Comprehensive Medical Research Guide

Step-by-Step Instructions From Idea to Publication

PHASE 1 – RESEARCH FOUNDATIONS

Module 3:

Study Design & Ethics

Key Steps Checklist :

- Match your research question to a suitable study design
- Define study population, intervention, comparator, outcomes
- Plan sampling & data collection carefully
- Reduce bias and improve validity
- Obtain ethical approval (IRB)
- Ensure informed consent
- Apply principles of good clinical research practice

1. Why Does Study Design Matter?

The design of your study is like the blueprint of a building . If the plan is weak, the results will collapse, no matter how hard you work.

A well-chosen design ensures that your study is scientifically sound, feasible, and ethical.

For example,

if you want to know the prevalence of diabetes in Jordan → you need a **cross-sectional study.**

If you want to test a new drug → you need a **randomized controlled trial (RCT).**

Choosing wrongly (e.g., using a case report to measure prevalence) will waste time and effort !!

2. Matching Question to Design

Research Aim	Best Design	Example
Measure frequency or prevalence	**Cross-sectional**	Smoking prevalence among university students
Identify risk factors	**Case-control**	Risk factors for lung cancer in smokers vs non-smokers
Study natural history of disease	**Cohort**	Following obese patients to see diabetes risk
Test effectiveness of interventions	**Randomized Controlled Trial (RCT)**	New antibiotic vs standard therapy
Summarize existing evidence	**Systematic Review / Meta-analysis**	Effect of vaccines on influenza prevention

3. Using PICO to Plan

The PICO framework keeps your research structured:
- P = Population
- I = Intervention / Exposure
- C = Comparator
- O = Outcome

Example:
Does hand hygiene training reduce hospital infections among nurses?
- P = Nurses
- I = Training program
- C = No training
- O = Infection rates

4. Validity & Bias

Every design has potential errors. Bias threatens the trustworthiness of your findings.

Common Biases and How to Reduce Them:

Bias	Example	How to Minimize
Selection bias	Studying only one hospital	Random sampling
Recall bias	Asking patients about diet 10 years ago	Use medical records
Observer bias	Researcher expecting outcome	Blinding
Publication bias	Negative results not published	Pre-register your study

5. Sampling & Data Collection

• Sampling methods: random, stratified, cluster, convenience.
• Sample size: should be large enough for reliable results. Software like G*Power or online calculators can help.
• Data collection: use validated tools (e.g., standardized questionnaires, calibrated devices).
Will be explained in next modules fully detailed !!

Example:
If you are studying asthma control, use validated tools like the Asthma Control Test (ACT) instead of making your own untested survey.

6. IRB Approval

Before starting, submit your proposal to an Institutional Review Board (IRB) or ethics committee.

Documents usually required:
• Study protocol (objectives, methods, risks, benefits)
• **Consent forms (in local language)**
• Confidentiality & data handling plan

⚠️ **No IRB approval = no publication. Journals will reject your paper immediately except in some cases.**
Will be explained in next modules fully detailed !!

7. Informed Consent

Consent must be clear, voluntary, and documented. It should include:
• Study purpose
• Risks & benefits
• Duration of participation
• Voluntary nature and right to withdraw

👉 In vulnerable groups (children, elderly, mentally impaired), special protections are required.
Will be explained in next modules fully detailed !!