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

No. S 623

HUMAN BIOMEDICAL RESEARCH ACT 2015 (ACT 29 OF 2015)

HUMAN BIOMEDICAL RESEARCH ACT 2015 (AMENDMENT OF THIRD, FOURTH AND FIFTH SCHEDULES) ORDER 2017

In exercise of the powers conferred by section 62 of the Human Biomedical Research Act 2015, the Minister for Health makes the following Order:

Citation and commencement

1. This Order is the Human Biomedical Research Act 2015 (Amendment of Third, Fourth and Fifth Schedules) Order 2017 and comes into operation on 2 November 2017.

Amendment of Third Schedule

2. The Third Schedule to the Human Biomedical Research Act 2015 is amended —

(*a*) by deleting paragraph 2 and substituting the following paragraph:

"2. Human biomedical research involving the implantation —

(*a*) of a human-animal combination embryo mentioned in paragraph 2(*a*)(i) or (iii) of the Fourth Schedule into the uterus of an animal; or

(*b*) of a human-animal combination embryo into the uterus of a human."; and

(*b*) by inserting, immediately after the words "kind of" in paragraph 4, the word "human".

Amendment of Fourth Schedule

3. Paragraph 2 of the Fourth Schedule to the Human Biomedical Research Act 2015 is amended by inserting, immediately after the word "animal" in sub-paragraph (*c*), the words "but excludes the introduction of such human pluripotent stem cells into immunodeficient mice solely for the analysis of teratoma induction".

Amendment of Fifth Schedule

4. The Fifth Schedule to the Human Biomedical Research Act 2015 is amended —

(*a*) by deleting sub-paragraph (*a*) of paragraph 3 and substituting the following sub-paragraphs:

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

(*aa*) the process of obtaining consent from the person, to which the individually-identifiable human biological material or health information relates, will involve a disproportionate amount of effort and resources relative to the research requirements;";

(*b*) by inserting, immediately after paragraph 3 in Part 2, the following paragraphs:

"3A. Where the institutional review board is satisfied that —

(*a*) the individually-identifiable health information was obtained or compiled before 1 November 2017;

(*b*) the research cannot reasonably be carried out without the use of the health information in an individually-identifiable form;

(*c*) the use of the individually-identifiable health information involves no more than minimal risk to the research subject;

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

(*e*) the process of obtaining consent from the person, to which the individually-identifiable health information relates, will involve a disproportionate amount of effort and resources relative to the research requirements.

3B. Where the institutional review board is satisfied that —

(*a*) the individually-identifiable human biological material was obtained or compiled before 1 November 2017;

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

(*c*) the use of the individually-identifiable human biological material involves no more than minimal risk to the research subject;

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

(*e*) reasonable effort has been made to re-contact the person to which the individually-identifiable human biological material relates for the purpose of obtaining his or her consent.";

(*c*) by inserting, immediately after the word "unproven" in paragraph 4(*b*), the words "or are unsatisfactory"; and

(*d*) by deleting the word "or" at the end of paragraph 4(*g*)(ii) and substituting the word "and".

Made on 30 October 2017.

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

[MH 78:69; AG/LEGIS/SL/131C/2015/6 Vol. 1]