CHUKWUANI OLUCHI FAVOUR

16/SCI05/002

MCB 406

1. Identification: The study identification number, or the number attributed to the protocol, must provide a means of uniquely identifying the study in the records of the laboratory and of confirming the identity of all data generated during the study.
2. Title and Statement of Purpose: It is important to state why a study is being performed. A study must be planned and designed in advance
3. Identification of Test (and Control) Items: This includes not only the chemical name and/or code number of the test item but also its specifications or characterizations or details about how these will be determined if they are not yet available.
4. Name of Sponsor and Address of Test Facility: The sponsor and the test facility may or may not be the same company. The protocol should indicate where the test is to be carried out and also include the address of any consultants involved.

1. Name of Study Director and Other Responsible personnel: The name of the study director must be included in the protocol. It is good practice to identify any other responsible scientists who are going to contribute significantly to the study.
2. Proposed Dates: The proposed dates for the study are the start and finish dates (corresponding to the date when the protocol is signed and the date when the report is signed by the study director) and the experimental dates.
3. Justification for Selection of the Test System: When animals are the test system being used in an experiment, the species and possibly the strain may be defined in scientific test guidelines.
4. Description of the Test System: For animal experiments, this will include the proposed species, strain, age, weight and source of animals and how they are to be identified.
5. Experimental Design:

• Dosing details:

– Dose levels

– Frequency of dosing

– Vehicles used

– Method of preparation

– Quality control.

• Method of assigning animals to their experimental groups.

• Parameters to be measured and examined: This section identifies the measurements to be made and the frequency of measurement. If certain procedures are not routine and not covered by SOPs complete details of the non standard procedures, or references to them, would be required.