

Human Biomedical Research Regulations 2017

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No. S 621

**HUMAN BIOMEDICAL RESEARCH ACT 2015
(ACT 29 OF 2015)**

HUMAN BIOMEDICAL RESEARCH REGULATIONS 2017

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

PART 1

PRELIMINARY

Citation and commencement

1. These Regulations are the Human Biomedical Research Regulations 2017 and come into operation on 1 November 2017.

Definitions

2. In these Regulations, unless the context otherwise requires —

“healthcare professional” means —

(a) a medical practitioner;

- (b) a dentist registered under the Dental Registration Act (Cap. 76);
- (c) a registered nurse or an enrolled nurse or a registered midwife, within the meaning of the Nurses and Midwives Act (Cap. 209);
- (d) a pharmacist registered under the Pharmacists Registration Act (Cap. 230);
- (e) an allied health professional within the meaning of the Allied Health Professions Act (Cap. 6B); or
- (f) a person registered under section 14 of the Traditional Chinese Medicine Practitioners Act (Cap. 333A) for the carrying out of any practice of traditional Chinese medicine prescribed under that Act;

“immediate family relationship”, in relation to an individual, means the individual’s relationship with another individual who is his or her spouse, child, adopted child, stepchild, brother, sister, parent or step-parent;

“lay person”, in relation to a member, means an individual who is none of the following:

- (a) an individual who is or was a healthcare professional;
- (b) an individual who possesses or previously possessed a qualification or registration, in a country or territory outside Singapore, which is equivalent to or corresponds with any of the qualifications in paragraphs (a) to (f) of the definition of “healthcare professional”;
- (c) an individual who is currently or was previously involved in the conduct of any research as an investigator;

“member” means an individual who is a member of an institutional review board;

“other relationship”, in relation to an individual, includes any relationship in the form of affiliation, participation, financial interest, or competition, in the research proposal under review, which may adversely affect the impartiality, objectivity and independence of the individual;

“relevant website” means the Internet website at <https://elis.moh.gov.sg/tiaras>;

“research” means human biomedical research;

“scientific person” means an individual who has such professional scientific or clinical qualification, knowledge or experience as to enable that individual to assist the institutional review board in understanding particular aspects of the research proposals under review by the board.

PART 2

RESEARCH INSTITUTIONS

Notification by research institution

3.—(1) For the purposes of section 23(1)(a) of the Act, the notification by the research institution must be submitted to the Director in the applicable form set out at the relevant website and must contain all of the following information:

- (a) the name of the research institution and the address, telephone number and email address at which that institution may be contacted;
- (b) such other information as may be required or specified in the form set out on that website.

(2) A research institution, that has not commenced any research before 1 November 2017, must submit the notification required by section 23(1)(a) of the Act, no later than 30 days before the commencement of its first human biomedical research.

Notification of research started before 1 November 2017

4.—(1) A research institution that has started any research before 1 November 2017 must submit a notification to the Director in the applicable form set out at the relevant website no later than 1 December 2017.

(2) The notification mentioned in paragraph (1) must contain all of the following information:

- (a) the name of the research institution and the address, telephone number and email address at which that institution may be contacted;
- (b) such other information as may be required or specified in the form set out at the relevant website.

(3) A research institution who or which contravenes paragraph (1) or (2) shall be guilty of an offence and shall be liable on conviction —

- (a) in the case of an individual, to a fine not exceeding \$10,000 or to imprisonment for a term not exceeding 12 months or to both; or
- (b) in any other case, to a fine not exceeding \$10,000.

Principal person in charge

5.—(1) The principal person in charge designated by the research institution under section 23(2)(b) of the Act must be an individual (however described by name) who —