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HUMAN BIOMEDICAL RESEARCH ACT 2015
(ACT 29 OF 2015)

HUMAN BIOMEDICAL RESEARCH (REQUIREMENTS FOR APPROPRIATE CONSENT — EXEMPTION) REGULATIONS 2019

ARRANGEMENT OF REGULATIONS

In exercise of the powers conferred by section 63 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 (Requirements for Appropriate Consent — Exemption) Regulations 2019 and come into operation on 1 November 2019.

Exemption from need for witness to research subject's consent

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 research subject where the research —

(*a*) is not invasive;

(*b*) is not interventional; and

(*c*) is not restricted human biomedical research.

(2) For the purposes of paragraph (1), research that comprises solely of a survey or collection of information from the research subjects is treated as not invasive and not interventional.

(3) Despite paragraph (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 research subject where —

(*a*) the research is interventional but the intervention involves no more than minimal risk to the research subject;

(*b*) the research subject is able to read and sign the appropriate consent form; and

(*c*) the research is not restricted human biomedical research.

(4) The requirement in section 6(*d*) of the Act does not apply to any consent to human biomedical research given by a research subject before 1 November 2017.

(5) In this regulation, research is interventional if the research involves 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.

Exemption from need for witness to tissue donor's consent

3.—(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 —

(*a*) is to be removed primarily for a therapeutic or diagnostic purpose; and

(*b*) is not to be used for restricted human biomedical research.

(2) 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 where —

(*a*) the removal of the tissue involves no more than minimal risk to the tissue donor;

(*b*) the tissue donor is able to read and sign the appropriate consent form; and

(*c*) the appropriate consent is not for the purpose of restricted human biomedical research.

(3) The requirement in section 6(*d*) of the Act does not apply to any consent to the removal, storage, supply or use of tissue given by a tissue donor before 1 November 2019.

Exemption from need to provide certain information if biological material or health information obtained before 1 November 2018

4.—(1) Sections 12, 22(2)(*c*) and 25 of the Act do not apply in relation to the use of any individually-identifiable biological material or health information of a research subject in research where —

(*a*) the individually-identifiable biological material or health information was obtained before 1 November 2018;

(*b*) there is documentary evidence indicating that the research subject or the person authorised to give consent mentioned in paragraph (2) —

(i) had given relevant consent in writing before 1 November 2018 for the use of the individually-identifiable biological material or health information; and

(ii) had been informed of the matters in section 12(1)(*a*), (*b*), (*c*), (*d*), (*h*), (*k*) and (*n*) of the Act, before such relevant consent was obtained; and

(*c*) the relevant consent was not withdrawn at any time before 1 November 2018.

(2) In paragraph (1), "relevant consent", in relation to research that is not restricted human biomedical research and a research subject who is a minor or an adult who lacks mental capacity or was deceased when the individually-identifiable biological material or health information was obtained, means the consent given on behalf of the research subject by any of the following individuals:

(*a*) the donee or deputy of the research subject;

(*b*) the spouse of the research subject;

(*c*) an adult son or daughter of the research subject;

(*d*) either parent or a guardian of the research subject;

(*e*) an adult brother or sister of the research subject.

Exemption from need for appropriate consent if tissue collected before 1 November 2019

5.—(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 was removed from a human body, whether living or dead, at any time before 1 November 2019;

(*b*) there is documentary evidence indicating that the donor or the person authorised to give consent mentioned in paragraph (2) —

(i) had given relevant consent in writing before 1 November 2019 for the use of the tissue in research; and

(ii) had been informed of the matters in section 12(2)(*a*), (*f*) and (*i*) of the Act, before such relevant consent was obtained; and

(*c*) the relevant consent was not withdrawn at any time before 1 November 2019.

(2) In paragraph (1), "relevant consent", in relation to a donor who is a minor or an adult who lacks mental capacity or was deceased

when the tissue was removed, means the consent given on behalf of the donor by any of the following individuals:

(*a*) the donee or deputy of the donor;

(*b*) the spouse of the donor;

(*c*) an adult son or daughter of the donor;

(*d*) either parent or a guardian of the donor;

(*e*) an adult brother or sister of the donor.

Exemption from need for appropriate consent of parent or guardian for storage, use or supply of blood donated by minor

6. The requirements in sections 8 and 10 of the Act that appropriate consent must be obtained from the adult parent or guardian of a minor 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 is the blood of a minor who is of or above 18 years of age;

(*b*) the tissue was donated by the minor for a therapeutic purpose under a national blood donation programme administered by the Health Sciences Authority established under the Health Sciences Authority Act (Cap. 122C);

(*c*) the minor has sufficient understanding and intelligence to enable the minor to understand what is proposed in the research or procedure; and

(*d*) the minor has given consent and has been informed of the matters in section 12(2) of the Act before such consent was obtained.

Made on 21 October 2019.

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

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