First published in the Government *Gazette*, Electronic Edition, on 30 October 2017 at 5.30 pm.

No. S 622

HUMAN BIOMEDICAL RESEARCH ACT 2015 (ACT 29 OF 2015)

HUMAN BIOMEDICAL RESEARCH (RESTRICTED RESEARCH) REGULATIONS 2017

ARRANGEMENT OF REGULATIONS

PART 4

MISCELLANEOUS

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.

(8) To avoid doubt, paragraph (3) does not apply to restricted research which started before 1 November 2017 and is expected to be completed before 1 November 2018.

Special requirements in consent-taking for restricted research

5. The appropriate consent of the research subject in a restricted research proposal —

(*a*) must be obtained from the research subject who has capacity to give consent in person; and

(*b*) must not be obtained from another person who is authorised under Part 3 of the Act to give consent on the subject's behalf.

Conditions for conduct of restricted research

6.—(1) In granting an approval for restricted research under regulation 3 or 4, the Director may impose such conditions as the Director may think fit and the research institution and every researcher involved in that research must comply with such conditions.

(2) Without limiting paragraph (1), in the case of any restricted research specified in paragraph 2 of the Fourth Schedule to the Act, the Director may impose conditions relating to the occurrence or likelihood of human sentience or human consciousness.

(3) Where any restricted research is stopped because of any condition imposed by the Director, the restricted research may only be resumed with the Director's approval in writing.

(4) Every restricted research must be carried out only at such location or facility, and by such researchers, as are approved by the Director.

Report by researcher

7.—(1) Every researcher must submit to the Director at the times and intervals the Director determines, a periodic report in the form set out on the Internet website at https://elis.moh.gov.sg/tiaras of the progress of the restricted research including the compliance with the conditions of the approval for the restricted research.

(2) Any person who contravenes paragraph (1) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 12 months or to both.

No deviation from approved application for restricted research

8. The researcher and the research institution conducting restricted research must ensure that the restricted research does not deviate from the research proposal approved by the Director under these Regulations without the prior written approval of the Director.

PART 3

RESEARCH INVOLVING OOCYTES AND EMBRYOS

Application of this Part

9. This Part, except for regulation 10, does not apply to oocytes and embryos imported from a place outside Singapore for the purpose of research in Singapore where there is documentary evidence that consent has been given in accordance with the legal or ethical requirements of that place.

Restrictions on growth of embryo

10. Every research institution and every researcher conducting restricted research must ensure that restricted research carried out does not involve a human embryo which is more than 14 days old from the time of creation of the embryo (excluding any period when the development of the embryo is suspended).

Further restriction on persons involved in assisted reproduction treatment or other therapy

11. Every research institution and every researcher must ensure that a person (*A*) (including that researcher) must not be involved in restricted research involving the use of any oocyte or embryo obtained from a woman (*B*) where *A* was previously involved in the assisted reproduction treatment or other therapeutic treatment of *B* during which the oocyte or embryo was obtained.

Special requirements in consent-taking for oocyte and embryo donors

12.—(1) The appropriate consent of the donor of any oocyte or embryo for the purpose of restricted research —

(*a*) must be obtained from the donor in person and only if the donor has capacity to give consent; and

(*b*) must not be obtained from another person who is authorised under Part 3 of the Act to give consent on the subject's behalf.

(2) Every research institution and every researcher must ensure that consent from the donor of any oocyte or embryo for the purpose of restricted research must be separately and independently obtained from any consent for assisted reproduction treatment or any other therapeutic purpose.

(3) So long as the consent from the donor of any oocyte or embryo for the purpose of restricted research is separately and independently obtained from any consent for assisted reproduction treatment or any other therapeutic purpose, the consent from the donor need not be taken on different days.

(4) The potential donor of any oocyte must confirm in writing at the time that her consent is taken that she has been informed of the full implications of the donation and that she does not require her oocyte for future reproductive use.

(5) The potential donor of any embryo and her husband at the time of the assisted reproduction treatment must both confirm in writing at the time that the consent is taken that —

(*a*) they have each been informed of the full implications of the donation; and

(*b*) they do not require the embryo for future reproductive use.

(6) The research institution and the researcher must ensure that —

(*a*) only surplus embryos created in assisted reproduction treatment may be used for research; and

(*b*) the consent of both the potential donor of the surplus embryo and her husband at the time of that assisted reproduction treatment have been obtained in accordance with paragraphs (1), (2), (3) and (5).

Cooling off period for oocyte and embryo donors

13.—(1) The consent from the donor of any oocyte or embryo for the purpose of restricted research, must be obtained only after a period of 8 days after the day all the relevant information necessary for the informed consent has been given to the donor.

(2) Paragraph (1) does not apply to any immature oocyte or non-viable embryo that is unsuitable for fertility treatment and would otherwise be discarded.

Institutional review board approval of research involving surplus oocytes and embryos

14. Where an institutional review board reviews a research proposal involving the use of surplus oocytes or surplus embryos or both, the board must ensure that —

(*a*) where a potential donor for research is also a woman undergoing fertility treatment, the restricted research will only use surplus oocytes or surplus embryos or both that are no longer required for therapeutic purposes;

(*b*) the research proposal has adequate provisions to ensure the safety and welfare of research participants;

(*c*) the research proposal has adequate provisions to ensure the ethical procurement of surplus oocytes or surplus embryos or both; and

(*d*) the research proposal adequately addresses the ethical concerns affecting individual research participants.

Release of oocytes or embryos for research

15.—(1) Every researcher conducting or intending to conduct restricted research involving the use of oocytes or embryos must apply to the Director, through his or her research institution, for approval for the relevant tissue bank, if any, to release oocytes or embryos or both.

(2) Paragraph (1) does not apply to any immature oocyte or non-viable embryo that is unsuitable for fertility treatment and would otherwise be discarded.

(3) In determining whether to grant any approval for the release of oocytes or embryos or both, the Director may consult the advisory committee established under section 5(2) of the Act.

(4) The advisory committee established under section 5(2) of the Act must, in advising the Director on whether to approve the release of oocytes or embryos or both —

(*a*) review the scientific merit of the research proposal; and

(*b*) consider the ethical issues and concerns with regard to conducting such a research at the wider societal level.

PART 4

MISCELLANEOUS

Electronic system

16.—(1) Every application for the issue, amendment or renewal of an approval under these Regulations must —

(*a*) be made using the electronic system of the Ministry of Health at https://elis.moh.gov.sg/tiaras or by such other means as the Director may determine; and

(*b*) be submitted to the Director in the form provided by that system.

(2) The Director may modify or amend the form for an application in order to facilitate the submission of that form.

False information

17. Any person who, in submitting an application, a notification, report, a form, a document or other information that is required to be submitted to the Director under these Regulations —

(*a*) makes any statement or furnishes any information that the person knows to be false or does not believe to be true; or

(*b*) by the intentional suppression of any material fact, furnishes information which is misleading,

shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 2 years or to both.

Made on 30 October 2017.

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

[MH 78:69; AG/LEGIS/SL/131C/2015/4 Vol. 1]