any restricted human biomedical research specified in the Second Schedule.

PART 6

REGULATION OF TISSUE BANKING

Part 6 deals with the regulation of tissue banking.

Clause 31 prohibits the commercial trading of human tissues. To avoid overlap, the clause and clause 32 will not apply to any human tissue to which the prohibition against commercial trading already applies in the Human Organ Transplant Act (Cap. 131A) and the Human Cloning and Other Prohibited Practices Act (Cap. 131B).

Clause 32 is supplementary to clause 31 and prohibits advertisements relating to commercial trading of human tissues.

Clause 33 imposes a duty on every tissue bank to notify the Director of its particulars. A research institution is also under a duty to notify the Director of any tissue bank which it is directly or indirectly operating or which is part of the research institution.

Clause 34 provides for the duties imposed on tissue banks.

Clause 35 imposes a duty on every tissue bank to submit a declaration of compliance for all tissue banking activities conducted under the supervision and control of the tissue bank.

Clause 36 imposes restrictions on certain tissue banking activities namely the removal, storage, supply and use of human tissues.

Clause 37 prohibits the coercion, intimidation or deception of another person against that person's will to allow his human tissue to be removed.

Clause 38 imposes restrictions on the disclosure of any individually-identifiable information of any research subject which has come to a person's knowledge.

PART 7

CODES OF PRACTICE AND ETHICS

Part 7 deals with codes of practice and codes of ethics.

Clause 39 empowers the Director to issue or approve codes of practice for the purpose of providing guidance with respect to the requirements of this Bill relating to safety and research practices and for standards. The clause also empowers the Director to issue or adopt codes of ethics for the ethical conduct of human biomedical research or tissue banking activity.

Clause 40 explains the use and effect of codes of practice and codes of ethics in criminal proceedings. The codes may be referred to in determining whether any activity or practice in or in relation to the conduct of human biomedical research or tissue banking activity is reasonable and in accordance with the generally accepted practices and principles of ethical conduct.

PART 8

ENFORCEMENT POWERS

Part 8 sets out the enforcement powers.

Clause 41 empowers the Director to make in certain specified circumstances a stoppage order to immediately stop all activities related to the human biomedical research or tissue banking.

Clause 42 empowers the Director to make a prohibition order to prohibit any person from conducting any, all or specified types of human biomedical research or tissue banking activities in specified circumstances.

Clause 43 allows the subject of a prohibition order to apply to the Director for the order to be reviewed.

Clause 44 provides for authorised officers to be conferred with the powers of entry, inspection and search, etc.

Clause 45 provides for the disposal of any document or article produced, detained or seized under clause 44.

Clause 46 empowers the Minister to appoint a committee of inquiry under the Inquiries Act (Cap. 139A) and direct it to inquire into the matters specified in that clause in addition to the matters specified in section 9(1) of the Inquiries Act. The additional matters are —

- (a) any actual or suspected serious adverse event that has occurred; or

- (b) any contravention or suspected contravention of the requirements of the Bill or any relevant code of practice or code of ethics by a research institution, institutional review board, tissue bank or researcher, as the case may be.

Clause 47 imposes a restriction on the disclosure of certain confidential information relating to the research being conducted or to be conducted by a person exercising any function under the Bill.

Clause 48 provides for an enhanced penalty not exceeding twice the prescribed fine if a body corporate is convicted of an offence under this Bill.

Clause 49 provides that any act done or conduct engaged in by an employee in the course of his employment is to be treated as done or engaged in by his employer as well as by him, whether or not it was done or engaged in with the employer's knowledge or approval.

Clause 50 relates to the liability of directors and partners for any offence under the Bill committed by a company or firm.

Clause 51 empowers the Director or any authorised officer authorised by the Director to compound an offence prescribed by regulations to be compoundable. This may be done by collecting from a person reasonably suspected of having committed the offence a sum not exceeding one half of the amount of the maximum fine that is prescribed for the offence or a sum of \$5,000, whichever is the lower.

PART 9

APPEALS

Part 9 deals with appeals.

Clause 52 provides for appeal to the Minister by any person aggrieved by certain decisions of or orders or directions made by the Director. The Minister may determine an appeal by confirming, varying or reversing any decision, notice or direction of, or code of practice or standard of performance issued by, the Director, or by directing the Director to reconsider its decision, notice, direction, code of practice or standard of performance, as the case may be. Before determining an appeal, the Minister may also consult such Appeals Advisory Panel established under clause 53 for the purpose of advising the Minister in respect of the appeal, but, in making such determination, he is not to be bound by such consultation.

Clause 53 empowers the Minister to form an Appeals Advisory Panel where the Minister considers that an appeal lodged under clause 52 involves issues of such nature or complexity that it ought to be considered and determined by persons with particular medical, scientific or other specialised knowledge. The Appeals Advisory Panel will comprise one or more of such persons with particular technical or other specialised knowledge and such other persons as the

Minister considers appropriate, and they will provide advice to the Minister with regard to the discharge of his functions under clause 52 in respect of any appeal.

PART 10

MISCELLANEOUS

Part 10 contains the miscellaneous provisions of the Bill.

Clause 54 deals with the application of the Bill to the Government. The Bill will apply to human biomedical research conducted under the supervision and control of the Government.

Clause 55 empowers the Minister to exempt any person, any ministry or department of the Government or any human biomedical research or any class of persons or any human biomedical research or class of human biomedical research from all or any of the provisions of the Bill.

Clause 56 relates to the service of documents.

Clause 57 confers on the District Court jurisdiction to try any offence under the Bill and power to impose the full penalty or punishment in respect of the offence.

Clause 58 confers upon the Director or any authorised officer immunity from liability for anything which is done or intended to be done in good faith and with reasonable care in the exercise or purported exercise of any power under the Bill or the performance or purported performance of any function or duty under the Bill.

Clause 59 empowers the Minister to amend the First, Second and Third Schedules by order published in the *Gazette*.

Clause 60 empowers the Minister to make regulations for certain matters.

Clause 61 provides for savings and transitional provisions for legacy human biological material.

Clause 62 provides for certain savings and transitional matters.

The First Schedule sets out the types of human biomedical research that are prohibited.

The Second Schedule sets out the types of human biomedical research that are restricted and subject to additional requirements.

The Third Schedule sets out the circumstances under which appropriate consent may be waived by an institutional review board.

EXPENDITURE OF PUBLIC MONEY

This Bill will involve the Government in extra financial expenditure, the exact amount of which cannot at present be ascertained.
