

Study Protocol

Study Protocols are articles that describe the design of planned or ongoing research. This includes study design for observational, qualitative, exploratory studies, experimental studies, and systematic reviews. Study designs for clinical trials are encouraged.

Cancer Control endorses the [SPIRIT](#) (Standard Protocol Items: Recommendations for Interventional Trials) Statement, which provides important guidance on drafting protocols, and the [PRISMA-P](#) (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines, which provide a 17-item checklist for preparing systematic review and meta-analysis protocols. Authors are encouraged to follow these guidelines when preparing a study protocol manuscript.

A study protocol should provide an overview of all aspects of the study to be conducted and contain a summary of the roles and responsibilities, the rationale and study objectives, a full description of the study design/methodology, including study settings, sample size, eligibility criteria, interventions and timelines, data collection and statistical methodologies, data monitoring, dissemination policies, and analysis of the proposed research.

The study protocol format should follow the general author guidelines for preparing an article, with the following variations:

Abstract

The abstract should be structured, if applicable, with the following sections: Background, Objective, Design, Results, Conclusions

Introduction

Describe the current setting that is the basis for the proposed research, including an outline of the problem (with references) and a review of current literature. Include a critical evaluation of current knowledge and preliminary studies related to the proposed research and describe how the proposal will enhance this knowledge. Describe the purpose of the study, including any specific primary or secondary objectives/hypotheses as appropriate.

Methods/Design and Analysis

Study protocols should be presented with sufficient detail to enable replication of the methods by others. The following information should be included where applicable:

- Description of study design
- Description of study population/framework and/or development of research proposal/questions
- Description of sample selection/data collection
- Clear description of all interventions and comparisons
- Sample size determination and power analyses, if appropriate
- Study outcomes/endpoints – when and how measured
- Data analysis plan

- Ethics approval and dissemination: ethics approval, and safety considerations, where applicable, should be outlined, and any plans for dissemination of findings should be included

Discussion/Conclusion

The following information can be considered for inclusion:

- Any practical/operational issues or other challenges involved in performing the study
- The importance/benefits of the study
- How the proposed study will fill any evidence gaps
- Future directions