



Crafting a research protocol: a stepwise comprehensive approach

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PRACTICAL SCENARIO

A group of researchers plan to conduct a cross-sectional study to estimate the prevalence of frailty in elderly patients with moderate to severe asthma and to report a measure of association between asthma control and frailty.⁽¹⁾ The research protocol outlines the complex interactions of asthma control in frail patients and motivation to address this research question. Study design, objectives, methods, ethical issues, risks, and impact were also detailed in the protocol.

WHAT IS A RESEARCH PROTOCOL?

A well-structured research protocol guides researchers through the intricate process of conducting rigorous research. A research protocol is designed to be concise and self-contained, and to summarize the core aspects of the study. Self-discipline is vital in this process, as it requires the investigator to structure the central concepts of the study and reveal particular issues that demand attention.⁽²⁾ The research protocol often serves as the foundation for the development of manual of operating

procedures, which includes comprehensive information on the organization and policies of the study, as well as an operational approach to the procedures outlined in the study protocol; therefore, both documents complement each other.

ELEMENTS OF A RESEARCH PROTOCOL

The research protocol framework (outlined in Chart 1) usually includes a title, rationale, background information, objectives, methodology, data management, statistical plan, quality control, ethics, budget, developing plan, timeline, references, and appendices, although the sections included vary depending on institutional templates.

The title should be concise, descriptive, and engage readers, effectively reflecting the core of the research.⁽³⁾ The background section outlines the driving factors and motivation for conducting the research. It should provide a broad context, elucidate the problem, address specific knowledge gaps, and establish the rationale for the study. In our practical example, the authors provided background information about how the multidimensional aspects of

Chart 1. Research protocol stepwise approach.

Step	Description
Title	Concise, reflecting study main ideas, and attracting reader's attention
Background and rationale	What is the problem? Why is it important? What is known about it?
Objectives	Specific, measurable, and established prior to carrying out the study
Relevance and study design	Contributions of the study to the field, aligned with rationale and objectives
Methods	Participants, exposures/intervention, outcomes, study setting, eligibility criteria, participant timeline, sample size, recruitment, and blinding Detailed script: How will the study be conducted? Why was the described design chosen?
Data collection, access, and management	Methods for data storage, security, privacy, and treatment of missing data
Statistical plan	Descriptive statistics, hypothesis testing, sample size, and power calculation
Quality control	Credibility of the research: instruments, data collection, data acquisition
Ethics	Ethical dilemmas, application to ethics research committees, Informed consent form
Roles and responsibilities	Affiliations, roles, and responsibilities of protocol contributors ⁽³⁾
Budget	Detailed expenses: personnel, equipment, consumables, logistics
Funding	Sources of financial support
Dissemination plan	Effective communication of research findings
Timeline	Be realistic about project management throughout the research
References	Check publishers' guidelines, consider using reference manager software
Appendices	Extensive descriptions of procedures, questionnaires, and informed consent forms
Protocol version	Indicator of version and date of the protocol

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frailty are imbricated into proper asthma management in patients with advanced age. This section should align with the objectives, highlighting the potential impact of the study. Research objectives should be clear, measurable, precise, and set before conducting the study.⁽²⁾ After the statement of the primary objective, secondary aims might be appropriate. The objectives will guide the study design and methodology, directing attention toward the intended research outcomes.

The methods section is a detailed blueprint of the research project and the basis for the manual of operating procedures. It should detail the study design, participant selection (eligibility, sampling, and recruitment), variables, data acquisition, data management (storage, security, privacy, and treatment of missing data), statistical plan, and sample size calculation. The scientific robustness of the study relies on its methodology, ensuring validity and replicability. The statistical plan should clearly outline the analysis methods, software used, and criteria for determining statistical significance. Quality control mechanisms uphold the internal validity of the study. This segment should describe measures to minimize bias and ensure data quality.⁽²⁾ Steps might include regular data verification, calibration and certification of instruments, as well as research personnel training.

Ethical considerations are paramount in research. This section should document the issues that are likely to raise ethical concerns, including informed consent forms, confidentiality, data protection, and potential

ethical dilemmas.⁽³⁾ Moreover, it should also mention approvals obtained from institutional review boards. The budget section details the financial requirements of the research. It includes costs with personnel, equipment, materials, logistics, consumables, and contingencies. A realistic and well-planned timeline is crucial for successful project management.

Deficiencies in effectively disseminating and transferring research-based knowledge into clinical practice can impair the potential benefits of the research project. Therefore, most health research funding agencies expect commitment from investigators to disseminate the study findings actively. Integrating a dissemination plan in the research protocol will facilitate effective communication of research outcomes to the scientific community and those who can apply the knowledge in real-world situations.

KEY MESSAGES

1. A comprehensive research protocol not only provides a roadmap for the implementation of the study but also ensures that the research question is addressed according to high-quality research standards.
2. Quality control is essential to improve internal validity of the study.
3. A structured approach to conducting research reduces the likelihood of misleading conclusions and biases, ensuring validity and reproducibility of the study.

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