**St Peter’s Institute of Pharmaceutical Sciences**

**Course : Bachelor of Pharmacy**

**Subject : Pharmaceutical Regulatory Science**

**Subject Code:** **BP804ET**

 **CLINICAL PROTOCOL DEVELOPMENT**

The development of protocol and complexity is highly dependent on the type of clinical research conducted. For example, interventions, multiple sites, larger than minimum-risk studies require more protocol content than less risk with a single site.

When conducting a successful study design and writing a protocol, the researcher must be concerned with a variety of important issues - including the types of data collected, (e.g., safety, laboratory), data management and record keeping, outcome measures, how monitoring and reporting will take place, and data analysis.

A research protocol is a document that describes the background, reasons, objectives, composition, methodology, statistical considerations, and planning of a clinical research project.

**General information**

• Protocol title, protocol identification number, and date. Any amendments must also contain amendment numbers and dates.

• Name and address of sponsor and monitor.

• The name and title of the person (s) authorized to sign the protocol and the protocol amendments for the sponsor.

• The name, title, address and telephone numbers of the medical professional (or dentist if necessary) in the case.

• The name and title of the investigating officer (s) in charge of conducting the trial, as well as the address and telephone numbers of the trial venues.

• The name, title, address, and telephone numbers of the appropriate physician (or dentist, if applicable), who is responsible for all medical (or dental) decisions relating to the trial site (if not the investigator).

• Names and addresses of the clinic laboratory and other medical and / or technical departments and / or institutions involved in the case.

**Background information**

• The name and description of the product / products of the investigation (s).

• Summary of findings from non-clinical studies that may have clinical significance and clinical trials related to trials.

• A summary of the potential risks and benefits, if any, of human studies.

• Justification of administration route, dosage, type of medication, and duration of treatment.

• Statement that the trial will be conducted in accordance with the protocol, GCP, and applicable regulatory requirements.

• Description of population to be studied.

• References to texts and data related to the trial and provide the basis for the trial.

**Trial Objectives and Purpose**: A detailed description of the objectives and purpose of the experiment.

**Experimental Design**: The scientific integrity of the test and the reliability of the data from the test are highly dependent on the design of the trial. The test design description should include:

• A specific statement of primary end points and secondary end points, if any, will be measured during the trial.

• A description of the type of trial / structure to be performed (e.g., double blinded, placebo control, parallel design) and a schematic diagram of the trial design, procedures, and phases.

• Description of steps taken to reduce / avoid bias like blinding and Randomization.

• A description of the experimental treatment and the dosage and dosage regimen of the product for the investigation. Also include a description of the dosage form, packing, and labeling form of the product.

• Expected duration of subject participation, as well as a description of the sequence and duration of all trial periods, including follow-up, if any.

• A description of the discontinuation of trial, for each subject and the whole trial.

• Accountability procedures for the product (s) of the study, including placebo (s) and comparisons, if any.

• Experimentation of trial treatment randomization codes and code-breaking procedures.

• Identification of any data that will be recorded directly to CRF (i.e., no written or electronic data record), and which will be regarded as source data.

**Selection and Withdrawal of Subjects**

* Inclusion criteria.
* Exclusion criteria.
* Withdrawal criteria (e.g., discontinuation of treatment products / case treatment) and procedures that describe:

 (a) When and how will you withdraw subjects from the case / investigation product treatment

(b) The type and timing of the data to be collected for withdrawn subjects.

(c) how subjects can be changed

(d) Follow-up of withdrawn subjects in the treatment / case treatment product.

**Treatment:**

• Therapies to be performed, including the name of all products, dose, dosage schedules, route of administration and treatment period, including periods of follow-up of each product / group treatment.

• Medication / treatment (treatment) is permitted (including recovery medication) and is not allowed before and / or during the trial.

• Procedures for subject compliance.

**Assessment of Efficacy**

• Defining efficacy parameters.

• Methods and time to evaluate, record and analyze efficacy parameters.

**Assessment of Safety**

• Defining safety parameters.

• Methods and time to test, record and analyze safety parameters.

• Procedures for recording and reporting adverse event reports and diseases from time to time.

• The nature and duration of follow-up after adverse events.

**Statistics**

• A description of the mathematical methods to be used is done.

• Number of subjects scheduled for enrollment. In a multicenter trials, the number of enrolled subjects considered for each trial site should be specified. Reason for choosing a sample size, including clinical justification.

• Level of significance used and the termination criteria.

• The process of accounting for lost, unused, and fraudulent data.

• Procedures for reporting any deviation from the actual statistical system • Selection of subjects to be included in the analysis (e.g., randomized, dosed, eligible and evaluable subjects).

**Ethics:** A description of the ethical principles relating to a trial.

Data Management and Record Keeping should be done.

**References**

1. Levin, Rona F., PHD, RN, Lewis-Holman, Seon.(2011). “Developing Guidelines for Clinical Protocol Development.” Research and Theory for Nursing Practice. vol 25, Issue 4, pp.233.
2. <https://hub.ucsf.edu/protocol-development>