Systematic Review Protocol

A systematic review protocol is a predefined plan that outlines the rationale, objectives, and methods of a planned systematic review.

It serves as a methodological roadmap and helps ensure transparency, **rigor**, and **reproducibility** in evidence synthesis.

Key Components

- **Research question** (often in PICO format)
- **Inclusion and exclusion criteria**
- **Databases and search strategies**
- **Data extraction and management plans**
- **Risk of bias assessment tools**
- **Planned analyses** (including meta-analysis, if applicable)
- **Timeline and dissemination plan**

Purpose

- Minimize bias by committing to a methodology before knowing the results
- Facilitate peer review and external input early in the process
- Allow for registration in platforms like PROSPERO

How to Perform a Systematic Review Protocol

A **systematic review protocol** is a structured plan that outlines how a systematic review will be conducted. It helps minimize bias and ensures transparency and reproducibility.

This guide follows standard methodology recommended by PRISMA-P (Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocols).

Step-by-Step Process

1. Define the Research Question

Use the PICO format:

- **P**opulation: Who is being studied?
- **I**ntervention: What is being tested?
- **C**omparator: What is the control or alternative?

- **O**utcome: What results are being measured?

2. Register the Protocol

- Recommended: PROSPERO
- Includes title, background, methods, inclusion/exclusion criteria, and update strategy

3. Develop the Search Strategy

- Choose databases: e.g., PubMed/MEDLINE, Embase, Cochrane Library
- Include grey literature if needed
- Define search terms and Boolean operators

4. Define Eligibility Criteria

- Study design (e.g., RCTs, observational studies)
- Language and date limits
- Population characteristics
- Intervention and outcome specifics

5. Plan the Study Selection Process

- Use two independent reviewers
- Screening titles/abstracts → full texts
- Resolve conflicts through consensus or third reviewer

6. Data Extraction

- Create standardized extraction forms
- Collect data on:
    1. Study characteristics
    2. Participants
    3. Interventions
    4. Outcomes
    5. Results

7. Assess Risk of Bias

Use a risk of bias tool appropriate for the study design:

- RoB 2 for RCTs
- ROBINS-I for non-randomized studies
- AMSTAR 2 for other reviews

8. Plan the Data Synthesis

- Qualitative (narrative) synthesis
- Quantitative synthesis (e.g., meta-analysis) if data are comparable
- Subgroup or sensitivity analysis if applicable

9. Ethics and Dissemination

- Ethical approval not typically required for secondary data
- Plan for publishing in peer-reviewed journals or open-access platforms

Template Registration Fields (Example)

- Title
- Background and rationale
- Objectives
- Eligibility criteria
- Information sources and search strategy
- Data management
- Selection and extraction process
- Bias assessment
- Strategy for data synthesis
- Timeline