



REPUBLIC OF SINGAPORE

GOVERNMENT GAZETTE

BILLS SUPPLEMENT

Published by Authority

NO. 25]

MONDAY, JULY 13

[2015

First published in the *Government Gazette*, Electronic Edition, on 13th July 2015 at 5:00 pm.

Notification No. B 25 — The Human Biomedical Research Bill is hereby published for general information. It was introduced in Parliament on 13th July 2015.

Human Biomedical Research Bill

Bill No. 25/2015.

Read the first time on 13 July 2015.

HUMAN BIOMEDICAL RESEARCH ACT 2015

(No. of 2015)

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A BILL

intituled

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, to prohibit commercial trading of human tissue, to provide for matters connected therewith and to make related amendments to certain other Acts.

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

1. This Act may be cited as the Human Biomedical Research Act
5 2015 and comes into operation on such date as the Minister may, by
notification in the *Gazette*, appoint.

General interpretation

2. In this Act, unless the context otherwise requires —

10 “adult” means a person who is 21 years of age or older or a
person below 21 years of age who was or is married;

“adult who lacks mental capacity” means an adult who lacks
capacity within the meaning of section 4 of the Mental
Capacity Act (Cap. 177A);

15 “appointed day”, in relation to a particular provision or Part of
this Act, means the date of commencement of that provision
or Part;

“appropriate consent” means the consent given by a person or,
where applicable, by another person on his or her behalf, in
accordance with Part 3;

20 “authorised officer” means any public officer or any officer of
any statutory body appointed by the Director under
section 4(2);

“biomedical research”, except for the purposes of section 3, has
the same meaning as “human biomedical research”;

25 “cytoplasmic hybrid embryo” means a human-animal
combination embryo created —

(a) by replacing the nucleus of an animal egg or of an
animal cell, or 2 animal pronuclei, with —

(i) 2 human pronuclei;

30 (ii) one nucleus of a human gamete or of any other
human cell; or

- (iii) one human gamete or other human cell; or
 - (b) by replacing the nucleus of a human egg or of a human cell, or 2 human pronuclei, with —
 - (i) 2 animal pronuclei;
 - (ii) one nucleus of an animal gamete or of any other animal cell; or 5
 - (iii) one animal gamete or other animal cell;
- “declaration of compliance” means a declaration by a research institution or a tissue bank of its compliance with the requirements of this Act; 10
- “deputy”, in relation to an adult who lacks mental capacity, means a deputy appointed by the court under the Mental Capacity Act;
- “Director” means the Director of Medical Services;
- “donee”, in relation to an adult who lacks mental capacity, means the donee of that adult’s lasting power of attorney; 15
- “donor”, in relation to human tissue, means a natural person, whether living or dead, from whose body the human tissue is obtained;
- “health information” means information pertaining to an individual — 20
- (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; 25
- “healthcare institution” means —
- (a) any private hospital, medical clinic, clinical laboratory or healthcare establishment licensed under the Private Hospitals and Medical Clinics Act (Cap. 248); or
 - (b) any facility, premises or conveyance which is declared 30
by the Minister, by order published in the *Gazette*, to be a healthcare institution for the purposes of this Act;

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

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

“human tissue” or “tissue” means any human biological material but excludes human biological material specified in the First Schedule;

10 “incidental finding”, in relation to human biomedical research, means a finding about a research subject that has potential health or reproductive importance to the research subject and is discovered in the course of conducting research but is unrelated to the purposes, objectives or variables of the study;

15 “individually-identifiable”, in relation to human biological material or health information pertaining to an individual, means that the individual can be identified —

(a) from the human biological material or health information; or

20 (b) from that human biological material or health information and other information to which the person, research institution, tissue bank or other organisation has or is likely to have access;

25 “institutional review board” means a board or committee appointed by a research institution under section 15 or 16 to conduct an ethics review of proposed human biomedical research;

“lasting power of attorney” means a valid lasting power of attorney registered under the Mental Capacity Act;

30 “medical practitioner” means a person who is registered, or deemed to be registered, as a medical practitioner under the Medical Registration Act (Cap. 174);

“minimal risk”, in relation to human biomedical research or tissue banking activity, means the probability and magnitude of harm and discomfort anticipated in the research or the

removal of human tissue that are not greater, in and of themselves, than those ordinarily encountered —

- (a) in the daily life of normal and healthy persons; or
- (b) during the performance of routine physical or psychological examinations or tests;

5

“minor” means a person who is below 21 years of age and who has never been married;

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

“research” means any systematic investigation with the intention of developing or contributing to generalisable knowledge;

10

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

- (a) engages, directly or indirectly (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;

15

20

“research subject” means a natural person, whether living or dead —

- (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;

25

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

30

“restricted human biomedical research” means any human biomedical research specified in the Fourth 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” —

- 5 (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;
 - 10 (iii) requires in-patient 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; or
 - 15 (vi) results in such other event as may be prescribed;
- (b) in relation to tissue banking activity, means any untoward occurrence associated with the procurement, testing, processing, storage or distribution of human
- 20 tissue (including gametes or embryos) intended for human application which —
- (i) results in or contributes to death;
 - (ii) is life-threatening;
 - (iii) requires in-patient hospitalisation or
 - 25 prolongation of existing hospitalisation;
 - (iv) results in or contributes to persistent or significant disability or incapacity;
 - (v) results in the transmission of a communicable disease;
 - 30 (vi) results in any misidentification or mix-up of any type of tissue, gametes or embryo; or
 - (vii) results in such other event as may be prescribed;

“tissue bank” means an individual or a body of persons, whether corporate or unincorporate, or other organisation, that carries on or conducts any tissue banking activity but excludes an individual, a body of persons or an organisation that conducts any tissue banking activity solely for the purpose of the person’s or organisation’s own human biomedical research approved or exempted from review by an institutional review board; 5

“tissue banking activity” means a structured and an organised activity involving human tissue for the purposes of facilitating current or future research or for public health or epidemiological purposes or any combination of such purposes including any of the following activities: 10

- (a) the collection, storage, procurement or importation of human tissue; 15
- (b) the supply, provision or export of human tissue.

Meanings of “human biomedical research” and “supervision and control”

3.—(1) In this Act, “human biomedical research” means the research specified in subsection (2) or (3) but subject to subsection (4). 20

(2) Any research that is intended to study —

- (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 25
- (c) the performance or endurance of human individuals,

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; 30

(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 —

5 (a) human gametes or human embryos;

(b) cytoplasmic hybrid embryos;

(c) the introduction of any human-animal combination embryo into an animal or a human;

10 (d) the introduction of human stem cells (including induced pluripotent stem cells) or human neural cells into an animal at any stage of development (including a prenatal animal foetus or animal embryo); or

(e) any entity created as a result of any process referred to in paragraph (c) or (d).

15 (4) Subsections (2) and (3) do not apply to such research, studies or activities that are specified in the Second Schedule.

(5) For the purposes of this Act, human biomedical research is 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.

20

PART 2

ADMINISTRATION OF ACT

Administration of Act

25 **4.—**(1) The Director is responsible for the administration and enforcement of this Act, subject to the general and special directions of the Minister.

(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.

30

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

(4) Every authorised officer when exercising any of his or her powers under this Act must, if not in uniform, declare his or her office and must, on demand, produce to any person affected by the exercise of that power such identification card as the Director may direct to be carried by the authorised officer when exercising such power. 5

(5) The Director may, in writing, delegate all or any of the powers conferred on the Director by this Act to any authorised officer subject to such conditions or restrictions as the Director thinks fit, except the power of delegation conferred by this subsection. 10

(6) The Director may, in writing, authorise any other person to assist the Director or an authorised officer in the administration and enforcement of this Act. 15

(7) Every authorised officer and every person authorised under subsection (6) is deemed to be a public servant for the purposes of the Penal Code (Cap. 224).

Advisory committees 20

5.—(1) The Minister may establish one or more advisory committees consisting of such persons as the Minister thinks fit to appoint for the purpose of advising the Minister 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 the Director thinks fit to appoint for the purpose of advising the Director on any matter arising out of the administration, functions and enforcement of this Act. 25

PART 3
CONSENT

Taking of appropriate consent

5 **6.** Any appropriate consent must for the purposes of this Act be obtained —

(a) in writing;

(b) from the research subject or tissue donor personally or otherwise obtained in accordance with section 7, 8, 9, 10 or 11, as the case may be;

10 (c) after the information referred to in section 12 has been provided and explained to the research subject or tissue donor or the persons authorised to give consent on the subject's or donor's behalf under this Part, as the case may be; and

15 (d) in the presence of a prescribed witness and in accordance with such other procedures and requirements as may be prescribed.

Consent for research involving adults who lack mental capacity

20 **7.—(1)** Where the prospective research subject is an adult who lacks mental capacity and there are reasonable grounds for believing that biomedical research of comparable effectiveness cannot be carried out without the participation of the class of persons to which the adult belongs, the appropriate consent for the adult must be obtained from the following persons in the following circumstances:

25 (a) where there is a donee or deputy who is authorised to give consent to the biomedical research on behalf of the adult, consent is obtained from the donee or deputy;

30 (b) where there is no donee or deputy who is authorised to give consent to the biomedical research on behalf of the adult, consent is obtained from 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:

(i) the spouse;

- (ii) an adult son or daughter;
- (iii) either parent or a guardian;
- (iv) an adult brother or sister;
- (v) any other person named by the adult as someone to be consulted on the matter in question or on matters of that kind. 5

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

- (a) an adult is assumed to have capacity to give consent unless it is established that he or she lacks capacity;
- (b) where a donee is a person specified in subsection (1)(b)(i) to (iv) but there is an express provision in the lasting power of attorney that the donee is not authorised to give consent to human biomedical research on behalf of the adult lacking mental capacity, that donee is not authorised to give consent under subsection (1)(b)(i) to (iv); 10 15
- (c) the donee or deputy of an adult lacking mental capacity or a person specified in subsection (1)(b)(i) to (iv) must, in determining whether to give consent under subsection (1), have regard to such matters, considerations and procedures as may be prescribed. 20

Consent for research involving minors

8.—(1) Where the prospective research subject is a minor, the appropriate consent must be obtained from the following persons in the following circumstances:

- (a) where the minor has sufficient understanding and intelligence to enable the minor to understand what is proposed in the biomedical research, consent is obtained from both the minor and at least one adult parent or guardian of the minor; 25
- (b) where the minor has sufficient understanding and intelligence to enable the minor to understand what is proposed in the biomedical research and an institutional review board has, in accordance with section 13, waived the requirement to obtain 30

the consent of at least one adult parent or guardian of the minor, consent is obtained from the minor;

(c) where the minor does not have sufficient understanding and intelligence to enable the minor to understand what is proposed in the biomedical research and there are reasonable grounds for believing that biomedical research of comparable effectiveness cannot be carried out without the participation of the class of minors to which the minor belongs, consent is obtained from at least one adult parent or guardian of the minor;

(d) where the minor lacks mental capacity and there are reasonable grounds for believing that biomedical research of comparable effectiveness cannot be carried out without the participation of the class of minors to which the minor belongs, consent is obtained from —

(i) a deputy who is authorised to give consent to the biomedical research on behalf of the minor; or

(ii) at least one adult parent or guardian of the minor.

(2) For the purposes of subsection (1), the deputy, adult parent or guardian of a minor must, in determining whether to give consent under subsection (1), have regard to such matters, considerations and procedures as may be prescribed.

Consent for removal or use of tissue for research involving adults who lack mental capacity

9.—(1) Where the prospective tissue donor is an adult who lacks mental capacity to consent to the removal or use of any human tissue and the removal of human tissue from that adult is primarily for a therapeutic or diagnostic purpose, the appropriate consent must be obtained from the following persons in the following circumstances:

(a) where there is a donee or deputy who is authorised to give consent to the removal or use of the tissue on behalf of the adult, consent is obtained from the donee or deputy;

(b) where there is no donee or deputy who is authorised to give consent to the removal or use of the tissue on behalf of the

adult, consent is obtained from 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: 5

- (i) the spouse;
- (ii) an adult son or daughter;
- (iii) either parent or a guardian;
- (iv) an adult brother or sister;
- (v) any other person named by the adult as someone to be consulted on the matter in question or on matters of that kind. 10

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

- (a) an adult is assumed to have capacity to give consent unless it is established that he or she lacks capacity; 15
- (b) where a donee is a person specified in subsection (1)(b)(i) to (iv) but there is an express provision in the lasting power of attorney that the donee is not authorised to give consent to the removal or use of tissue on behalf of the adult lacking mental capacity, that donee is not authorised to give consent under subsection (1)(b)(i) to (iv); and 20
- (c) the donee or deputy of an adult lacking mental capacity or a person specified in subsection (1)(b)(i) to (iv) must, in determining whether to give consent under subsection (1), have regard to such matters, considerations and procedures as may be prescribed. 25

(3) To avoid doubt, subsections (1) and (2) apply as if there is no requirement that the removal of the tissue is primarily for a therapeutic or diagnostic purpose where the institutional review board has waived such requirement under section 37(3). 30

Consent for removal or use of tissue for research from minors

10.—(1) Where the prospective tissue donor is a minor, the appropriate consent for the removal or use of human tissue must be obtained from the following persons in the following circumstances:

- 5 (a) where the minor has sufficient understanding and intelligence to enable the minor to understand what is proposed in the procedure, consent is obtained from both the minor and at least one adult parent or guardian of the minor;
- 10 (b) where the minor does not have sufficient understanding and intelligence to enable the minor to understand what is proposed in the procedure and the removal of the tissue is primarily for a therapeutic or diagnostic purpose, consent is obtained from at least one adult parent or guardian of the minor;
- 15 (c) where the minor lacks mental capacity and the removal of the tissue is primarily for a therapeutic or diagnostic purpose, consent is obtained from —
- (i) a deputy who is authorised to give consent for the removal or use of the tissue on behalf of the minor; or
- 20 (ii) at least one adult parent or guardian of the minor.

(2) For the purposes of subsection (1), the deputy, adult parent or guardian of a minor must, in determining whether to give consent under that subsection, have regard to such matters, considerations and procedures as may be prescribed.

- 25 (3) To avoid doubt, subsections (1)(b) and (c) and (2) apply as if there is no requirement that the removal of the tissue is primarily for a therapeutic or diagnostic purpose where the institutional review board has waived such requirement under section 37(3).

Consent for research or removal or use of tissue for research in case of deceased persons

11.—(1) Where the prospective research subject or tissue donor is a deceased person, the appropriate consent —

- (a) for the use of the deceased person's individually-identifiable —
- (i) biological material;
 - (ii) body or any part of the body; or
 - (iii) health information; or
- (b) for the removal or use of human tissue for research from the deceased person,

5

must 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 the deceased person, or actual notice of opposition of a member of the same class or a prior class:

10

- (i) the spouse;
- (ii) an adult son or daughter;
- (iii) either parent or a guardian of the deceased person at the time of the person's death;
- (iv) an adult brother or sister;
- (v) the administrator or executor of the estate of the deceased person;
- (vi) any other person authorised or under obligation to dispose of the body of the deceased person.

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(2) The person specified in subsection (1)(i) to (v) must, in determining whether to give appropriate consent under subsection (1), have regard to such matters, considerations and procedures as may be prescribed.

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Information to be provided before taking appropriate consent

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

30

- (a) the investigational nature of the biomedical research;

- (b) the purpose of the biomedical research;
- (c) the reasonably foreseeable risks, discomforts or inconveniences to a living research subject arising from this biomedical research;
- 5 (d) the benefits which the research subject may reasonably expect from the biomedical 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;
- 10 (f) any compensation and treatment available to the research subject in the event of injury arising from participation in the research;
- (g) any anticipated expenses the research subject is likely to incur as a consequence of participating in the biomedical research;
- 15 (h) the extent to which information identifying the research subject will be kept confidential;
- (i) whether individually-identifiable information obtained from the research subject will be used for future biomedical research;
- 20 (j) where applicable, whether biological material taken from the research subject will be destroyed, discarded or stored for future biomedical research;
- (k) whether the participation of the research subject involves information in individually-identifiable form;
- 25 (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, including but not limited to changes in the proposed research, serious adverse events that would lead to a change in the proposed research, the development of capacity by minors to make decisions and
- 30 any other circumstances which could be specific to a particular research proposal;

- (m) whether the research subject would wish to be re-identified in the case of an incidental finding if the proposed biomedical research expressly provides for such re-identification;
 - (n) the research subject's right to withdraw his or her consent in the circumstances specified in section 14 and the limitations of such withdrawal as specified in that section; 5
 - (o) the person or persons to contact to obtain further information on the biomedical research and to provide feedback in relation to the biomedical research, respectively;
 - (p) such other information as the institutional review board may require; 10
 - (q) such other information as may be prescribed.
- (2) In the case of the removal, donation or use of human tissue, the appropriate consent must 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: 15
- (a) the specific research 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; 20
 - (b) whether the tissue will be used for any purpose other than research and if so, the specific purpose for which the tissue will be used;
 - (c) the proposed areas of research approved by the institutional review board in a case where it has waived the requirement that the removal of the tissue is primarily for a therapeutic or diagnostic purpose under section 37(3); 25
 - (d) the reasonably foreseeable risks, discomforts or inconveniences to a living donor arising from the removal of the tissue; 30
 - (e) 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;

- (*f*) the donor's right to withdraw his or her consent in the circumstances specified in section 14 and the limitations of such withdrawal as specified in that section;
- 5 (*g*) any compensation and treatment available to the donor in the event of injury arising from participation in the process of tissue donation;
- (*h*) any anticipated expenses the donor is likely to incur as a consequence of donating tissue;
- 10 (*i*) the extent to which records identifying the donor will be kept confidential;
- (*j*) whether individually-identifiable information obtained from the tissue donor will be used for future research;
- (*k*) where applicable, whether biological material taken from the tissue donor will be destroyed, discarded or stored and used for future research;
- 15 (*l*) 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;
- (*m*) whether the tissue donation would result in the use of the donor's tissue in an individually-identifiable form;
- 20 (*n*) whether the tissue will be used in restricted human biomedical research involving human-animal combinations;
- (*o*) 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 if the future research expressly provides for such re-identification;
- 25 (*p*) the person or persons to contact to obtain further information on the purposes for which the tissue will be used and to provide feedback in relation to such purposes, respectively;
- 30 (*q*) whether the tissue will be exported or removed from Singapore to a place outside Singapore;
- (*r*) such other information as may be prescribed.

(3) Where the research subject or tissue donor is a minor who has sufficient understanding and intelligence to understand what is proposed in the biomedical research or procedure, as the case may be, it is sufficient compliance with this section in respect of that minor if only such information as may be prescribed is provided to that minor. 5

(4) Subsection (3) does not affect the duty to provide the information specified in this section to the adult parent or guardian of the minor where the consent of the adult parent or guardian in addition to the consent of the minor is required under this Part. 10

Waiver of appropriate consent by institutional review board

13.—(1) Despite anything in this Part, an institutional review board which is the reviewing authority of a human biomedical research proposal may waive the requirement —

- (a) for the appropriate consent obtained for the participation of a person as a research subject or for the use of human tissue, as the case may be, to be in writing, in such circumstances as are specified in Part 1 of the Fifth 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 Fifth Schedule; 20
or
- (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 Fifth Schedule. 25

(2) Despite sections 8 and 10, 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 adult 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; and

(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 research subject population for which parental or guardian consent is not a reasonable requirement to protect the research subjects (such as neglected or abused minors), and an appropriate mechanism for protecting the minors is substituted;

10 (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

(iii) is within the description of such circumstances as may be prescribed.

15 (3) To avoid doubt —

(a) subsection (1) does not apply to the waiver of consent for the removal of human tissue from a person;

20 (b) a waiver under subsection (1) or (2) does not affect a person's duty to protect individually-identifiable information from unauthorised disclosure under sections 29 and 39 or imposed by law; and

25 (c) nothing in this section provides immunity to the custodian of any individually-identifiable information for such information if disclosed, unless the disclosure was done in accordance with this Act.

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

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

Withdrawal of consent

14.—(1) A research subject or any person who is authorised to give consent on the subject’s behalf under this Part may, at any time, withdraw the consent to the subject’s participation in the human biomedical research. 5

(2) A donor of human tissue or any person who is authorised to give consent on the donor’s behalf under this Part may, at any time, withdraw the consent to the use of the donor’s tissue for 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) does not affect the research information obtained before the consent is withdrawn and such information may be retained and used for the research. 15

(4) Any penalty or damages imposed solely by reason of the withdrawal of consent permitted by this section is void and unenforceable. 20

PART 4

INSTITUTIONAL REVIEW BOARDS

Appointment and notification of institutional review boards

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

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

(3) A person who is appointed as a member concurrently of 2 or more institutional review boards is not 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 must notify the Director of —

(a) any institutional review board which it has appointed under this section or section 16; 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) must be submitted to the Director in such form and manner and within such time as the Director may require, and must 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 12 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 that person knows to be false or does not believe to be true; or

(b) by the intentional suppression of any material fact, furnishes information which is misleading,

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

Appointment of institutional review boards by multiple research institutions

16.—(1) This section applies where human biomedical research is conducted jointly or in collaboration with more than one research institution and there is an agreement among the research institutions

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

(2) For the purposes of their common human biomedical research, the research institutions may, instead of appointing the institutional review boards appointed by them under section 15, 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 among the institutions.

(3) This Act applies, with the necessary modifications, to the common institutional review board designated by the research institutions under subsection (2) in the same manner as it applies to the institutional review board appointed by the research institution under section 15.

Functions and duties of institutional review boards

17.—(1) The functions and duties of an institutional review board are —

- (a) to carry out a review (called in this Act an initial review) of any proposed human biomedical research (called in this section 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 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 the participation by the minors who lack sufficient understanding and intelligence to give consent or the class of such minors, or the adults or minors who lack mental capacity or the class of such adults or minors, if any, in

the proposed research is scientifically necessary and ethically appropriate for the conduct of the proposed research;

(*f*) to assess that the requirements in Part 3 of the Fifth Schedule are fulfilled before approving any proposed emergency research;

(*g*) 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;

(*h*) to assess if a data and safety monitoring board is necessary for the purposes of the proposed research;

(*i*) to assess the suitability and adequacy of the system of oversight of the research institution conducting the particular research proposal;

(*j*) to assess the suitability of the premises for the proposed research;

(*k*) 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; or

(iii) to disallow the conduct or continuation of the proposed research, as the case may be, with written justifications; and

(*l*) to make such other assessments or carry out such other functions or duties as may be required or imposed under this Act.

(2) Despite 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 the research subjects, the chairman or the authorised member may, if he or she 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,

5

subject to such conditions as may be prescribed or imposed by the board.

Composition, quorum and proceedings of institutional review board

18.—(1) The composition, quorum and proceedings of an institutional review board must be in accordance with regulations made under section 63.

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

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

15

(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.

25

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

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

30

- (a) by any defect in the appointment or qualification of any member of the board;

(b) by any contravention of section 19(1) by any member of the board; or

(c) by any contravention of the regulations relating to the procedures of institutional review boards except for the requirements relating to the quorum for meetings of the board.

Conflicts of interest

19.—(1) A member of an institutional review board must 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, including such circumstances as may be prescribed in regulations made under section 63.

(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 otherwise connected or related —

(a) is not disqualified from participating in the proceedings of the boards on the ground of conflicts of interests by reason only of such concurrent memberships; but

(b) must disclose his or her participation in each board's proceedings to all the other boards.

Application to institutional review board for review

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

Appeal against decision of institutional review board

21.—(1) Any researcher who, having submitted an application to an institutional review board for initial review, is aggrieved by the decision of the institutional review board (called in this section the first board) not to grant approval for the research to be conducted or continued, as the case may be, may within 30 days after 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 subsection (1) may —

(a) dismiss the appeal; 5

(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 institution (called in this section the second board) for a second initial review. 10

(3) No appeal under subsection (1) is allowed unless the first board has confirmed in writing that it has disallowed the conduct or continuation of the research.

(4) To avoid doubt, there is no appeal against the decision of the research institution or the second board referred to in subsection (2). 15

PART 5

REGULATION OF HUMAN BIOMEDICAL RESEARCH

Conduct of human biomedical research and duties of researcher

22.—(1) No human biomedical research can be conducted except under the supervision and control of a research institution with — 20

(a) a place of business in Singapore; and

(b) at least 2 individuals ordinarily resident in Singapore who are responsible on behalf of the research institution for the supervision and control of the biomedical research. 25

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

(a) he or she has made the necessary contractual or other arrangements with a research institution referred to in subsection (1) for the proposed research to be conducted under the supervision and control of the research institution; 30

(b) he or she has ensured that the proposed research has been —

(i) reviewed and approved by an institutional review board appointed by the research institution referred to in paragraph (a); or

5 (ii) exempted from review by an institutional review board under section 17(2);

(c) he or she has ensured that, except in such circumstances as may be prescribed, appropriate consent has been obtained in accordance with Part 3 prior to 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, as the case may be;

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(d) he or she has ensured that where the human biomedical research involves human gametes or embryos, whether individually-identifiable or not, the appropriate consent must be obtained from the research subject or donor who has capacity to give consent in person and not from a person authorised under Part 3 to give consent on the subject's or donor's behalf.

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20 (3) A researcher must ensure that —

(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

25

(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;

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(b) any research is immediately discontinued if the institutional review board has withdrawn its approval for the research unless the immediate discontinuation will result in a risk of harm to the research subject;

(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 immediately discontinued if the consent has been withdrawn or is otherwise invalid unless the immediate discontinuation will result in a risk of harm to the research subject; and 5

(d) all such appropriate and necessary measures are taken to mitigate any risk of harm that has arisen under paragraph (b) or (c).

(4) A researcher must ensure that a minor who lacks sufficient understanding and intelligence, or an adult or minor who lacks mental capacity to give consent, must not be a research subject in any biomedical research unless there are reasonable grounds for believing that biomedical research of comparable effectiveness cannot be carried out without the participation of the class of persons to which the minor or adult belongs, as the case may be. 10 15

(5) To avoid doubt, the delegation of any obligation or duty under this Act to another person or service provider under a contract or other arrangement does not absolve or relieve the person of any of his or her obligations or duties under this Act. 20

(6) Any person who contravenes subsection (1), (2), (3) or (4) 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 25

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

(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; 30

(b) submit, in accordance with section 24(1), a declaration of compliance in respect of all human biomedical research

conducted under its supervision and control in the preceding 12 months, or such other period of time as the Director may require; and

5 (c) ensure that there is in force an approval for the human biomedical research under section 17(1) issued by an institutional review board which the research institution had appointed or is an exemption under section 17(2) of the requirement for that research to be approved by the institutional review board appointed by the research
10 institution.

(2) Every research institution must, in respect of any human biomedical research which is carried out under its supervision and control —

15 (a) supervise, review and proactively monitor the conduct of the research;

(b) designate a principal person in charge to be responsible for ensuring that the research institution complies with this Act;

20 (c) formulate and implement appropriate standards, policies and procedures to supervise, review and monitor the conduct of the research;

(d) establish a data and safety monitoring board if its institutional review board considers that it is necessary for the purposes of any particular research proposal;

25 (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

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

30 (g) ensure that, where the human biomedical research is conducted jointly or in collaboration with more than one research institution, there is an agreement among the research institutions for one research institution to be appointed as the

lead research institution for the purpose of coordinating the research; and

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

(3) Every research institution must 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 research institution under subsection (2)(*b*) does not absolve or relieve the institution of any of its obligations or duties under this Act.

(5) To avoid doubt, the delegation of any obligation or duty under this Act to another person or service provider under a contract or other arrangement does not absolve or relieve the research institution of any of its obligations or duties under this Act. 15

(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. 20

(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. 25

(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 30

24.—(1) The declaration of compliance that a research institution is required to submit to the Director under section 23(1) for all research conducted under the supervision and control of the research institution

must be in such form and submitted in such manner and within such time as may be prescribed and must be accompanied by —

(a) such particulars, information and documents as may be prescribed;

5 (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 must notify the Director —

10 (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

15 (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
20 subsection (2) —

(a) makes any statement or furnishes any document which he or she 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,

25 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
30 \$10,000 or to imprisonment for a term not exceeding 12 months or to both.

Appropriate consent from research subjects

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

5

Compelling person to participate in research

26.—(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;

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

15

(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

20

(d) by means of deception or misrepresentation, causes another person (*A*) to give *A*'s consent or to refrain from withdrawing *A*'s consent for the participation of another person (*B*) 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.

25

(2) It is 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;

30

(b) the possibility of the deception or misrepresentation was disclosed to the research subject;

- (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.

5 **27.**—(1) Every person who has obtained individually-identifiable information or human biological material for the purposes of human biomedical research must take all reasonable steps and safeguards as may be necessary, including rendering information or material non-identifiable, to protect such information or material against
10 accidental or unlawful loss, modification or destruction, or 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
15 both.

(3) In this section and section 28, 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
20 be readily discovered or ascertained by a person who subsequently accesses or receives the information or material.

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

25 **28.**—(1) This section applies to any information or human biological material —

(a) relating to human biomedical research; and

(b) which was individually-identifiable but which has been rendered non-identifiable within the meaning of section 27(3).

30 (2) No person who is in possession of or in contact with any information or human biological material referred to in subsection (1) can 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 the research subject's 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; 5
- (c) when ordered to do so by a court;
- (d) where the information on the identity is publicly available;
- (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; 10
- (f) where it is permitted or provided for under this Act or any other written law or rule of law; or
- (g) in such other circumstances and to such persons as may be prescribed.

(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. 15

Restrictions on disclosure of information

29.—(1) No person may disclose any individually-identifiable information of any research subject which has come to his or her knowledge in the course of discharging his or her functions or duties under this Act, or by virtue of his or her conduct or review of the human biomedical research, as the case may be, except — 20

- (a) with the consent of the research subject or the person authorised under Part 3 to give consent on his or her behalf, as the case may be; 25
- (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; 30
- (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;

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

(g) in such other circumstances and to such persons as may be prescribed.

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

15 (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.

Prohibited human biomedical research

20 **30.**—(1) Despite anything in this Act, no research institution or person can conduct, supervise or control any prohibited human biomedical research specified in the Third Schedule.

25 (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

30 **31.**—(1) No research institution or person can conduct, supervise or control any restricted human biomedical research specified in the Fourth Schedule except in accordance with such requirements as the Minister may prescribe and such prescribed requirements are in addition to and not in lieu of the requirements in this Act.

(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; 5
- (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;
- (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; 10
- (d) that the restricted human biomedical research should be conducted only by certain specified persons; 15
- (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; 20
- (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) No person can use any human tissue in restricted human biomedical research unless — 25

- (a) one of the following types of consent for the tissue to be used for the particular restricted human biomedical research has been obtained:
 - (i) in a case where the donor is not a minor and has capacity to give consent, appropriate consent obtained from the donor in person and not from a person authorised under Part 3 to give consent on the donor's behalf; 30

(ii) in a case where the donor is a minor who has sufficient understanding and intelligence to enable the minor to understand what is proposed in the procedure, appropriate consent obtained from both the minor and, unless waived under section 13(2), at least one adult parent or guardian of the minor;

(iii) in the case of human tissue imported from a place outside Singapore, consent obtained in accordance with the legal or ethical requirements of that place; and

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

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

PART 6

REGULATION OF HUMAN TISSUE ACTIVITIES AND TISSUE BANKS

Commercial trading of human tissue prohibited

32.—(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 herself or to another person, to the sale or supply of any human tissue from his or her body or from the body of another person, whether before or after his or her death or the death of the other person, as the case may be, is 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 or her body; 5
- (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; 10
- (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 or her body; or 15
- (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),

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. 20

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

- (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 human tissue in accordance with the provisions of any other written law; 25
- (b) any scheme introduced or approved by the Government granting medical benefits or privileges to any human tissue donor and any member of the donor's family or any person nominated by the donor; and 30
- (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;
- 5 (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 or her body; and
- 10 (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 or her supplying any human tissue from his or her body.

(5) Nothing in this section will 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).

(6) This section and section 33 do 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);
- 25 (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 tissue prohibited

30 **33.**—(1) No person may 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 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 is construed accordingly. 5

(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. 10

Notification of tissue bank

34.—(1) A research institution must notify the Director of any tissue bank which the research institution is directly or indirectly operating or which is part of the research institution. 15

(2) A tissue bank must notify the Director of its particulars unless a research institution has made a notification of that tissue bank in accordance with subsection (1). 20

(3) A notification for the purposes of subsection (1) or (2) must be submitted to the Director in such form and manner, with such particulars and within such time as may be prescribed, and must 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 12 months or to both. 25

(5) Any person who, in submitting a notification for the purposes of subsection (1) or (2) — 30

(a) makes any statement or furnishes any document which he or she 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 **35.**—(1) Every tissue bank must, in respect of any tissue banking activity to be conducted under its supervision and control —

(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; and

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(b) submit, in accordance with section 36, a declaration of compliance in respect of all tissue banking activities conducted under its supervision and control in the preceding 12 months, or such other period of time as the Director may require.

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(2) Every tissue bank must, 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;

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

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(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

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

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(f) ensure that if any human tissue under its supervision and control is to be exported or otherwise removed from

Singapore to a place outside Singapore, the export or removal is carried out in accordance with prescribed requirements, including but not limited to requirements in relation to consent from the donor;

- (g) ensure that if any human tissue is to be removed from its supervision and control in circumstances other than in paragraph (f), the removal is carried out in accordance with prescribed requirements, including but not limited to requirements in relation to approval for the removal of individually-identifiable tissue from an institutional review board and scientific endorsement by experts on the merits of the research for which the tissue rendered non-identifiable within the meaning of section 27(3) are removed; and
- (h) perform such other functions and duties as may be prescribed by the Minister.

(3) Every tissue bank must 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
- (c) such other matters as may be prescribed.

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

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

(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

5 **36.**—(1) The declaration of compliance that a tissue bank is required to submit to the Director under section 35(1) for all tissue banking activities conducted under the supervision and control of the tissue bank must be in such form and submitted in such manner and within such time as may be prescribed and must be accompanied by —

10 (a) such particulars, information and documents as may be prescribed;

(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

15 (c) such fee as may be prescribed.

(2) A tissue bank must 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 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.

25 (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 or she 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,

30 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.

Restrictions on activities relating to human tissue

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37.—(1) No person may remove any human tissue from a donor unless —

(a) where the tissue is to be removed for a therapeutic or diagnostic purpose but will also be or is likely to be used for research purposes, appropriate consent has been obtained for these research purposes in addition to the consent obtained for the therapeutic or diagnostic purpose; or

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(b) where the tissue is to be removed for a research purpose, appropriate consent has been obtained for the tissue to be removed from the donor.

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(2) No person may remove any human tissue from any of the following persons unless the removal of the tissue was primarily for a therapeutic or diagnostic purpose:

(a) an adult who lacks mental capacity;

(b) a minor who lacks mental capacity;

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(c) a minor who lacks sufficient understanding and intelligence to give consent.

(3) Despite subsection (2), an institutional review board may waive the requirement that the tissue be removed, from any person referred to in that subsection, primarily for a therapeutic or diagnostic purpose if the board is satisfied that —

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(a) the removal of the tissue involves no more than minimal risk to that person; and

(b) there are reasonable grounds for believing that the proposed areas of research cannot be carried out without the use of the tissue from the class of persons to which that person belongs.

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(4) No person may store any human tissue for subsequent use in research unless that person is reasonably satisfied that —

(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.

5 (5) No person may supply any human tissue to another person for use in research unless that person is reasonably satisfied that —

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

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

(c) the recipient is informed of the requirements referred to in paragraphs (a) and (b).

(6) No person may use any human tissue in research unless that person is reasonably satisfied that —

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

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

(7) No person may use any human tissue that has been —

20 (a) removed from the donor where the sole purpose or one of the purposes of the removal is research;

(b) stored for use in research; or

(c) supplied for use in research,

25 for any purpose other than research unless that person is reasonably satisfied that the use is in accordance with the conditions or restrictions, if any, specified as part of the appropriate consent for its use in research.

30 (8) In the case of any human tissue which has been imported from a place outside Singapore, whether on its own or as part of a human body or body part, it is sufficient compliance with subsection (4), (5), (6) or (7) for a person to prove that there is documentary evidence that

consent has been given in accordance with the legal or ethical requirements of that place.

(9) Where the human tissue was removed from a donor for a therapeutic or diagnostic purpose, no person may store, supply or use the tissue for research or for any other purpose unless the medical practitioner or healthcare institution responsible for the medical treatment of the donor had completed all necessary therapeutic or diagnostic procedures and no longer requires the tissue or part of the tissue for the treatment.

(10) This section does not apply to —

(a) the removal, storage or supply of any human tissue in the course of a post-mortem examination conducted in accordance with the Coroners Act (Cap. 63A) or carried out pursuant to the order of a Coroner made under that Act;

(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; and

(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).

(11) 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

38. Any person who —

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

(b) by means of coercion or intimidation, compels another person (A) against A's will to give A's consent or to refrain from withdrawing A's consent for the removal of tissue from the body of another person (B);

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

5 (d) by means of deception or misrepresentation, causes another person (*A*) to give *A*'s consent or to refrain from withdrawing *A*'s consent for the removal of tissue from the body of another person (*B*),

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 10 years or to both.

Restrictions on disclosure of information on tissue donor

39.—(1) No person may disclose any individually-identifiable information on any donor of human tissue which has come to that person's knowledge except —

15 (a) with the consent of the donor or the donor's 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;

20 (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;

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

(g) in such other circumstances and to such persons as may be prescribed.

(2) No person receiving any individually-identifiable information of a donor may disclose any individually-identifiable information of the
30 donor, if at the time when the person received the information or material, the person knew or had reasonable grounds to believe that it had been communicated or supplied to him or her 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.

PART 7

5

CODES OF PRACTICE AND ETHICS

Codes of practice or ethics

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

- (a) issue one or more codes of practice for the purpose of providing guidance with respect to the requirements of this Act relating to the taking of consent, safety and research practices and for standards; 10
- (b) issue one or more codes of practice for the protection of the identity of individuals in relation to individually-identifiable human biological material and health information; 15
- (c) issue one or more codes of ethics for the ethical conduct of human biomedical research or tissue banking activity;
- (d) 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; and 20
- (e) amend or revoke the whole or part of any code of practice or code of ethics issued under paragraph (a), (b) or (c) or approved under paragraph (d).

(2) The Director must publish any code of practice or code of ethics issued or approved under subsection (1), including any amendment or revocation of the code, in such manner as the Director thinks fit. 25

(3) Any code of practice or code of ethics issued or approved under this section does not have any legislative effect and need not be published in the *Gazette*. 30

Use of codes of practice or ethics

41.—(1) A person is not liable to any criminal proceedings by reason only that the person has failed to observe any code of practice or code of ethics issued or approved under section 40.

5 (2) In any proceedings for an offence under this Act, a code of practice or code of ethics issued or approved under section 40 that is relevant to any matter which it is necessary for the prosecution to prove in order to establish the commission of the offence is admissible in evidence in the proceedings.

10 (3) In determining for the purposes 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 must be had to any relevant code of practice
15 or code of ethics issued or approved under section 40.

PART 8

ENFORCEMENT POWERS

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

20 **42.**—(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 —

25 (i) any provision of this Act; or

(ii) any relevant code of practice or code of ethics issued or approved under section 40;

(c) is not being or has not been properly reviewed by an institutional review board appointed by the research
30 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 of the activities, 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. 5

(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: 10

- (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; 15
- (c) direct the research institution which appointed the institutional review board to —
 - (i) remove or replace any member of the institutional review board; or 20
 - (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 activities, as the case may be, under the supervision and control of that research institution or tissue bank. 25

(4) Any person who contravenes an order, direction or notification given to him or her 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 30

exceeding \$2,000 for every day or part of a day during which the offence continues after conviction.

Prohibiting person from conducting research or tissue banking activities

5 **43.**—(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;

10 (b) the person has been convicted in Singapore or elsewhere of any offence involving fraud, dishonesty or moral turpitude;

(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
15 may be; or

(d) for medical reasons, the person is unable to perform his or her 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
20 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.

Review of prohibition order

25 **44.**—(1) A person who is the subject of a prohibition order made under section 43(1) may, on the payment of such fee as may be prescribed, apply to the Director for the prohibition order to be reviewed.

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

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

- (a) the character and fitness of the applicant to conduct human biomedical research or tissue banking activities; and
- (b) any other matter which the Director considers relevant. 5

(4) No application to review a prohibition order under subsection (1) may 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. 10

Powers of entry, inspection and search, etc.

45.—(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 the authorised officer 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 42; 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; and 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, even though the prior consent of such person has not been obtained;

10 (c) inspect any apparatus, appliance, equipment or instrument used or found in the premises;

(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; and

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.

25 (3) In the exercise of the powers and duties under this section, an authorised officer may be accompanied and assisted by a person authorised by the Director under section 4(6) for the purposes of facilitating the exercise of such powers and duties.

(4) An authorised officer may seize from any premises or place —

(a) any biological material or organism or any product of human biomedical research; or

30 (b) any book, document, 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.

(5) Where any article or document has been seized under subsection (4) —

- (a) the authorised officer who seized the article or document must give notice in writing of the seizure to the person from whom it was seized, if the name and address of that person are known; 5
- (b) the article or document may be kept or stored in the premises or place where it was seized or may, at the direction of the authorised officer, be removed to any other place to be kept or stored; and 10
- (c) the authorised officer may —
 - (i) mark, seal or label the article or document in such manner as the officer thinks fit for the purpose of indicating that it is under detention; and
 - (ii) lock or seal the whole or part of the premises or place in which the article or document is being detained. 15

(6) Any person who, without the permission of the authorised officer —

- (a) interferes, tampers with, removes or otherwise disposes of the article or document; 20
- (b) alters, counterfeits, defaces, destroys, erases or removes any mark, seal or label placed by the authorised officer under subsection (5)(c)(i); or
- (c) opens, breaks or otherwise tampers with the lock or seal placed by the authorised officer on the whole or part of any premises or place under subsection (5)(c)(ii), 25

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) Any person who is present in any premises referred to in subsection (1) must render all necessary assistance and cooperation to the authorised officer as are necessary for an entry, inspection, investigation or otherwise for the exercise of his or her powers under this Act in relation to those premises. 30

(8) An authorised officer may —

(a) require any person —

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

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

(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 must —

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

(ii) read the statement over to the person so examined; and

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

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

(9) Any person who —

(a) obstructs, hinders or impedes an authorised officer in the exercise of the officer's powers under this section; or

30 (b) fails without reasonable excuse 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 that person 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.

(10) For the purposes of subsection (9), 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 that person.

Disposal of articles or documents

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

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

(b) where the owner of the article or document consents to its disposal, be deemed to be forfeited; or

(c) in any other case —

(i) be returned to the owner; or

(ii) be reported to a Magistrate's Court.

(2) Where the report of any article or document produced, detained or seized under section 45 is made to a Magistrate's Court under subsection (1)(c)(ii), the Magistrate's Court may order the article or document —

(a) to be forfeited; or

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

(3) Subject to any order to the contrary by the Magistrate's Court, any article or document forfeited or deemed to be forfeited under this section must be delivered to the Director and must be disposed of in such manner as the Director thinks fit.

(4) This section does not prejudice any right to retain or dispose of any property which may exist in law apart from this section.

Information and identity of informers not to be disclosed

47.—(1) Except as provided in subsection (3) —

(a) no information disclosed by an informer for an offence under this Act may be admitted in evidence in any civil or criminal proceedings; and

(b) no witness in any civil or criminal proceedings is obliged —

(i) to disclose the name and address of any informer who has given information with respect to an offence under this Act; or

(ii) to answer any question if the answer to the question would lead, or would tend to lead, to the discovery of the name or address of the informer.

(2) If any document, record or thing which is in evidence or liable to inspection in any civil or criminal proceedings contains any entry in which any informer is named or described or which may lead to his or her discovery, the court must cause those entries to be concealed from view or to be obliterated so far as may be necessary to protect the informer from discovery.

(3) If in any proceedings —

(a) before a court for an offence under this Act, the court, after full inquiry into the case, is satisfied that an informer wilfully made a material statement which the informer knew or believed to be false or did not believe to be true; or

(b) other than that referred to in paragraph (a), the court is of the opinion that justice cannot be fully done between the parties to the proceedings without the disclosure of the name of an informer,

the court may permit inquiry and require full disclosure concerning the informer.

Minister may appoint committee of inquiry under Inquiries Act

48. In addition to the matters on which the Minister may in writing appoint a committee of inquiry under section 9(1) of the Inquiries Act

(Cap. 139A), the Minister may in writing 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 this Act or any relevant code of practice or code of ethics, issued or approved under section 40, by a research institution, an institutional review board, a tissue bank or a researcher, as the case may be.

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Protected information

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49.—(1) If a person exercising any function under this Act obtains protected information relating to the research being conducted or to be conducted, that person must 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.

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(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.

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(3) For the purposes of this section —

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

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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 **50.** 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 **51.—**(1) Any act done or conduct engaged in by a person in the course of employment (called in this section the employee) is treated for the purposes of this Act as done or engaged in by the employer as well as by the employee, 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 or she 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 the
20 employee's employment, acts or conduct, as the case may be, of that description.

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

Offences by bodies corporate, etc.

25 **52.—**(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 of the body corporate; or

30 (b) to be attributable to any neglect on the officer's part,
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) applies in relation to the acts and defaults of a member in connection with the member's functions of management as if the member were a director of the body corporate.

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

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

(b) to be attributable to any neglect on the partner's part,
the partner as well as the partnership shall be guilty of the offence and shall be liable to be proceeded against and punished accordingly. 10

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

(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 15

(b) to be attributable to any neglect on the part of such an officer or a member,
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. 20

(5) In this section —

“body corporate” includes a limited liability partnership which has the same meaning as in section 2(1) of the Limited Liability Partnerships Act (Cap. 163A); 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;

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

(6) The Minister may make regulations to 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.

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Composition of offences

53.—(1) The Director or any authorised officer authorised by the Director may, in the Director’s or officer’s 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 offence a sum not exceeding the lower of the following:

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

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(b) \$5,000.

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

(3) All sums collected under this section are to be paid into the Consolidated Fund.

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PART 9
APPEALS

Appeal to Minister

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

(a) any decision of the Director in the exercise of any discretion vested in the Director by or under this Act other than section 43; or 5

(b) any order made or direction given by the Director under this Act other than section 43,

may, within 14 days after being notified of the decision, order or direction, 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 43 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) must, within the period specified in subsection (1) or (2) — 20

(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.

(4) Where an appeal has been made to the Minister under subsection (1) or (2), the Minister may require — 25

(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 subsection (1) or (2), 30

to provide the Minister with all such information as the Minister 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.

5 (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 must be complied with until the determination of the appeal.

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

(a) by confirming, varying or reversing any decision, order or direction of the Director; or

(b) by directing the Director to reconsider the Director's decision, order or direction, as the case may be.

15 (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, is not bound by such consultation.

20 (9) The decision of the Minister in any appeal is final.

(10) Every appellant must be notified of the Minister's decision under subsection (7).

Appeals Advisory Panel

25 **55.**—(1) Where the Minister considers that an appeal lodged under section 54(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, the Minister may establish an Appeals Advisory Panel, comprising one or more of such persons with particular medical, scientific or other specialised
30 knowledge and such other persons as the Minister considers appropriate, to provide advice to the Minister with regard to the discharge of the Minister's functions under section 54 in respect of any appeal that has been made to the Minister under section 54(1) or (2).

(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;
- (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 is 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 is the decision of that Panel. 20

(4) An Appeals Advisory Panel is independent in the performance of its functions.

PART 10

MISCELLANEOUS

Act binds Government 25

56.—(1) Except as otherwise provided in subsection (2), this Act binds the Government and applies to the Government, including any human biomedical research conducted under the supervision and control of the Government.

(2) Nothing in this Act renders the Government liable to prosecution for an offence under this Act. 30

(3) To avoid doubt, no person is 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 **57.**—(1) The Minister may, either generally or in a particular case, and subject to such conditions as the Minister may impose, exempt, either permanently or for such period as the Minister may think fit, from all or any of the provisions of this Act —

(a) any person, research institution or tissue bank;

10 (b) any class of persons, research institutions or tissue banks;

(c) any ministry or department of the Government;

(d) any human biomedical research or tissue banking activity;

(e) any class of human biomedical research or tissue banking activity;

15 (f) any human biological material or human tissue; or

(g) any class of human biological material or human tissue.

(2) In the exercise of the Minister's powers under subsection (1), the Minister may consult any advisory committee appointed under section 5 but the Minister is not bound by such consultation.

20 **Designation of persons by Minister**

58.—(1) The Minister may designate any of the persons specified in subsection (2) —

(a) to hear and determine in the Minister's place any appeal or a specific appeal under section 54;

25 (b) to refer any appeal or a specific appeal to an Appeals Advisory Panel established under section 55(1); or

(c) to exercise all or any of the Minister's powers conferred under section 55 or 57,

30 and any reference to the Minister in section 54, 55 or 57 includes a reference to the person so designated.

(2) The following are the persons who may be designated by the Minister for the purposes of subsection (1):

- (a) the Second Minister, if any, for his or her Ministry;
- (b) any Minister of State or Senior Minister of State, for his or her Ministry.

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Service of documents

59.—(1) A document that is permitted or required by this Act to be served on a person may be served as described in this section.

(2) A document permitted or required by this Act to be served on an individual may be served —

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- (a) by giving it to the individual personally;
- (b) by sending it by prepaid registered post to the address specified by the individual for the service of documents or, if no address is so specified, to the individual's residential address or business address;
- (c) by leaving it at the individual's residential address with an adult apparently resident there, or at the individual's business address with an adult apparently employed there;
- (d) by affixing a copy of the document in a conspicuous place at the individual's residential address or business address;
- (e) by sending it by fax to the fax number last known to the Director or authorised officer giving or serving the document as the fax number for the service of documents on the individual; or
- (f) by sending it by email to the individual's last email address.

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(3) A document permitted or required by this Act to be served on a partnership (other than a limited liability partnership) may be served —

- (a) by giving it to any partner, secretary or other similar officer of the partnership;
- (b) by leaving it at, or by sending it by prepaid registered post to, the partnership's business address;

30

(c) by sending it by fax to the fax number used at the partnership's business address; or

(d) by sending it by email to the partnership's last email address.

5 (4) A document permitted or required by this Act to be served on a body corporate (including a limited liability partnership) or an unincorporated association may be served —

(a) by giving it to the secretary or other similar officer of the body corporate or the unincorporated association, or the limited liability partnership's manager;

10 (b) by leaving it at, or by sending it by prepaid registered post to, the body corporate's or unincorporated association's registered office or principal office;

(c) by sending it by fax to the fax number used at the body corporate's or unincorporated association's registered office or principal office; or

15 (d) by sending it by email to the body corporate's or unincorporated association's last email address.

(5) Service of a document under subsection (1) takes effect —

20 (a) if the document is sent by fax and a notification of successful transmission is received, on the day of transmission;

(b) if the document is sent by email, at the time that the email becomes capable of being retrieved by the person to whom it is addressed; and

25 (c) if the document is sent by prepaid registered post, 2 days after the day the document was posted (even if it is returned undelivered).

(6) This section does not apply to documents to be served in proceedings in court.

(7) In this section —

30 "business address" means —

(a) in the case of an individual, the individual's usual or last known place of business; or

- (b) in the case of a partnership (other than a limited liability partnership), the partnership’s principal or last known place of business;

“last email address” means —

- (a) the last email address given by the addressee concerned to the Director or authorised officer giving or serving the document as the email address for the service of documents under this Act; or 5
- (b) the last email address of the addressee concerned known to the Director or the authorised officer giving or serving the document; 10

“residential address” means an individual’s usual or last known place of residence.

Jurisdiction of courts

60. Despite any provision to the contrary in the Criminal Procedure Code (Cap. 68), a District Court has jurisdiction to try any offence under this Act and has power to impose the full penalty or punishment in respect of the offence. 15

Protection from personal liability

61. No liability is to lie personally against the Director, any authorised officer or any other person authorised by or acting under the direction of the Director who, acting in good faith and with reasonable care, does or omits to do anything in the execution or purported execution of this Act. 20

Amendment of Schedules

62.—(1) The Minister may at any time, by order published in the *Gazette*, amend the First, Second, Third, Fourth or Fifth Schedule. 25

(2) The Minister may, in any order made under subsection (1), make such incidental, consequential or supplementary provision as may be necessary or expedient. 30

Regulations

63.—(1) The Minister may make regulations for carrying out the purposes and provisions of this Act and for prescribing anything which may be prescribed.

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

(a) the duties of research institutions, appointing bodies of institutional review boards, and researchers;

10 (b) the qualifications of researchers;

(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;

15 (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;

20 (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;

25 (iii) the appropriate consent required for the participation of minors and other vulnerable persons as research subjects in human biomedical research;

30 (iv) the records and documents to be maintained by research institutions, researchers or tissue banks and the information to be contained in such records and documents;

(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

- (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; 5
- (g) the requirements for the protection of the identity of individuals in relation to individually-identifiable human biological material and health information;
- (h) the requirements in relation to the reporting of and investigations into any serious adverse event; 10
- (i) the duties, procedures, responsibilities and powers of inquiries committees;
- (j) 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; 15
- (k) the licensing of tissue banks and tissue banking activities;
- (l) the forms necessary for the administration of this Act; and
- (m) the fees and charges payable under or for the purposes of this Act. 20

(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 \$20,000 or with imprisonment for a term not exceeding 2 years or with both. 25

Savings and transitional provisions for legacy human biological material

64.—(1) This Act, with the exception of sections 30 (prohibited human biomedical research), 31 (restricted human biomedical research), 32 (commercial trading of human tissue prohibited) and 33 (advertisements relating to commercial trading of human tissue prohibited), does not apply to any legacy human biological material or any information derived from such material. 30

(2) Despite subsection (1), regulations made under section 63 may provide for the 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.

5 (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 appointed day;

10 (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 27(3) at any time before the appointed day.

Savings and transitional provisions

15 **65.**—(1) Every research institution which immediately before the appointed day was supervising and controlling the conduct of human biomedical research may continue supervising and 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
20 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
25 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 the Minister may consider necessary or expedient.

30 Related amendment to Health Products Act

66. Paragraph 1 of the Second Schedule to the Health Products Act (Cap. 122D, 2008 Ed.) is amended by deleting sub-paragraph (i) and substituting the following sub-paragraph:

- “(i) for regulating the conduct of clinical trials of health products, and prescribing the matters relating to any consent for a subject to participate in such a trial, including —
- (i) the persons who may so consent;
 - (ii) the considerations which any such person must take into account before so consenting; 5
 - (iii) the circumstances in which the consent of such person may be relied upon; and
 - (iv) the circumstances in which no consent of any person is required for the subject’s participation in the trial, 10
- and whether any matter so prescribed has effect in addition to or despite any other written law or rule of law;”.

Related amendment to Medicines Act

67. Section 18 of the Medicines Act (Cap. 176, 1985 Ed.) is amended by deleting paragraph (a) and substituting the following paragraph: 15

- “(a) the conduct of clinical trials, the issue of clinical trial certificates, the exemption of clinical trials from sections 5 and 6, and matters relating to any consent for a subject to participate in a clinical trial, including — 20
- (i) the persons who may so consent;
 - (ii) the considerations which any such person must take into account before so consenting;
 - (iii) the circumstances in which the consent of such person may be relied upon; and 25
 - (iv) the circumstances in which no consent of any person is required for the subject’s participation in the trial,
- and whether any matter so prescribed has effect in addition to or despite any other written law or rule of law;”.
- 30

Related amendments to Mental Capacity Act

68.—(1) Section 2(1) of the Mental Capacity Act (Cap. 177A, 2010 Ed.) is amended by inserting, immediately before the definition of “clinical trial”, the following definition:

5 ““appropriate consent” has the same meaning as in the Human Biomedical Research Act 2015;”.

(2) Section 6 of the Mental Capacity Act is amended by inserting, immediately after subsection (5), the following subsection:

10 “(5A) Where the determination relates to the giving, refusal or revocation of —

 (a) appropriate consent of the person concerned under the Human Biomedical Research Act 2015, the person must take into account such matters, considerations and procedures as may be prescribed under Part 3 of that Act; or

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 (b) consent of the person concerned under any written law relating to a clinical trial, the person must take into account such matters, considerations and procedures as may be prescribed in such written law.”.

20 (3) Section 7(3) of the Mental Capacity Act is amended —

 (a) by deleting the word “or” at the end of paragraph (b); and

 (b) by deleting the full-stop at the end of paragraph (c) and substituting the word “; or”, and by inserting immediately thereafter the following paragraph:

25 “(d) applies to the conduct of human biomedical research within the meaning of the Human Biomedical Research Act 2015 or the removal or use of human tissue under that Act.”.

30 (4) Section 13 of the Mental Capacity Act is amended by inserting, immediately after subsection (7), the following subsection:

 “(7A) Where a lasting power of attorney authorises the donee (or, if more than one, any of them) to make decisions about P’s personal welfare, the authority extends to giving, refusing or

revoking appropriate consent involving P under the Human Biomedical Research Act 2015 if, and only if, the instrument contains express provision to that effect.”.

(5) Section 22(1) of the Mental Capacity Act is amended by inserting, immediately after paragraph (d), the following paragraph: 5

“(da) giving, refusing or revoking of appropriate consent involving P under the Human Biomedical Research Act 2015; and”.

(6) The Mental Capacity Act is amended by renumbering section 29 as subsection (1) of that section, and by inserting immediately thereafter the following subsection: 10

“(2) To avoid doubt, it is declared that nothing in this Act is to be taken to affect the giving, refusing or revoking of consent on behalf of a person who lacks mental capacity by a person who is expressly authorised to do so under — 15

(a) the Human Biomedical Research Act 2015; or

(b) any written law relating to a clinical trial.”.

FIRST SCHEDULE

Sections 2 and 62(1)

HUMAN BIOLOGICAL MATERIAL EXCLUDED FROM DEFINITION OF HUMAN TISSUE 20

1. Hair shaft, cut without dermal hair root or follicle.
2. Nail plate, cut without underlying dermal tissue.
3. Naturally excreted bodily fluids and waste products such as saliva, sweat, urine and faeces. 25

4.—(1) Any other human biological material that is not individually-identifiable and has been processed in such a manner that its functional, structural and biological characteristics are substantially manipulated as compared to the time of collection.

(2) For the purposes of and without prejudice to the generality of sub-paragraph (1), human biological material is not deemed to be substantially manipulated merely because it has been processed by any of, or any combination of, the following methods: 30

FIRST SCHEDULE — *continued*

- (a) cutting;
- (b) grinding;
- (c) shaping;
- 5 (d) centrifugation;
- (e) soaking in antibiotic or antimicrobial solutions;
- (f) sterilization;
- (g) low-level irradiation;
- (h) cell separation, concentration or purification;
- 10 (i) filtering;
- (j) lyophilisation;
- (k) freezing;
- (l) cryopreservation;
- (m) vitrification.

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SECOND SCHEDULE

Sections 3(4) and 62(1)

RESEARCH, STUDIES AND MATTERS EXCLUDED FROM DEFINITION
OF HUMAN BIOMEDICAL RESEARCH

- 20 1. Research and studies on normal human psychological responses and behaviours —
 - (a) which are not designed or intended to study psychiatric or psychological disorders; and
 - (b) which involve no more than minimal risk to the research subject.
- 25 2. Research, studies and tests to measure human intelligence —
 - (a) which are not designed or intended to study mental or intellectual disability; and
 - (b) which involve no more than minimal risk to the research subject.
- 30 3. Public health research on infectious diseases conducted for the purposes of and in accordance with section 59A of the Infectious Diseases Act (Cap. 137).
- 4. Collection and compilation by the National Registry of Diseases of health information for epidemiological or statistical purposes in accordance with the National Registry of Diseases Act (Cap. 201B).

SECOND SCHEDULE — *continued*

5. Collection and compilation of health information for statistical purposes in accordance with the Statistics Act (Cap. 317).

6. Clinical trials of health products conducted in accordance with the Health Products Act (Cap. 122D). 5

7. Clinical trials of medicinal products conducted in accordance with the Medicines Act (Cap. 176).

THIRD SCHEDULE

Sections 2, 30(1) and 62(1) and
paragraph 3 of Fourth Schedule 10

PROHIBITED HUMAN BIOMEDICAL RESEARCH

1. Human biomedical research involving the development of human-animal combination embryos referred to in paragraph 2(a)(i) or (iii) of the Fourth Schedule beyond 14 days or the appearance of the primitive streak, whichever is the earlier.

2. Human biomedical research involving the implantation of any human-animal combination embryo into the uterus of an animal or a human. 15

3. Human biomedical research involving the introduction of human stem cells (including induced pluripotent stem cells) or human neural cells into the brain of living great apes whether prenatal or postnatal.

4. Human biomedical research involving the breeding of animals which have had any kind of pluripotent stem cells (including induced pluripotent stem cells) introduced into them. 20

FOURTH SCHEDULE

Sections 2, 31(1) and 62(1) and
paragraph 1 of Third Schedule 25

RESTRICTED HUMAN BIOMEDICAL RESEARCH

1. Human biomedical research involving human eggs or human embryos.

2. Human biomedical research involving —

(a) the following types of human-animal combination embryos:

(i) cytoplasmic hybrid embryos; 30

(ii) human-animal combination embryos created by the incorporation of human stem cells (including induced pluripotent stem cells);

FOURTH SCHEDULE — *continued*

(iii) human-animal combination embryos created in-vitro by using —

(A) human gametes and animal gametes; or

(B) one human pronucleus and one animal pronucleus;

- 5 (b) the introduction of human stem cells (including induced pluripotent stem cells) into a prenatal animal foetus or animal embryo;
- (c) the introduction of human pluripotent stem cells (including induced pluripotent stem cells) into a living postnatal animal;
- 10 (d) the introduction of human stem cells (including induced pluripotent stem cells) or human neural cells into the brain of a living postnatal animal; or
- (e) any entity created as a result of any process referred to in sub-paragraphs (b), (c) and (d).

3. Nothing in this Schedule is to be construed to permit any human biomedical research that is prohibited under the Third Schedule.

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FIFTH SCHEDULE

Sections 13(1), 17(1)(f) and 62(1)

WAIVER OF REQUIREMENTS FOR APPROPRIATE CONSENT
BY INSTITUTIONAL REVIEW BOARD

PART 1

20

WAIVER OF REQUIREMENTS
FOR APPROPRIATE CONSENT TO BE IN WRITING

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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).

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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 the unauthorised disclosure of confidential information such as the research subject's identity and the fact of the subject's participation in the research.

FIFTH SCHEDULE — *continued*

PART 2

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

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3. Where the institutional review board is satisfied that —

- (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; 10
- (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. 15

PART 3

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 — 20

- (a) the research subjects are in a life-threatening situation;
- (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; 25
- (d) participation in the proposed research holds out the prospect of direct benefit to the research subjects;
- (e) obtaining appropriate consent is not feasible because —
 - (i) the subjects will not have capacity within the time available to give their appropriate consent as a result of their medical condition or situation; and 30
 - (ii) no person who is authorised to give appropriate consent on behalf of the research subject under section 6 is available;

FIFTH SCHEDULE — *continued*

(f) the human biomedical research may not practicably be carried out unless there is a waiver;

(g) provision is made for one of the following, whichever occurs first:

5 (i) the research subject is to be informed as soon as is practicable after he or she regains capacity of his or her participation in the research and given an opportunity to withdraw from further participation in the research; or

10 (ii) the person who is authorised to give appropriate consent on behalf of the research subject under section 6 to be informed as soon as is practicable of the subject's participation in the research and to be given an opportunity to request that the subject be withdrawn from further participation in the research; or

15 (h) provision is made for a medical practitioner who is registered under the Medical Registration Act (Cap. 174) as a specialist in the specialty relating to the research and who is not involved in the research as a researcher or supervisor to certify, prior to the enrolment of the research subject to the best of the specialist's knowledge that sub-paragraphs (a) to (e) have been complied with.

20 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 is obtained from his or her body, or any of his or her individually-identifiable health
25 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 banks and tissue banking activities; and

(d) prohibit the commercial trading of human tissue.

The Bill also makes related amendments to certain other Acts.

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” and “supervision and control” of such 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 also provides for the appointment of authorised officers and empowers the Director to delegate the powers conferred under the 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 the Minister on any matter arising out of the administration of the Bill. The Director is also empowered to establish advisory committees for the purpose of advising the Director 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 from research subjects or tissue donors for the purposes of the Bill must be taken.

Clause 7 provides for how consent for human biomedical research may be obtained in the case of adults who lack mental capacity.

Clause 8 provides for how consent for human biomedical research involving minors may be obtained.

Clause 9 provides for how consent for the removal or use of tissue involving adults who lack mental capacity may be obtained.

Clause 10 provides for how consent for the removal or use of tissue involving minors may be obtained.

Clause 11 provides for how consent for research or removal of tissue may be obtained in the case of deceased persons.

Clause 12 specifies the information that has to be provided to the research subject or tissue donor or the person authorised to give consent on behalf of the subject or donor before taking appropriate consent.

Clause 13 empowers an institutional review board to waive certain requirements relating to appropriate consent in circumstances specified in the Fifth Schedule.

Clause 14 provides that a research subject or tissue donor or any person who is authorised to give consent on their behalf may, at any time, withdraw consent to the research subject's participation in the human biomedical research or the use of the donor's tissue for research. 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 15 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 supervision and control of that research institution. A research institution is also under a duty to inform the Director of any appointment or revocation of appointment of its institutional review board.

Clause 16 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 17 sets out the functions and duties of an institutional review board and provides for expedited reviews performed solely by the chairman or another authorised member of the board.

Clause 18 relates to the composition, quorum and proceedings of institutional review boards.

Clause 19 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 20 provides that every application to an institutional review board for the review of human biomedical research must be made by one or more researchers responsible for the conduct and supervision of the research in accordance with prescribed requirements.

Clause 21 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 22 deals with the conduct of human biomedical research. The clause prohibits the conduct of human biomedical research except under the supervision and control of a research institution with a place of business in Singapore and with at least 2 Singapore residents who are responsible on behalf of the research institution for the supervision and control of the research. The clause also sets out the duties of a researcher.

Clause 23 deals with the functions and duties of research institutions.

Clause 24 imposes a duty on every research institution to submit a declaration of compliance in respect of all human biomedical research conducted under its supervision and control within a prescribed time frame.

Clause 25 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 the subject's biological material or individually-identifiable health information. The appropriate consent must be obtained in accordance with the requirements of Part 3.

Clause 26 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 27 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 28 prohibits the re-identification of individually-identifiable information or human biological material relating to human biomedical research that has been rendered non-identifiable.

Clause 29 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 or her functions or duties under the Bill, or by virtue of his or her conduct or review of the human biomedical research.

Clause 30 prohibits any research institution or person from conducting, supervising or controlling any prohibited human biomedical research specified in the Third Schedule.

Clause 31 imposes additional requirements on any research institution or person conducting, supervising or controlling any restricted human biomedical research specified in the Fourth Schedule.

PART 6

REGULATION OF HUMAN TISSUE ACTIVITIES AND TISSUE BANKS

Part 6 deals with the regulation of human tissue activities and tissue banks.

Clause 32 prohibits the commercial trading of human tissue. To avoid overlap, the clause and clause 33 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 33 is supplementary to clause 32 and prohibits advertisements relating to commercial trading of human tissue.

Clause 34 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 35 provides for the duties imposed on tissue banks.

Clause 36 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 37 imposes restrictions on certain activities relating to human tissue for research purposes namely the removal, storage, supply and use of human tissue.

Clause 38 prohibits the coercion, intimidation or deception of another person against that person's will to allow his or her human tissue to be removed.

Clause 39 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 40 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. Codes of practice may also be issued for the protection of the identity of individuals in relation to individually-identifiable human biological material and health information. 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 41 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 42 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 43 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 44 allows the subject of a prohibition order to apply to the Director for the order to be reviewed.

Clause 45 provides for authorised officers to be conferred with the powers of entry, inspection and search, detention or seizure of any document or article, etc.

Clause 46 provides for the disposal of any document or article produced, detained or seized under clause 45.

Clause 47 provides that the information and identity of an informer who has given information with respect to an offence under the Bill is not to be disclosed.

Clause 48 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 the 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 49 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 50 provides for an enhanced penalty not exceeding twice the prescribed fine if a body corporate is convicted of an offence under the Bill.

Clause 51 provides that any act done or conduct engaged in by an employee in the course of his or her employment is to be treated as done or engaged in by his or her employer as well as by him or her, whether or not it was done or engaged in with the employer's knowledge or approval.

Clause 52 relates to the liability of directors and partners for any offence under the Bill committed by a company or firm.

Clause 53 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 54 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 the Director, or by directing the Director to reconsider the decision, notice or direction, as the case may be. Before determining an appeal, the Minister may also consult such Appeals Advisory Panel established under clause 55 for the purpose of advising the Minister in respect of the appeal, but, in making such determination, he or she is not to be bound by such consultation.

Clause 55 empowers the Minister to form an Appeals Advisory Panel where the Minister considers that an appeal lodged under clause 54 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 the Minister's functions under clause 54 in respect of any appeal.

PART 10

MISCELLANEOUS

Part 10 contains the miscellaneous provisions of the Bill.

Clause 56 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 57 empowers the Minister to, either generally or in a particular case, 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 58 empowers the Minister to designate the Second Minister, if any, or any Senior Minister of State or Minister of State to exercise certain specified powers and duties of the Minister under the Bill.

Clause 59 relates to the service of documents.

Clause 60 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 61 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 62 empowers the Minister to amend the First, Second, Third, Fourth or Fifth Schedule by order published in the *Gazette*.

Clause 63 empowers the Minister to make regulations for certain matters.

Clause 64 provides for savings and transitional provisions for legacy human biological material.

Clause 65 provides for certain savings and transitional matters.

Clause 66 makes a related amendment to the Health Products Act (Cap. 122D) to widen the powers to make regulations for clinical trials in order that the provisions of such regulations may be aligned in certain aspects with the provisions of the Bill.

Clause 67 makes a related amendment to the Medicines Act (Cap. 176) to widen the powers to make regulations for clinical trials in order that the provisions of such regulations may be aligned in certain aspects with the provisions of the Bill.

Clause 68 makes related amendments to the Mental Capacity Act (Cap. 177A) to enable a donee of a lasting power of attorney, a deputy appointed by the court under that Act and the court to make decisions relating to consent under the Bill. The amendment will also clarify that the Mental Capacity Act will not prevent a person who is expressly authorised under the Bill or any written law relating to a clinical trial from giving consent on behalf of a mentally incapacitated person.

The First Schedule sets out the human biological material excluded from the definition of “human tissue”.

The Second Schedule sets out the research, studies and matters excluded from the definition of “human biomedical research”.

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

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

The Fifth 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.
