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HUMAN BIOMEDICAL RESEARCH ACT 2015
(ACT 29 OF 2015)

HUMAN BIOMEDICAL RESEARCH
(EXEMPTION) REGULATIONS 2018

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 (Exemption) Regulations 2018 and come into operation on 1 November 2018.

Exemption from appropriate consent if biological material or health information obtained before 1 November 2018

2.—(1) Sections 12, 22(2)(*c*) and 25 of the Act do not apply in relation to 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 that the research subject had given relevant consent before 1 November 2018 for the use

of the individually-identifiable biological material or health information; 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(*c*) the relevant consent was not withdrawn at any time before 1 November 2018.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 appropriate consent if ethics committee waived consent before 1 November 2017

3.—(1) Sections 12, 22(2)(*c*) and (*d*) and 25 of the Act do not apply in relation to individually-identifiable biological material or health information of a research subject in a research where an ethics committee has before 1 November 2017 waived the requirement for consent for the use of such material or information on all the following grounds:

(*a*) the research cannot reasonably be carried out without the use of the human biological material or health information in an individually-identifiable form;

(*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;

(*c*) the waiver concerned will not otherwise adversely affect the rights and welfare of the research subject.

(2) It does not matter that the ethics committee had decided on the waiver on other grounds that were additional to the grounds mentioned in paragraph (1) so long as all the grounds in paragraph (1)(*a*), (*b*) and (*c*) formed part of the grounds for the ethics committee's decision.

(3) In paragraph (1), "ethics committee" means a board or committee, by whatever name called, appointed at any time before 1 November 2017 by a research institution to conduct an ethics review of proposed human biomedical research.

Expiry

4. These Regulations expire at the end of 31 October 2019.

Made on 31 October 2018.

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

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