Encyclopedia of Research Design

Protocol

http://dx.doi.org/10.4135/9781412961288.n343

In research, *protocol* refers to the written procedures or guidelines that provide the blueprint for the research study, as well as good and ethical practices that should be observed when conducting research, such as good etiquette when dealing with participants, adherence to ethical principles and guidelines to protect participants, compliance with institutional review board requirements, not engaging in academic dishonesty, and so on. Good protocol is a critical component of high-quality research. A well-written research protocol is particularly important for obtaining institutional review board clearance for the research, as well as for seeking funding opportunities. In addition, the written research protocol serves as a manual to guide the entire research effort, and it can also be used as a monitoring and evaluation tool to monitor progress throughout the research and to evaluate success at the completion of the research. This entry describes the structure of the written proposal and discusses other types of protocols.

Structure of the Written Research Protocol

The written research protocol is a detailed descriptive text of how the research will be conducted, and its length and complexity are affected by the nature and scope of the research. The principal investigator generally has some flexibility in determining the comprehensiveness and layout of a particular protocol; however, each research protocol must comply with the requirements (i.e., structure, context, format, length, etc.) for the institutional review board that will grant its approval. A well-written research protocol can contribute greatly to making a research effort high quality. Comprehensive information provides not only guidance and clarity on how to conduct each and every aspect of the research, but also advice on what should be done (e.g., whom to contact) if an unusual situation occurs that was unforeseen. The aforementioned structure and details are fundamental to good research protocols.

Cover Page and Title

The cover page should include the full title of the study, as well as the version number, and version date (e.g., Version 1.0 dated May 1, 2010). The document should also indicate if the protocol is a "draft" or "final" document (e.g., Draft Protocol). The title should be short and concise, and also include key words such as the proposed research design, population to be investigated, and location of data collection. For example, a study on juvenile delinquency might be titled "Study of Juvenile Delinquency in Country A Using Convenience Sampling." These key words are important to facilitate classification/indexing of the project. A short title should also be specified for use throughout the document. The short title should be first abbreviated in the project summary. The cover page should also include the names, roles, and contact information for the primary authors/investigators/advisors, as well as any major sponsors. If this information is too much to place on the cover page, it should be placed on a separate page after the cover page.

Signature Page

This page should include the signatures of the individuals listed on the cover page.

Contents Page

This page details the various sections and appendixes contained in the protocol, along with corresponding page numbers.

Acronym/Abbreviation Page

This page provides a list of all acronyms and/or abbreviations used in the protocol, along with a definition for each one.

Summary or Abstract

The summary is the most important section of most documents/reports—the research protocol is no exception. It provides a succinct sketch (i.e., a snapshot) of the entire protocol. It is located at the front of the document but is generally prepared after the entire protocol is written. It summarizes the research objectives; presents the main research question or hypothesis; provides a brief description of the methods and procedures that will be used to conduct the research (e.g., research design, study population, place, timing of interventions); discusses the anticipated study outcomes; and provides the dates for important milestones as well as the estimated time frame and budgeted cost for the research.

Background

The background describes existing knowledge and research in the area of study. It is supported by a comprehensive literature review of both published and unpublished work that should highlight any deficiencies or gaps in existing knowledge. The justification for the study, as well as a clear articulation of the research questions or hypotheses, and a detailed discussion of the study objectives (general and specific) are also generally included in this section. Some protocols, however, may use separate sections to discuss one or more of the aforementioned issues. For example, objectives may be discussed under a section titled "Specific Aims of the Study," research questions may be discussed under "Problem Statement," and so on. Alternatively, some protocols use a section called "Introduction" instead of "Background."

The justification should clearly outline the nature of the problem, its size, and its effect; the raison d'#tre for the study; the feasibility of the study; the potential benefits or outcomes that are expected to be derived from the study (categorized into participant, short-term/long-term, population, knowledge base, etc.); how the results might be used (e.g., national policy, organizational policy, community level, future research); how the study might help to correct the deficiency; how the study will add to the existing body of knowledge, and so on. The objectives should follow from the research questions or

hypotheses—they should be smart, measurable, achievable, relevant, and time based (SMART).

Methodology

The methodology provides a detailed description of the methods and procedures that will be used to conduct the study. It includes a description of the following, but may not necessarily be discussed under the separate subheads outlined below.

[p. 1135 ↓]

Limitations of the Study

The limitations of the study should be clearly outlined so that the users of the information can make informed judgments in light of the limitations.

Dissemination or Publication of Results

This section should discuss the stakeholder groups that will have access to the research findings and how the results will be communicated (e.g., written report, presentation, town hall meeting, journal article, news media). It should also discuss who will have publication rights.

References

A list of all references quoted in the preparation of the protocol should be listed in sequential order.

$SAGE researchmethods**

Appendixes

Research instruments, consent and assent forms, letter to participants assuring anonymity and confidentiality, interview guides, detailed schedules and budgets, and so on, should be appended to the protocol. The curriculum vitae of each principal and secondary investigator should also be appended. If advertising is done in order to recruit participants, all recruitment materials, such as press releases and radio, television, and newspaper advertisements, should also be appended to the protocol that is being submitted for institutional review board approval.

Other Types of Protocol

In addition to the written protocol that is important for institutional review board purposes, written protocols for interview guides and schedules may also be prepared to guide the research effort in its quest for high-quality data. In addition, other types of protocol, such as appropriate behavior when dealing with participants (e.g., greeting, listening attentively to participants, keeping an appropriate distance from the participants, etc.) and dress protocol, are usually discussed in training sessions.

Nadini Persaud

http://dx.doi.org/10.4135/9781412961288.n343
See also

Further Readings

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1979, April). The Belmont report: Ethical principles and guidelines for the protection of human subjects of research [Online]. Retrieved May 1, 2009, from http://ohsr.od.nih.gov/guidelines/belmont.html

SAGE researchmethods

Pan American Health Organization (n.d.). Guide for writing a research protocol [Online]. Retrieved May 1, 2009, from http://www.paho.org/English/DD/IKM/RC/Protocol-ENG.doc

Singh, S., Suganthi, P., Ahmed, J., & Chadha, V. K. (2005). Fomulation of health research protocol: A step-by-step description [Online]. Retrieved May 1, 2009, from http://medind.nic.in/nac/t05/i1/nact05i1p5.pdf

Western Michigan University (2005, June). Human subjects institutional review board: Application for project review [Online]. Retrieved May 1, 2009, from http://www.wmich.edu/coe/fcs/cte/docs/hsirbproposal_vandermolen.doc