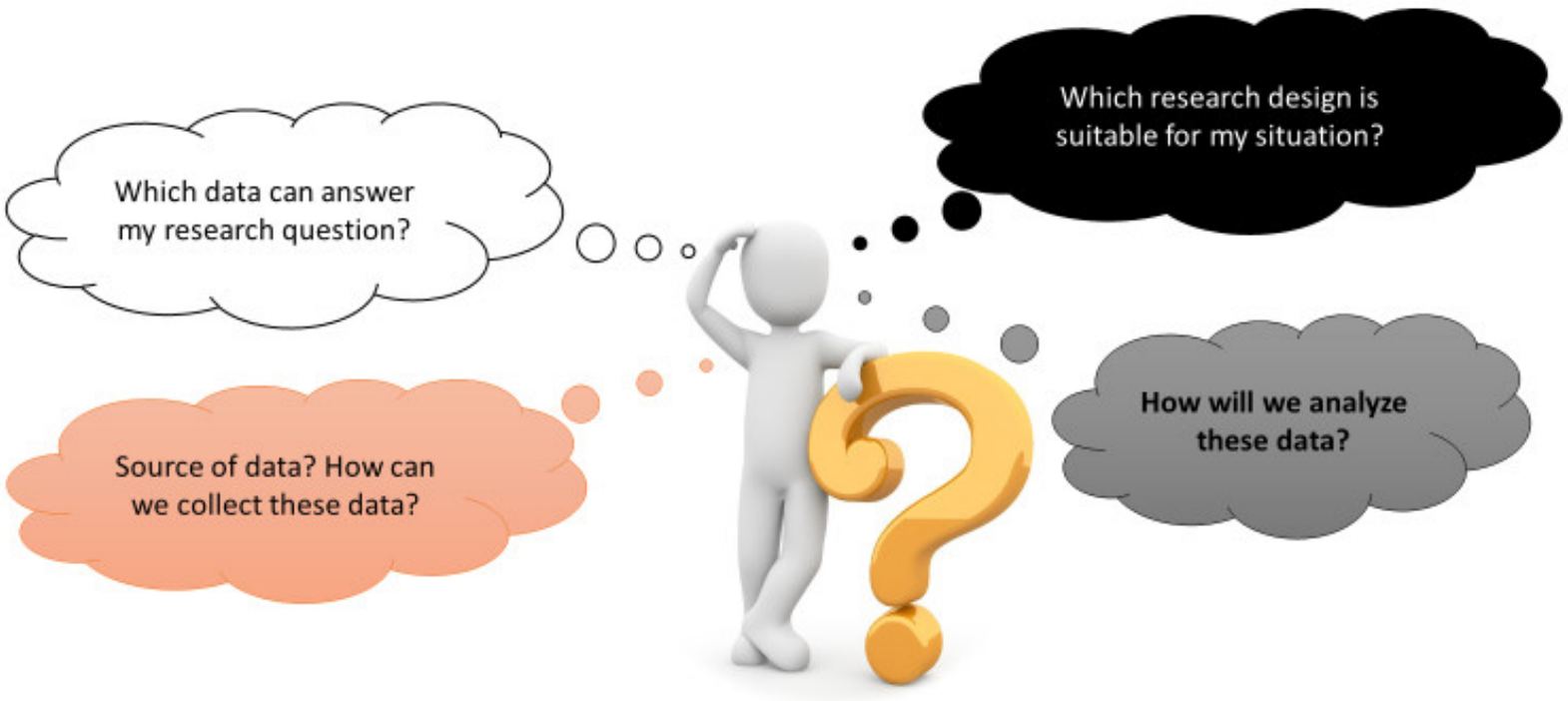
Chapter 4 **Protocol Writing**

Planning is the most crucial step in the research process. Proper planning is critical for a successful research project. Poorly designed research studies are not likely to be published in top journals, are likely to be criticized by other scholars, and might not be informative for clinical practice. On the contract, poor research design can be misleading for clinical practice.

In this step, researchers discuss and plan for the methodology of the research study. They write the study protocol, which emphasizes on the study rationale, study aims, and objectives, research hypothesis, study design, data collection methods, as well as the ethical considerations of the research study. Moreover, the study statistician plan for the statistical analysis methods that will be useful to analyze the study data and determine whether the data support rejecting or not rejecting the null hypothesis.



Definitions

Research Protocol

- A systematic description of your research study
- Must meet regulatory requirements to justify research and protecting research participants
- Reviewed and approved by the Ethics committee

Research Proposal

- Statement of work (statement of purpose)
- Must meet the requirements of the funding agency
- Reviewed and approved by the funding agency

Importance of the study protocol

A well-structured detailed research protocol is essential to gain ethical approval from the institutional review board or the ethics committee of your institution. In addition to ethical review, top tier journals usually require prospective protocol registration of clinical trials and systematic reviews to eliminate some sources of bias that might occur by changing the methods during the study implementation process to obtain favorable outcomes. When you perform changes to the details of your registered study, these changes are deposited and registered as old versions of the registration and can be accessed by journal reviewers to evaluate your study.

Registration of the study protocol

Clinical trials and systematic reviews should be prospectively registered on the international registration databases before starting the process of data collection or data extraction, respectively. For clinical trials, the United States NIH maintains a database of registered clinical trials called clinicaltrials.gov[1] While for systematic review, the United Kingdom NHS maintains a database of registered systematic reviews called PROSPERO[2]. Nowadays, most medical journals will require your prospective registration ID during the submission and peer-review process.

Publication of the study protocol

Publication of the study protocol is not obligatory. However, many investigators are interested in making their research methods publicly available for the scientific community. Recently, new databases such as protocol.io[3] offer online publication of your study protocol. However, this is not considered a peer-reviewed publication since your protocol is not reviewed by experts in the field prior to publication on the online website. For peer-reviewed protocol publication, some medical journals offer the option of publishing study protocols, especially if your research methods include some novelty in the design or might be useful for the journal readership to read and follow. These journals are BMJ open, journal of internet medical research, and most of the journals published by Biomed Central.

Components of the study protocol

The structure of the study protocol is variable from an institution to another. Investigators should follow the protocol guidelines of their institutions and their corresponding ethics committee or institutional review board (IRB). However, the

[1] Available at: https://clinicaltrials.gov/
[2] Available at: https://www.crd.york.ac.uk/prospero/
[3] Available at: https://www.protocols.io/

following list shows some essential items to be included in the study protocol (for guidance):

- Title Page (General Information)
- Background
- Aim & objectives
- Study Design
- Selection and Exclusion of Subjects
- Treatment of Subjects
- Assessment of Efficacy
- Assessment of Safety
- Adverse Events
- Statistical analysis plan
- Data management
- Ethical considerations
- Publication Policy
- Project Timetable/Flowchart
- References
- Supplements/Appendices

How to write the study protocol

The first step is to retrieve the study protocol template, style, or guidelines from your institutional ethics committee or IRB. Then, start by writing a protocol summary, a two-page description of the summary of your study background, aims, objectives, and methods. The next step is to discuss the protocol summary with your team, supervisors, as well as your team statistician. Once all small details are discussed and you reach an agreement on the final methodology, start drafting the study protocol as per your institutional guidelines. To know more about the style of scientific writing used in research papers and research protocols, you can study the following chapters of this book. When you finish the study protocol, get it revised by all the study team, and get the PI signature on the protocol. Then submit the protocol to your institutional ethics committee or IRB for ethical review and approval.

Audit study

Audit means an evaluation of the current practice. In some institutions, there is a dedicated audit department responsible for continuous monitoring and evaluation of the clinical practice decision, physician performance, and patient outcomes to compare it against the institutional standards (i.e., evaluating success rate and mortality rate following major operations). Some observational research studies might be classified by the audit department as "clinical audit." Once your research study is classified as an audit, ethical approval is no longer required. The classification of your

research study is an audit represents a waiver from ethics committee approval in most institutions. However, many institutions do not make this classification.