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HUMAN BIOMEDICAL RESEARCH ACT 2015
(ACT 29 OF 2015)

HUMAN BIOMEDICAL RESEARCH
(AMENDMENT) REGULATIONS 2019

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 (Amendment) Regulations 2019 and come into operation on 1 November 2019.

Amendment of regulation 8

2. Regulation 8 of the Human Biomedical Research Regulations 2017 (G.N. No. S 621/2017) (called in these Regulations the principal Regulations) is amended —

(*a*) by inserting, immediately after the words "relevant information" in paragraph (1), the words "(except for the information specified in paragraph (3))"; and

(*b*) by inserting, immediately after paragraph (2), the following paragraph:

> "(3) For the purposes of section 23(3)(*a*) of the Act, a research institution must ensure that relevant information relating to contraventions in relation to human biomedical research conducted under the supervision and control of that research institution and that did not cause harm to and had no potential to cause harm to any research subject is recorded and submitted to the Director —

(*a*) at the same time the declaration of compliance is submitted in accordance with regulation 7(3); and

(*b*) on an annual basis aggregating the information in the applicable form set out at the relevant website.".

New regulation 8A

3. The principal Regulations are amended by inserting, immediately after regulation 8, the following regulation:

"**Definition of "serious adverse event"**

8A. The untoward medical occurrences which result in any of the following are prescribed events for the purposes of paragraph (*a*)(vi) of the definition of "serious adverse event" in section 2 of the Act:

(*a*) the transmission of a communicable disease;

(*b*) any misidentification or mix-up of any type of human biological material, gamete or embryo.".

New regulations 10A, 10B, 10C and 10D

4. The principal Regulations are amended by inserting, immediately after regulation 10, the following regulations:

"**Notification of cessation of research institution's operations**

10A.—(1) A research institution must notify the Director of its intention to cease operating as a research institution as soon as possible and in any event not less than 30 days before the cessation of operation or such shorter period as the Director may allow in any particular case.

(2) The research institution must ensure that the notification required under paragraph (1) must be accompanied by —

(*a*) a declaration as to whether ongoing human biomedical research will cease, or be transferred to the supervision of another research institution and if

applicable, a plan for the transfer of such ongoing human biomedical research;

(*b*) a plan for the manner of disposal or transfer of the health information and human biological material held by or in the possession of the research institution;

(*c*) where the plan mentioned in sub-paragraph (*a*) or (*b*) involves the transfer of any ongoing human biomedical research, health information or human biological material to another research institution (called in this regulation the receiving institution) —

(i) the name, address and contact particulars of the receiving institution; and

(ii) the plan of the receiving institution as to whether the institutional review board of the research institution ceasing operations will be appointed to continue reviewing the human biomedical research which are to be transferred or whether the receiving institution's own institutional review board will conduct a fresh review of the transferred research;

(*d*) the date of the cessation of operation of the research institution and the reason for the cessation; and

(*e*) any other information as the Director may in any particular case require.

(3) The notification and the information, mentioned in paragraphs (1) and (2), must be submitted to the Director in the applicable form set out at the relevant website.

(4) 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.

Management of contamination of human biological material

10B.—(1) Every research institution must establish a system to prevent or control the spread of any communicable disease which is or may be due to the contamination or infection of any human biological material used in transplantational human biomedical research conducted under the supervision and control of that research institution.

(2) The research institution must ensure that the system mentioned in paragraph (1) must at the minimum take into consideration the following in relation to the human biological material used in transplantational human biomedical research conducted under the supervision and control of the research institution that is or may be contaminated or infected in any other way:

(*a*) the traceability of the human biological material;

(*b*) the traceability of the equipment and material used in the processing of the human biological material;

(*c*) the processing and preservation of the human biological material;

(*d*) the recall procedure for the human biological material.

(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 $20,000 or to imprisonment for a term not exceeding 2 years or to both; or

(*b*) in any other case, to a fine not exceeding $20,000.

Safety and welfare of research subjects

10C.—(1) Every research institution that is involved in the removal of human biological material from research subjects for

use in research, must establish a system to ensure the safety and welfare of the research subjects.

(2) The research institution must ensure that the system mentioned in paragraph (1) must at the minimum take into consideration the following in relation to the research subjects:

(*a*) the measures to prevent or control the spread of any communicable disease which is or may be due to the contamination or infection of any human biological material;

(*b*) the management of quality control and maintenance of instruments and equipment used for the removal of human biological material.

(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 $20,000 or to imprisonment for a term not exceeding 2 years or to both; or

(*b*) in any other case, to a fine not exceeding $20,000.

Policy on incidental findings

10D. Every research institution must —

(*a*) formulate a policy on whether or not the research subject should be re-identified and informed in the case of an incidental finding in relation to the human biomedical research; and

(*b*) inform all research subjects of the details of the policy mentioned in paragraph (*a*).".

Deletion of regulation 26

5. Regulation 26 of the principal Regulations is deleted.

Amendment of First Schedule

6. Paragraph 2 of the First Schedule to the principal Regulations is amended by inserting, immediately after the words "Act 2015", the words "or regulation 8 of the Human Biomedical Research Regulations 2017 (G.N. No. S 621/2017)".

Made on 21 October 2019.

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

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