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No. S 731

HEALTH PRODUCTS ACT
(CHAPTER 122D)

HEALTH PRODUCTS (CLINICAL TRIALS) (AMENDMENT NO. 2) REGULATIONS 2021

In exercise of the powers conferred by section 72(1) of the Health Products Act, the Health Sciences Authority, with the approval of the Minister for Health, makes the following Regulations:

Citation and commencement

1. These Regulations are the Health Products (Clinical Trials) (Amendment No. 2) Regulations 2021 and come into operation on 1 October 2021.

Amendment of regulation 2

2. Regulation 2(1) of the Health Products (Clinical Trials) Regulations 2016 (G.N. No. S 331/2016) (called in these Regulations the principal Regulations) is amended by inserting, immediately after the definition of "protocol", the following definition:

" "qualified pharmacist" means a person who —

(*a*) is registered as a pharmacist under the Pharmacists Registration Act (Cap. 230);

(*b*) holds a valid practising certificate granted under section 23 of that Act; and

(*c*) is in active practice as defined in regulation 2 of the Pharmacists Registration (Practising Certificates) Regulations 2008 (G.N. No. S 438/2008);".

Amendment of regulation 5

3. Regulation 5(1) of the principal Regulations is amended —

(*a*) by inserting, immediately after the word "practitioner" in sub-paragraph (*a*), the words "or qualified pharmacist"; and

(*b*) by inserting, immediately after the word "by" in sub-paragraph (*b*), the word "education,".

Amendment of regulation 8

4. Regulation 8(3) of the principal Regulations is amended by deleting the words "who is conducting the trial" and substituting the words ", who is a qualified practitioner and who is conducting the trial,".

Amendment of regulation 9

5. Regulation 9(3) of the principal Regulations is amended by deleting the words "who is conducting the trial" and substituting the words ", who is a qualified practitioner and who is conducting the trial,".

Amendment of regulation 18

6. Regulation 18(1) of the principal Regulations is amended by deleting the words "by an investigator who is a qualified practitioner" and substituting the words "by a principal investigator or an investigator authorised by a principal investigator,".

Amendment of regulation 19

7. Regulation 19 of the principal Regulations is amended —

(*a*) by inserting, immediately after sub-paragraph (*t*) of paragraph (1), the following sub-paragraph:

"(*ta*) where the trial involves the collection of tissue from the subject for use in the trial —

(i) that the provision of the tissue is voluntary, and the renunciation of the subject's rights to the tissue and any

intellectual property rights that may be derived from the tissue;

(ii) whether the tissue will be exported or removed from Singapore to a place outside Singapore; and

(iii) whether the subject would wish to be re-identified in the case of an incidental finding, if the clinical trial expressly provides for such re-identification;"; and

(*b*) by inserting, immediately after paragraph (3), the following paragraph:

"(4) In this regulation —

"incidental finding", in relation to a clinical trial, means a finding about a subject that has potential health or reproductive importance to the subject and is discovered in the course of conducting the clinical trial but is unrelated to the purposes, objectives or variables of the clinical trial;

"tissue" means any human biological material but does not include —

(*a*) any hair shaft that is cut without the dermal hair root or follicle;

(*b*) any nail plate that is cut without the underlying dermal tissue; or

(*c*) any naturally excreted bodily fluid or waste products.".

[G.N. No. S 107/2021]

Made on 17 September 2021.

KANDIAH SATKUNANANTHAM
Chairman,
Health Sciences Authority,
Singapore.

[401:04/01-000; AG/LEGIS/SL/122D/2020/9 Vol. 1]

(To be presented to Parliament under section 72(5) of the Health Products Act).