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nova scotia health	Investigational Product (Drug and Natural Health Products Only)	Effective Date: March 5 2021
Clinical Trials Standard Operating Procedures		Version: V1.0
Page # 1-5		Next Review Date: March 2023
SOP Owner: Research Quality		

1. **Purpose:**
   This Standard Operating Procedure (SOP) describes the proper handling of Investigational Products (IPs) for safe and appropriate administration, dispensing, allotment, and provision to meet Regulatory Requirements, International Council for Harmonization Good Clinical Practice Guidelines (ICH-GCP), and Nova Scotia Health requirements.

2. **Definitions:**

   Administration:
   Occurs when a study participant receives the IP, in any form, for use prior to leaving the clinical trial site.

   Administering Personnel:
   A trained, qualified, and appropriately licensed study team member, nurse practitioner, registered nurse or licensed practical nurse.

   Delegation Log:

   Document which lists appropriately qualified persons to whom the principal investigator has delegated significant trial related duties.

   Dispensing:

   In the context of a clinical trial, the provision of the IP, usually prepackaged with a number or code that corresponds with information generated by a system to allot IP based on a specific research protocol and as ordered by the PI or delegated member of the research team.

   Informed Consent:

   A process by which a subject voluntarily confirms their willingness to participate, or continue to participate, in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate.

   Investigational Product (IP):

   A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used

or assembled (formulated or packaged) in a way that is different from the approved form, or when used for an unapproved indication, or used to gain further information about an approved use.

Licensed Health Care Professional:

A health professional who is licensed or registered to provide health care under an Act of the Province specific to his or her profession and who provides health care or who is a member of a class of persons prescribed as regulated health professionals.

(Personal Health Information Act, 2010)

Specific to this SOP, we are referring to Registered Nurses (RN), Nurse Practitioners (NP) Licensed Practical Nurses (LPN), Pharmacists, and Physicians.

Non-Licensed Employee:

Research or non-Research employees of NS Health who do not have a designated health care profession but have a role in Supplying the IP to a study participant (e.g. Porter Services employee, research assistant, or other research team member).

Phase IV study:
All studies performed within the approved indication after the drug has been approved by the regulator for the market. These studies are often important for optimizing the drug's use. They may be of any type but must have valid scientific objectives. Commonly conducted studies include safety studies and studies designed to support use under the approved indication (e.g., mortality and morbidity studies, or epidemiological studies).

Principal Investigator (PI):

The person responsible to the study's sponsor for the conduct of the clinical trial at a clinical trial site, who is entitled to provide health care under the laws of the province where that clinical trial is located. Also known as Qualified Investigator.

Representative:

A person chosen or appointed to act or speak for another or others.

Research Coordinator:

Reporting to the PI and/or the Research Manager, the Research Coordinator is a licensed health care professional (including but not limited to Registered Nurse, Registered Dietitian, Occupational Therapist, etc.) who coordinates research projects within NS Health. This coordination includes the administration of the study or clinical trial, management of documents and data collected throughout the study period, and interactions with the subjects participating in the study (within their scope of practice).

Substitute Decision Maker:

The legally appointed person able to make treatment decisions when the patient is incapable.

Unlicensed Research Coordinator:

Reporting to the PI and/or the Research Manager, the Unlicensed Research Coordinator, who is not a licensed health care professional, coordinates research projects within NS Health. This coordination includes the administration of the study or clinical trial, management of documents and data collected throughout the study period, and interaction with the subjects participating in the study (within their scope of employment).

3. **Statement: Prior to dispensing IP:**

3.1) The following must be approved by the Nova Scotia Health Research Ethics Board:

- Clinical trial research protocol
- Investigator Brochure or Product Monograph, and
- Consent form for the clinical trial.

3.2) Informed Consent must be obtained from the Study participant or Substitute Decision Maker to participate in the clinical trial.

3.3) The Principal Investigator (PI) may delegate Administration, Dispensing, supplying, or other tasks related to the IP, but must ensure individuals have appropriate qualifications, training, and license to carry out each task as per International Council for Harmonization Good Clinical Practice (ICHGCP).

3.4) The PI may choose to be responsible for IP independent of Pharmacy Department. All relevant aspects related to the IP including records of receipt, maintenance, monitoring of storage conditions, inventory, accountability, destruction, and security precautions become the responsibility of the PI.

3.5) A physician's order must be completed by the PI or a qualified and delegated study team member prior to the IP being obtained.

- **Phase IV clinical trials** may include the PI or a qualified and delegated study team member providing a prescription to study participant.

3.6) The IP must be Dispensed by a pharmacist, physician, dentist, or in certain circumstances, a Research Coordinator (Licensed or Unlicensed).

- If Dispensing is independent of a pharmacy, a Research Coordinator must only dispense in the context of the clinical trial and delegated by the PI.
- If Dispensing is independent of a pharmacy, all relevant identifying IP information and the study participant must be checked by two persons prior to releasing the IP to the study participant. At least one person must

be a member of the research team and assigned on the delegation log, and at least one person must be a Licensed Health Care Professional.

4. Procedure

4.A IP Administered On or Off Site

- The PI, a member of the study team who is qualified and delegated by the PI, or Administering Personnel is responsible to administer the IP as directed in the study specific research protocol.
- If applicable, Research Coordinators, Unlicensed Research Coordinators, and Non-Licensed Employees are responsible to:

  Provide the IP to a designated area for the Administering Personnel.

  Document the process.

4.B IP Taken Home

- The PI or Licensed Health Care Professional assigned on the Delegation Log is responsible to instruct the study participant to properly and safely take and store the IP in accordance with the study specific research protocol.
- Unlicensed Research Coordinator may review instructions previously provided by the PI or Licensed Health Care Professional.
- Study Participants may also pick up their own IP from the Research Pharmacy, or if applicable, their community pharmacy, as instructed by a Research Coordinator/PI/Sub-investigator, as appropriate.

Note: A Non-Licensed Employee, delivering IP from pharmacy or other dispensing research team members to a study participant or their Representative, **is not authorized** to provide or review instructions for use of the IP.

Reference

Legislative Acts/References

Food and Drugs Act and Regulations, Drugs for Clinical Trials Involving Human Subjects. (2019). Part C, Division 5. Retrieved from Health Canada website:

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Other

International Council For Harmonisation of Technical Requirements for Pharmaceuticals For Human use. (2016). *Integrated addendum to ICH E6(R1): Guideline for good clinical practice E6(R2)*. Retrieved from https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf

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