Capstone Project

RESEARCH PROTOCOL

Please read the guidelines carefully, adhere to the number of words specified per section and be sure to follow APA style guidelines.

• Project title
• Project summary: 250 Words
• Project description: 1000 Words
  • Rationale
  • Objectives
  • Study Design
  • Methodology

• Data management and analysis: 100
• Ethical considerations: 300 Words
• Expected outcomes of the study: 100
• References

Project summary

Like the abstract of a research paper, the project summary, should be no more than 300 words and at the most a page long (font size 12, single spacing). Provided preferably on a separate page, it should summarize all the central elements of the protocol, for example the rationale, objectives, methods, populations, time frame, and expected outcomes. It should stand on its own, and not refer the reader to points in the project description.

Project Description

Rationale & background information-

The Rationale specifies the reasons for conducting the research in light of current knowledge. It should include a well documented statement of the need/problem that is the basis of the project, the cause of this problem and its possible solutions. It is the equivalent to the introduction in a research paper and it puts the proposal in context. It should answer the question of why and what: why the research needs to be done and what will be its relevance. The magnitude, frequency, affected geographical areas, ethnic and gender considerations, etc of the problem should be followed by a brief description of the most relevant studies published on the subject.

Study goals and objectives

Goals are broad statements of what the proposal hopes to accomplish. They create a setting for the proposal. Specific objectives are statements of the research question(s). Objectives should be simple (not complex), specific (not vague), and stated in advance (not after the research is done). After statement of the primary objective, secondary objectives may be mentioned.
**Study Design**

The scientific integrity of the study and the credibility of the study data depend substantially on the study design and methodology. The design of the study should include information on the type of study, the research population or the sampling frame, and who can take part (e.g. inclusion and exclusion criteria, withdrawal criteria etc.), and the expected duration of the study.

The same study can be described in several ways, and as complete a description of the study as possible should be provided. For example, a study may be described as being epidemiologic or health policy or health and social behavioral research, it may also be described as observational or interventional; if observational, it may be either descriptive or analytic, if analytic it could either be cross-sectional or longitudinal etc. If experimental, it may be described as a controlled or a non-controlled study (this is not a comprehensive list).

**Methodology**

The methodology section is the most important part of the protocol. It should include detailed information on the interventions to be made, procedures to be used, measurements to be taken, observations to be made etc. If multiple sites are engaged in a specified protocol, methodology should be standardized and clearly defined.

Interventions should be described in detail, including a description of the intervention, education, training etc. provided to groups or individuals.

Describe the procedures to be conducted. For example: a questionnaire survey, carrying out a focus group discussion as part of formative research, observation of the participant's environment, etc.).

Standardized and/or documented procedures/techniques should be described and bibliographic references, if not provided earlier should be provided. Instruments which are to be used to collect information (questionnaires, FGD guides, observation recording form, case report forms etc.) must also be provided.

**Ethical/Safety Considerations**

The protocol should have a description of ethical considerations relating to the study. This should not be limited to providing information on how or from whom the ethics approval will be taken, but this section should document the issues that are likely to raise ethical concerns. It should also describe how the investigator(s) plan to obtain informed consent from the research participants (the informed consent process).

The safety of research participants is foremost. Safety aspects of the research should always be kept in mind and information provided in the protocol on how the safety of research participants will be ensured. This can include procedures for recording and reporting adverse events and their follow-up, for example. It is useful to remember that even administering a research questionnaire can have adverse effects on individuals.
Data Management and Statistical Analysis

The protocol should provide information on how the data will be managed, including data handling and coding for computer analysis, monitoring and verification. The statistical methods proposed to be used for the analysis of data should be clearly outlined, including reasons for the sample size selected, power of the study, level of significance to be used, procedures for accounting for any missing or spurious data etc. For projects involving qualitative approaches, specify in sufficient detail how the data will be analyzed.

Expected Outcomes of the Study

The protocol should indicate how the study will contribute to advancement of knowledge, how the results will be utilized, not only in publications but also how they will likely affect health care, health systems, or health policies.

References (of literature cited in preceding sections)