

No.

HUMAN BIOMEDICAL RESEARCH ACT 2015
(ACT 29 OF 2015)

HUMAN BIOMEDICAL RESEARCH
(EXEMPTIONS) REGULATIONS 2018

ARRANGEMENT OF REGULATIONS

Regulation

1. Citation and commencement
2. Exemption from requirement for witness
3. Exemption from need for appropriate consent if tissue collected before [date to be inserted]
4. Exemption for tissue banking activities regulated under other legislation

In exercise of the powers conferred by section 63 read with section 57 of the Human Biomedical Research Act 2015, the Minister for Health makes the following Regulations:

Citation and commencement

1. These Regulations are the Human Biomedical Research (Exemptions) Regulations 2018 and come into operation on [date to be inserted].

Exemption from requirement for witness

2.—(1) The requirement in section 6(*d*) of the Act that appropriate consent must be obtained in the presence of a prescribed witness does not apply to the appropriate consent of a tissue donor whose tissue is removed primarily for a therapeutic or diagnostic purpose.

(2) The requirement in section 6(*d*) of the Act does not apply to any consent of a tissue donor given before [date to be inserted].

Exemption from need for appropriate consent if tissue collected before [date to be inserted]

3.—(1) Sections 12 and 37 of the Act do not apply in relation to the storage of tissue for use in research, the supply of tissue for use in research and the use of tissue for research where—

- (a) the tissue which has been removed from a human body, whether living or dead, at any time before [date to be inserted]; and
- (b) there is documentary evidence indicating that the relevant consent of the donor has been obtained, before [date to be inserted], for the use of the tissue in research even though some or all of the requirements for appropriate consent in sections 12 and 37 of the Act were not complied with.

(2) In paragraph (1), “relevant consent”, in relation to the donor means —

- (a) the consent of the donor; or
- (b) in the case where the donor is a minor or lacks capacity or was deceased when the tissue was removed, the consent of any of the following individuals on behalf of the donor, where applicable:
 - (i) the donee or deputy of the donor;
 - (ii) the spouse of the donor;
 - (iii) an adult son or daughter of the donor;
 - (iv) either parent or a guardian of the donor;
 - (v) an adult brother or sister of the donor;
 - (vi) any other person named by the adult donor as someone to be consulted on the donation of tissue.

Exemption for tissue banking activities regulated under other legislation

4.—(1) Sections 34, 35 and 36 of the Act do not apply to any tissue bank who conducts any tissue banking activity solely for the purpose

of any of the following research or clinical trials conducted under the supervision and control of the tissue bank:

- (a) public health research on infectious diseases conducted for the purposes of and in accordance with section 59A of the Infectious Diseases Act (Cap. 137);
- (b) clinical trials of health products conducted in accordance with the Health Products Act (Cap. 122D);
- (c) clinical trials of medicinal products conducted in accordance with the Medicines Act (Cap. 176).

(2) To avoid doubt, an individual, body of persons or tissue bank who conducts any tissue banking activity concurrently with, or in addition to, or which is not solely for, the purposes specified in paragraph (1) must comply with sections 34, 35 and 36 of the Act in relation to that activity.

Made on 2018.

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

[AG/LEGIS/SL/131C/2015/8]

Note 1: Human Biomedical Research (Exemption) Regulations (15-8-18)(v1.09)