

# **Human Biomedical Research (Restricted Research) Regulations 2017**

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**No. S 622**

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

**HUMAN BIOMEDICAL RESEARCH  
(RESTRICTED 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 (Restricted Research) Regulations 2017 and come into operation on 1 November 2017.

**Definitions**

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

“assisted reproduction treatment” means the assisted reproduction services specified in the Second and Third Schedules to the Private Hospitals and Medical Clinics Regulations (Cap. 248, Rg 1);

“institutional animal care and use committee” means an institutional animal care and use committee appointed under rule 7 of the Animals and Birds (Care and Use of Animals for Scientific Purposes) Rules (Cap. 7, R 10) by the research institution supervising the restricted research in its capacity as a licensee under those Rules;

“restricted research” means any restricted human biomedical research.

## PART 2

### APPROVAL AND CONDUCT OF RESTRICTED RESEARCH IN GENERAL

#### **Approval for restricted research starting on or after 1 November 2017**

3.—(1) This regulation applies to any restricted research which starts on or after 1 November 2017.

(2) The researcher must, before starting any restricted research mentioned in paragraph (1) ensure that the conduct of the restricted research is approved by all of the following:

- (a) an institutional review board of the research institution under whose supervision or control the restricted research is to be conducted by the researcher;
- (b) an institutional animal care and use committee where any living postnatal animal, living animal foetus or a living animal embryo is to be used in the restricted research;
- (c) the Director.

(3) The application to the Director for approval mentioned in paragraph (2)(c) for any restricted research must —

- (a) contain the following information and particulars:
  - (i) particulars of the principal researcher and any other individual who is involved in the restricted research;

- (ii) the title of the research proposal;
  - (iii) the name of the research institution under whose supervision or control the restricted research is to be conducted by the researcher;
  - (iv) the location or facility where the restricted research will be carried out;
  - (v) such other information or particulars as may be specified in the electronic application system on the Internet website at <https://elis.moh.gov.sg/tiaras>;
- (b) be accompanied by the approvals or certified true copies of the approvals mentioned in paragraph (2)(a) and if applicable, (b); and
- (c) be submitted through the research institution.

(4) A research proposal for or involving restricted research must not be reviewed by an institutional review board through an expedited process, and not be exempted from review by an institutional review board.

(5) In determining whether to grant approval under paragraph (2)(c), the Director may consult an advisory committee established under section 5(2) of the Act.

(6) The Director's approval under paragraph (2)(c) is valid for such period as the Director may determine.

### **Restricted research started before 1 November 2017**

4.—(1) This regulation applies to any restricted research which started at any time before 1 November 2017 and has not been completed before that date.

(2) The research institution under whose supervision or control the restricted research mentioned in paragraph (1) is conducted must —

- (a) notify the Director of the conduct of all such restricted research no later than 1 December 2017; and
- (b) ensure that the restricted research is conducted only by the persons named in a research proposal approved by an institutional review board.

(3) Where the restricted research mentioned in paragraph (1) is not expected to be completed before 1 November 2018, the researcher conducting that research must before that date, ensure that the conduct of the restricted research is approved by all of the

following:

- (a) an institutional review board of the research institution under whose supervision or control the restricted research is to be conducted by the researcher;
- (b) an institutional animal care and use committee where any living postnatal animal, living animal foetus or a living animal embryo is to be used in the restricted research;
- (c) the Director.

(4) The application to the Director for approval mentioned in paragraph (3)(c) for any restricted research must —

- (a) contain the following information and particulars:
  - (i) particulars of the principal researcher and any other individual who is involved in the restricted research;
  - (ii) the title of the research proposal;
  - (iii) the name of the research institution under whose supervision or control the restricted research is to be conducted by the researcher;
  - (iv) the location or facility where the restricted research will be carried out;
  - (v) such other information or particulars as may be specified in the electronic application system on the Internet website at <https://elis.moh.gov.sg/tiaras>;
- (b) be accompanied by the approvals or certified true copies of the approvals mentioned in paragraph (3)(a) and if applicable, (b); and
- (c) be submitted through the research institution.

(5) A research proposal for or involving restricted research must not be reviewed by an institutional review board through an expedited process, and not be exempted from review by an institutional review board.

(6) In determining whether to grant approval under paragraph (3)(c), the Director may consult an advisory committee established under section 5(2) of the Act.

(7) The Director's approval under paragraph (3)(c) is valid for such period as the Director may determine.