Study Protocol and Analysis Plan

Experiment 3 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To complete the study protocol and analysis plan stage of a supervised pharmacy-practice project.

Principle

A protocol specifies who or what is studied, what is measured and how a valid answer will be obtained.

Requirements

- Supervisor-approved project topic, institutional requirements and authorised project documents.
- Project record and analysis tools appropriate to the approved design.

Procedure

1. Choose the design

Justify an observational, audit or other institution-approved design for the question.

2. Define eligibility

State setting, inclusion/exclusion rules, recruitment/record selection and the justified study-size approach.

3. Define variables

Create outcome, exposure and covariate definitions with units and timing.

4. Plan analysis

Specify descriptive measures, intended comparisons, missing-data handling and the need for statistical advice.

5. Plan conduct

List roles, timeline, access arrangements and change-control procedure.

Observations and Record

Project record item	Entry
Design and justification	_____
Eligibility / study-size rationale	_____
Variable definitions	_____
Analysis and missing-data plan	_____
Timeline / responsibilities	_____

Result

Project stage: ____. Completed record: ____. Supervisor feedback: ____. Next action: ____.

Precautions

- This is a project-work guide and blank record, not a completed research study or an approval certificate.
- Use only authorised data and keep participant identifiers separate from the analysis dataset.
- Report actual findings, protocol departures and limitations; never fill missing data with invented observations.

Viva Questions and Answers

1. Why specify the question before collecting data?

The question determines design, measures and the intended analysis.

2. What makes the project reviewable?

An approved plan, traceable data, an appropriate analysis and an honest account of limitations.

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