Ethical Review Consent and Data Governance

Experiment 4 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To complete the ethical review consent and data governance stage of a supervised pharmacy-practice project.

Principle

Ethical review and data protection are part of project design. Record access does not itself authorise research use.

Requirements

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

Procedure

1. Identify review needs

Use the institutional process for ethics approval and permissions required for the proposed project.

2. Prepare participant materials

Where applicable, develop clear information and consent documents for review, with voluntary participation and the authorised withdrawal process.

3. Plan privacy

Use coded records, separate the identifier key and define role-based access and retention.

4. Record decisions

Enter actual approval number/date and authorised conditions only when issued; leave pending fields blank.

5. Manage changes

Obtain required review before a protocol amendment or new use of data.

Observations and Record

Project record item	Entry
Review / permission status	_____
Consent process where applicable	_____
Coding and access plan	_____
Retention / disposal plan	_____
Amendment record	_____

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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