Updates to the Health Products Act

Health Products (Clinical Trials) Regulations 2016 (Version in force from 1 October 2021) – Allowing Qualified Pharmacist to Be Principal Investigators In Clinical Trials

Group Research

National Healthcare Group

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You are strongly advised to:

- **Read the Health Products Act, Health Products (Clinical Trials) Regulations 2016 – version in force from 1 October 2021, the Regulatory Guidance and other applicable regulations/Acts/guidance (where applicable).**
- **Follow/ seek advise from your respective IRBs with regards to the submissions and the application processes for your research applications.**

Qualified Pharmacist as Principal Investigator

Background

Effective **01 October 2021**, the Health Products (Clinical Trials) Regulations was amended to allow "qualified pharmacists" to be Principal Investigators (PI) of clinical trials. Per the revised regulations section 2, a "qualified pharmacist" is an individual 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).

As a PI, the pharmacist must be qualified by education, training and experience, and has adequate resources, to properly conduct the trial.

Reference: Health Products (Clinical Trials) Regulations 2016 (version in force from 01 Oct 2021), Section 2 and 5

Qualified Pharmacist as Principal Investigator

Background

The Chief Pharmacist's Office, Ministry of Health (MOH) has prepared a guidance document (**Guidance For Pharmacist Principal Investigator** – Version 01 October 2021) to provide further advice and considerations when a pharmacist is involved in a clinical trial as a PI.

The guidance document covers the following areas:

1) General Requirements for Pharmacist PIs
2) Qualifications and Experience of Pharmacist PIs
3) Types of clinical trials which Pharmacists could be involved as PIs
4) Requirement for a physician as a Co-Investigator
5) Monitoring and audits

General Requirements for Pharmacist to be a Principal Investigator (PI)

Reference: Guidance For Pharmacist Principal Investigator, Version 1, Dated 1 October 2021

The following conditions should be satisfied for Pharmacist PIs:

i. The pharmacist are appropriately qualified by education, training and experience;

ii. The pharmacist have adequate resources; and

iii. The pharmacist are able to fulfil the responsibilities of the [1]PI under the Health Products (Clinical Trials) Regulations and the Medicines (Clinical Trials) Regulations.

[1]PI: The legal responsibilities of a PI include trial supervision and study task delegation, medical care of trial subject, consent-taking, serious adverse event report investigational product management and labelling, and trial record keeping.

***Note**: Pharmacist PI should also refer to any additional requirements/ eligibility conditions that may be imposed by a the funding agency(ies) and/or IRBs for being a PI.*

Qualifications & Experiences of Pharmacist to be a Principal Investigator (PI)

Reference: Guidance For Pharmacist Principal Investigator, Version 1, Dated 1 October 2021

The Pharmacist PI must have:

i. A PhD and/or PharmD and/or other appropriate Postgraduate Qualification,
ii. Holds a primary appointment in a local institution and
iii. Salaried by the institution with a demonstrated track record of research (e.g. as evidence by the award of nationally competitive funding, substantial publication record or a laboratory or clinical research program that carries out research in Singapore.)

Important Note: Requirement for physician as a Co-investigator

Pharmacist PI should **involve physicians who are locally registered, as their co-Investigators for all interventional trials**. This allows the physicians to provide direct medical supervision and monitoring of the trial subjects. This fulfills the regulatory requirement that all medical care given to a trial participant, and all medical decisions relating to the trial made on behalf of the trial participant should be responsibility of a qualified physician. This includes obtaining medical history, physical exam and reviewing adverse events.

Types of Clinical Trials Conducted by Pharmacist Principal Investigators (PI)

Reference: Guidance For Pharmacist Principal Investigator, Version 1, Dated 1 October 2021

What type of trials can be conducted by Pharmacist PIs?

Pharmacists may be the PIs for lower risk clinical trials involving locally registered products. These may include but not limited to:

- Health Services Research,
- Pharmacokinetics/dynamics/genomics,
- Therapeutic Drug Monitoring/ Drug optimisation, Diagnostic Tools, Non-interventional and clinical trials.

Such studies should meet the minimal definition in the HBRA and be in compliance with the ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) E6 Guideline for GCP.

Monitoring & Audits of Clinical Trials Conducted by Pharmacist Principal Investigator (PI)

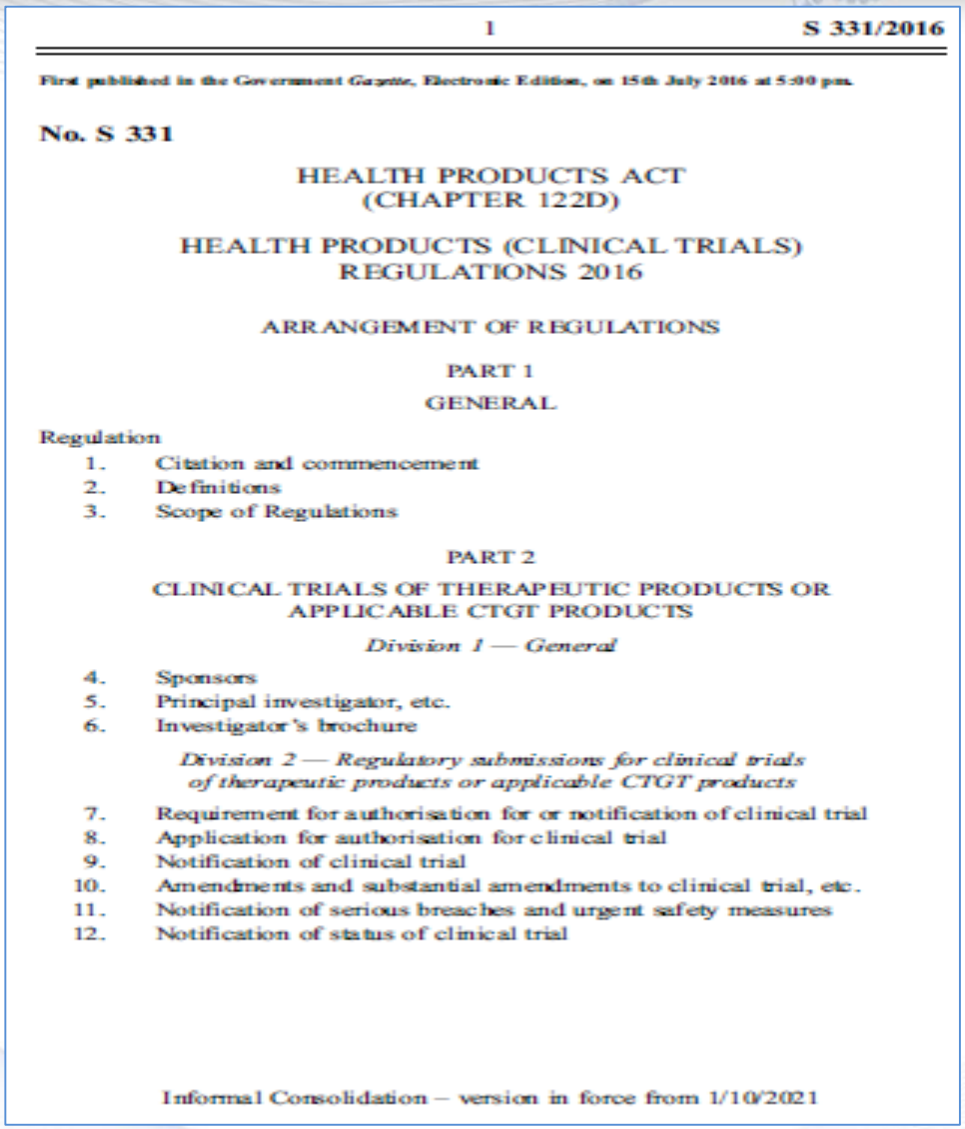
Reference: Guidance For Pharmacist Principal Investigator, Version 1, Dated 1 October 2021

The healthcare institution (who is the trial sponsor of an investigator-initiated trial) should perform routine monitoring and/or audit of the pharmacist-initiated clinical trials to ensure proper conduct of the clinical trial as part of the legal responsibility of a trial sponsor under the Health Products (Clinical Trials) Regulations.

PIs should maintain proper documentation and be prepared to provide the required documentation to show that proper research protocol has been carried out in compliance with applicable regulatory requirements and principles of GCP.

All clinical trials regulated by HSA, including trials where the PI is a pharmacist, may be subject to GCP inspection to assess compliance with protocol and applicable regulations, GCP and SOPs.

Reference



1 S 331/2016

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No. S 331

HEALTH PRODUCTS ACT
(CHAPTER 122D)

HEALTH PRODUCTS (CLINICAL TRIALS) REGULATIONS 2016

ARRANGEMENT OF REGULATIONS

PART 1

GENERAL

Regulation

1. Citation and commencement
2. Definitions
3. Scope of Regulations

PART 2

CLINICAL TRIALS OF THERAPEUTIC PRODUCTS OR APPLICABLE CTGT PRODUCTS

Division 1 — General

4. Sponsors
5. Principal investigator, etc.
6. Investigator's brochure

Division 2 — Regulatory submissions for clinical trials of therapeutic products or applicable CTGT products

7. Requirement for authorisation for or notification of clinical trial
8. Application for authorisation for clinical trial
9. Notification of clinical trial
10. Amendments and substantial amendments to clinical trial, etc.
11. Notification of serious breaches and urgent safety measures
12. Notification of status of clinical trial

Informal Consolidation – version in force from 1/10/2021

For more information, download a copy of the Regulations from https://sso.agc.gov.sg/SL/HPA2007-S332-2016

CONTACT INFORMATION

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Reference

GUIDANCE FOR PHARMACIST PRINCIPAL INVESTIGATOR

Background and Purpose

During the public consultation on the Therapeutics Products Port-over to the Health Products Act in 2015, HSA received suggestions to consider allowing registered pharmacists to be principal investigators (PIs) in clinical trials. MOH noted the potential benefit of having registered pharmacists as PIs in appropriate trials in the push for meaningful clinical research and pharmacists can add value to research by leading and carrying out translational and implementation science type research, tailored to the local setting. This could also strengthen the types of research done.

The Health Products (Clinical Trials) Regulations were hence amended on 1 October 2021 to allow registered pharmacists to be PIs of clinical trials.

Scope of guidance

The guidance is intended to apply to clinical research involving locally registered products of lower risk profiles, including regulated clinical trials.

General Requirements for Pharmacist PIs

The following conditions should be satisfied:

(i) the pharmacists are appropriately qualified by education, training and experience;

(ii) the pharmacists have adequate resources; and

(iii) the pharmacists are able to fulfil the responsibilities of the PI[1] under the Health Products (Clinical Trials) Regulations and the Medicines (Clinical Trials) Regulations ("the CT Regulations")

Other Considerations:

Scope of clinical trials

The risk profile of clinical trials of therapeutic/medicinal products and risks to research participants may vary, depending on whether the product is locally registered (and if so, whether its use in the clinical trial is a well-established use or a new unapproved use), or locally unregistered (e.g., investigational products comprising new chemical/biological entities).

[1] The legal responsibilities of a PI include trial supervision and study task delegation, medical care of trial subjects, consent-taking, serious adverse event reporting, investigational product management and labelling, and trial record keeping.

For more information, download a copy of the guidance from https://www.moh.gov.sg/hpp/pharmacists/guidelines.

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