ESSENTIAL GUIDELINES FOR WRITING SCIENTIFICALLY AND ETHICALLY SOUND RESEARCH PROPOSALS

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Dedication

To the countless researchers who strive for knowledge with integrity, and to the research participants whose trust is the cornerstone of ethical inquiry.

Acknowledgements

The development of this guideline was made possible through the valuable contributions of the following.

- Focus Group Participants (FGDs) who attended discussions on the challenges facing scientific and ethical review and potential solutions to the identified challenges.
- Special thanks to the experts who reviewed the draft guideline and provided essential insights for its improvement.
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Contents

Preface

A well-crafted proposal is the cornerstone of any successful research endeavor. It is not merely a blueprint for a study but a testament to a researcher's critical thinking, methodological rigor, and ethical commitment. This book is designed to equip researchers with the essential tools to construct research proposals that are both scientifically sound and ethically impeccable.

A scientifically sound proposal is characterized by clarity, coherence, and feasibility. It is rooted in a clear research question, a comprehensive literature review, and a meticulously planned methodology. A strong proposal anticipates potential challenges and outlines a robust data analysis plan. Equally crucial is the ethical dimension. Research must be conducted with integrity, respect for participants, and adherence to ethical guidelines. This book delves into the core principles of ethical research, emphasizing informed consent, risk minimization, data privacy, and fairness.

This book aims to empower researchers to undertake studies that generate reliable findings and contribute positively to society by providing a comprehensive framework for developing research proposals. We hope that this guide will serve as an invaluable resource for students, early-career researchers, and seasoned

professionals alike, fostering a culture of excellence in research.

Foreword

The landscape of research is evolving rapidly, demanding increasingly rigorous standards for scientific soundness and ethical conduct. Researchers must possess a deep understanding of the methodological rigors required to produce reliable and valid findings. Equally critical is a steadfast commitment to ethical principles that safeguard the rights and well-being of research participants. This book excels in providing a comprehensive framework that addresses both of these imperative dimensions.

By equipping researchers with the tools to construct scientifically sound and ethically impeccable proposals, this book contributes significantly to the advancement of knowledge.

It is a valuable resource for students, early-career researchers, and experienced scholars alike. I wholeheartedly commend this work and encourage its widespread use.

Prof Jackson Kitetu
Chair, Scientific and Ethics Review Committee
Kabarak University.

Introduction

A scientifically sound research proposal is well-designed and is highly probable to generate reliable results (Barlösius, 2019). Its first hallmark is a clear research question that acts as a roadmap, guiding the entire study. Second, the proposal is built on a solid foundation grounded in existing research and identifies gaps in knowledge that the study aims to fill. Third, the methodology chosen is appropriate for answering the research questions and ensures accurate data collection. Fourth, it outlines a rigorous analysis plan to guide the data analysis, facilitating valid and meaningful conclusions. Finally, it acknowledges potential limitations in the study design and considers any potential biases that might influence the results.

An ethically sound research proposal ensures the research is conducted with respect to participants and minimizes potential harm (Bromley et al., 2015). This is achieved by adhering to core ethical principles. Informed consent is paramount, guaranteeing participants fully understand the study, any potential risks involved, and their right to withdraw at any point. The research design itself should prioritize minimizing risk, both physical and emotional, for the participants. It ensures confidentiality and protects the privacy of participants and their data. It ensures justice in the fair selection of participants, and the potential benefits of the research outweigh the risks for everyone involved.

In essence, "**a scientifically and ethically sound research proposal**" excels on both fronts (Weinbaum et al., 2019): adhering to a structured framework that ensures clarity, rigor, and compliance with ethical standards in producing reliable results through well-designed methods while conducting the research in a way that respects the rights and well-being of all participants.

Purpose of the Guideline

The Scientific and Ethics Proposal Preparation Guideline is designed to assist researchers, academicians, and professionals in preparing high-quality research proposals. It is concise yet comprehensive and covers pertinent scientific and ethical issues.

The guideline provides expectations regarding scientific considerations, such as the preliminaries, objectives, research questions, hypothesis, justification, significance, limitations, assumptions, the scope of a study literature review, and choice of research design.

The methodology section of the guideline outlines considerations on primary and secondary data collection, sampling, informed consent, assent, privacy and confidentiality, data management, data analysis, and risk-benefit analysis.

It further highlights aspects of research proposals that often need to be improved in most proposal guidelines, such as professional, legal, and regulatory requirements, researcher credentials, qualifications and competencies, conflict of interest, and dissemination.

How to Use the Guideline

The relevance, inclusion, and order of the sections in this guideline will vary in proposals as dictated by various disciplines and organizations. Therefore, they are to be referred to and applied in context.

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Essential Guidelines for Writing Scientifically and Ethically Sound Research Proposals

PRELIMINARIES

The preliminary section of a proposal, sometimes called the front matter, sets the stage for the proposal and provides essential information at a glance (Denscombe, 2012).

1. **Title:** The title should be concise and summarise the study's main ideas in as few words as possible.
2. **Abstract:** The abstract should provide a concise summary of the study and cover the following aspects: a brief background, the study problem, the main objective of the study, research design, study population, sample size, method of sampling, data collection procedure, data analysis procedures and the proposed significance and method of disseminating the findings. Its length is typically 250 to 300 words.
3. **Preliminaries**: The proposal should also have the preliminary pages as required in the applicable proposal guidelines. All the investigators should sign the document with the respective and applicable details provided.

INTRODUCTION

The introductory section provides a comprehensive research proposal overview (Belwal, 2016).

1. **Section overview:** Provide a summary of the kind of information the chapter will contain (Word count 200)
2. **Background of the Study:** The background should introduce the study area and explicitly demonstrate the gap/need to conduct the study. (Use a structure such as the Inverted pyramid format, e.g., Global statistics/perspective, regional/perspective, local/perspective, and demonstrate the gap at every level.
3. **Statement of the Problem:** A well-constructed problem statement should clearly articulate the issue at hand, connecting it to the broader research context. It should specify the problem's impact, the affected population, and the setting. Crucially, it must identify a gap in existing knowledge, underscoring the significance of the study. By clearly outlining the problem and its implications, the statement justifies the need for the research and sets the stage for the investigation.

   Note: There are different schools of thought regarding the inclusion of secondary literature in

the problem statement. Some find it necessary to reinforce the problem, while others believe that literature should not be referenced in this section. Both perspectives have merit depending on the researcher involved and are subject to the applicable institutional guidelines.

4. **General Objective(s) / Aim(s) / Purpose of the Study:** These should mirror the study's title and indicate the study's output. They should cover the specific objectives in a broad sense and be SMART (specific, measurable, achievable, relevant, and time-bound). The breadth and depth of the proposed study determine the number of objectives.

5. **Hypothesis / Research Questions / Specific Research Objectives**

    i. **Qualitative Research -** Provide specific objectives and research questions

    ii. **Quantitative Research -** Provide specific objectives and research questions *(if applicable)* or hypothesis *(if applicable)*

    iii. **Mixed Methods Research -** Provide specific objectives, research questions, and hypotheses. The specific mixed methods

design that combines quantitative and qualitative approaches should be clear.

6. **Justification/Rationale of the Study:** This section should present its rationale and how it fits into global, national, and regional development blueprints.
7. **Significance of the Study:** This section should clearly outline positive outcomes/gains for individuals or communities that will accrue from the study.
8. **Limitations and delimitations of the Study:** This section should clearly outline potential challenges and weaknesses that may limit the achievement of the study objectives. Approaches for addressing the limitations should also be provided.

   Note: In some contexts, issues such as finances and time, commonly mentioned by upcoming researchers, are often dismissed as not qualifying as limitations. Determining an appropriate limitation is beyond the scope of this book and is best left to the institutions to guide.
9. **Assumptions of the Study:** This section should present issues or circumstances that are assumed to be true or at least plausible and necessary to

achieve the study objectives.

10. **Scope of the Study:** This section should mention the depth of the study in terms of the geographical area, the participants, and the problem statement.

LITERATURE REVIEW

The literature review critically analyses existing scholarly work on a specific topic (Terrell, 2022). It is an in-depth investigation into what is already known about the research area.

1. **Introduction:** This section should clearly describe the type of review undertaken, the content of the review, the organisation of the review, and the strategy used for searching the literature. It should be provided clearly and concisely.
2. **Empirical review of Literature:** This section should provide clear and detailed content covering the broad area of the study and the problem, critical outcomes of previous research in the area, essential research methods or approaches in previous studies, and comparisons and contrasts of different points of view, outcomes, and approaches in previous research.
3. **Summary of gaps:** This section should present a clear and concise summary of the literature, pinpointing the key problems, methods/approaches, outcomes, and

shortcomings of works reviewed in the literature.

4. **Theoretical Framework (where applicable):** This section should present clear constructs that inform pertinent aspects of the study, such as the objectives, variable selection, and methodology.
5. **Conceptual Framework:** This section should present a textual and visual representation that illustrates the relationship among variables (independent, dependent, confounding, components or constructs) and their relationship with the expected outcome/solution.

RESEARCH METHODOLOGY

Research methodology refers to the systematic approach and techniques used to collect, analyse, and interpret data in a research study. It encompasses the procedures and strategies for designing the research, selecting samples, collecting data, and analysing results (Kapur, 2018).

Research methodology ensures the findings' validity, reliability, and accuracy by employing appropriate tools and methods, such as qualitative, quantitative, or mixed methods. It also involves ethical considerations and adherence to standards to maintain the integrity of the research.

RESEARCH DESIGN

Research design refers to the overall study plan (Dannels, 2018). It outlines the methods you will use to collect data, analyse it and draw conclusions.

The choice of a research design: Depending on the type of research chosen, qualitative, quantitative, or mixed methods, it is essential to state and justify why it is the most preferred approach (Harwell, 2011).

- In qualitative research, designs such as ethnography, phenomenology, and grounded theory are commonly used to explore complex phenomena in-depth.
- Quantitative research typically employs experimental, quasi-experimental, and survey approaches.
- Mixed methods research combines both approaches, using explanatory sequential and convergent parallel designs to understand the research problem comprehensively. (Harwell, 2011).

For mixed methods research: a clear description of the type of mixed methods approach that will be utilised, the integration of quantitative and qualitative approaches (objectives, study participant selection, sampling,

inclusion and exclusion criteria, recruitment, consenting process, data collection, data analysis) and the triangulation arising from the use of the approach.

DATA COLLECTION

Primary Data Collection

Primary data collection involves gathering new, original data directly from legally competent, naturally occurring, or mentally sound individuals (Guest et al., 2013). This process typically includes obtaining information through various methods such as surveys, interviews, focus groups, and observations.

Location of the Study

1. *Geographical Location:* Indicate the specific geographic location where the research will occur. This could include a city, state, country, or even a particular region or community.
2. *Study Site:* Describe the specific study site within the location. This might be a particular building, institution, or natural area.
3. *Rationale:* Explain why the location is important and why it was chosen for the study. This could include factors such as access to resources, existing research infrastructure, or unique characteristics of the location.

4. *Accessibility:* Discuss how the research team will access the location and any challenges that may arise during the study. This could include travel logistics, language barriers, or cultural differences.
5. *Ethics and Safety:* Address any ethical considerations related to conducting research in the chosen location and any safety concerns that may need to be addressed.

Study Population

i. Describe the study population and the parameter of interest depending on the research design chosen.

ii. **Inclusion of Vulnerable Populations:** If a vulnerable population is included, justify why they should be included, i.e., they should be included only if necessary. The 'Inclusion of Vulnerable Population's form' must be comprehensively completed.

iii. **Sampling** *(if applicable)*

a) **Sample Size Computation / Determination:** The formula or approach used to determine the number of participants in the study should be provided, and its use should be demonstrated through computations resulting in the study sample size.

b) **Inclusion and Exclusion Criteria:** Provide the

criteria that will be used to identify participants who will participate and those who are not eligible to participate.

c) **Sampling Method:** Describe the approach used to identify a subset of a population from the general population.

iv. **Census** *(if applicable)*

a) **Inclusion criteria:** Provide the criteria that will be used to identify participants in the census.

b) **Recruitment method:** Outline the process for identifying or screening the study participants based on the inclusion and exclusion criteria.

v. **Recruitment Process:** Describe how researchers will contact prospective participants to inform them of the study.

vi. **The Consenting / Assenting Process**:

a) Outline the procedure through which a competent subject or guardian will voluntarily provide their willingness (consent/assent) to participate in the study after receiving and understanding all the research-related information.

b) Provide the informed consent/assent form in

the proposal appendices.

vii. **Payment for Participation:** Indicate if participants will be paid to participate in the study, the rates, and the specific activities to be paid for.

DATA COLLECTION TOOLS AND INSTRUMENTS

For each tool or instrument to be used for data collection, provide the following information:

1. **Type of data collection tool or instruments:** Indicate and justify the type of data collection tool or instruments.
2. **Variables and Constructs**
    - **Variables** *(where applicable)***:** Describe the variables of interest in the study (dependent, independent, and covariates / intervening), their levels of measurement, the data collection tool, data collection approach, data source, and their purpose in the study (related to achieving the study objectives).
    - **Constructs** *(Where applicable)***:** Describe the constructs of interest in the study, the data collection tool, the data collection approach, the data source, and their purpose (*related to achieving the study objectives*).

- **Validity and Reliability:** Provide all the measures that will be taken to ensure the validity and reliability of the tools, instruments, approaches, or methods to be used for data collection, e.g., pre-testing, piloting, calibration, settings, or configuration of instruments.

DATA COLLECTION PROCEDURES

Describe how, when, and by whom the data will be collected and recorded, the location of data collection, the time of data collection, the safety, privacy, and confidentiality of the participants during data collection, and the researcher's safety.

Secondary Data

Secondary, archival, or pre-existing data refers to information already collected and available in new research (Sherif, 2018). This data can come from various sources, including published studies, government reports, institutional records, or previously gathered datasets.

1. **Justification for the use of Secondary Data:** Justify the use of secondary data and why the chosen secondary/archival or pre-existing data set/s
2. **Data Source:** Describe the source of all the pre-existing data sets, the usage rights, and conditions for the use, e.g., acknowledgements of source and

funders

3. **Data Acquisition:** Describe the legitimate process of acquiring the data.
4. **Location of the Study:** Describe the location of the original data collection.
5. **Use of the secondary data set/s**
    i. **Study Population:** Describe the study population in the pre-existing data and, if applicable, justify the inclusion of vulnerable populations from the pre-existing data in the current study.
    ii. **Sample Size Determination:** Provide the approach used to determine the sample size for the current study from the pre-existing data.
    iii. **Sampling Method:** Describe the sampling technique to select records from the pre-existing data.
    iv. **Variable identification and extraction:** Describe the criteria for selecting the specific variables to be extracted from the pre-existing data for use in the current study.
    v. **Inclusion and Exclusion Criteria:** Describe the criteria that will be used to identify candidate

records from the pre-existing data.

vi. **Consent:** Provide information on the consent provided by the study subjects in the original data collection and consent for secondary use of the pre-existing data.

DATA MANAGEMENT

Privacy and Confidentiality

Privacy is a multifaceted concept encompassing the right to be free from unauthorised intrusion and the ability to control personal information (Koops et al., 2016). Confidentiality is a specific aspect of privacy that focuses on keeping information secret and only disclosing it to authorised individuals.

Describe measures to be taken to ensure the privacy and confidentiality of the data and data subjects in the primary or pre-existing data during its use in the current study.

If identifier information will be collected or extracted,

i. Explain its nature and why it is necessary for the study.

ii. Explain when and how the data set will be de-identified.

Data Safeguards

Data safeguards are a collection of measures and practices designed to ensure the efficient management, security, and privacy of information within an organisation (Damaraju, 2023).

Describe administrative, physical, and technical safeguards that will be put in place to protect the study data from unauthorised destruction, loss, misuse, unauthorised disclosure, or alteration.

Data Monitoring and Safety Plan

A data safety and monitoring plan outlines measures to ensure participants' safety and the data's validity and integrity (Charoo et al., 2023).

i. Specify the frequency and method of data monitoring for adherence to data collection procedures, safety, privacy, and confidentiality.
ii. Specify who will monitor the data and how often they will review it.
iii. Provide the criteria for data review, including when and why certain data will trigger a review.

Data Entry and Cleaning

Data entry is where raw data is captured and introduced into a digital format (Selwyn, 2015). It involves manually

typing information from physical sources (like paper forms) or electronically transferring data from various sources (like online surveys) into a database or spreadsheet. Data cleaning involves identifying and correcting errors, inconsistencies, and missing values within the dataset (Chu et al., 2016).

Provide the procedures for data entry and cleaning.

Data Storage, Archiving, and Disposal

Data Storage refers to the methods and technologies used to hold and maintain data for ongoing access and use (Lemieux et al., 2019). Data archiving involves moving less frequently accessed data to a long-term storage solution. Data disposal is when data is securely and permanently erased or destroyed when it is no longer needed.

Provide the provisions for data storage, archiving, and disposal.

Data Analysis

Data analysis involves inspecting, cleaning, transforming, and modelling data to discover useful information, informing conclusions, and support decision-making (Osborne, 2012). Analysis methods include qualitative and quantitative approaches, such as statistical tests. They also detail the software to be used (Field, 2018).

1. Describe and justify the data analysis procedures and methods for each study objective/research question or hypothesis.
2. If a software program will be used in the analysis, describe it and justify the choice.

RISK-BENEFIT ANALYSIS

Risk-Benefit Analysis (RBA) is a systematic process for assessing the potential risks and benefits of a proposed action or decision (Crouch and Wilson, 1982). It weighs the potential downsides (risks) against the potential upsides (benefits) to determine whether an action is worthwhile.

Participant / Subject Risk-Benefit Analysis

1. **Risks:** Outline any risks (physical harm, psychological distress, loss of privacy, and social or economic consequences.) that participants in your study may be exposed to at any stage of the study, such as data collection, data processing, and analysis, data storage, and dissemination stages of the work.
2. **Benefits:** Outline benefits (e.g., advancement of knowledge, medical advancements, improved treatments, or societal benefits) that the participants may experience directly, indirectly, or through third parties, immediately or in the longer term.

3. **Risk-Benefit Analysis Computation:** Assess the risks identified as follows:

    i. **Risk Scoring:** Compute a risk score by multiplying the likelihood (*a probability between 0 and 1*) of the risk occurring by its potential severity (*on a three-, five- or seven-point scale*).

    ii. **Benefits Scoring:** Compute the benefits score by multiplying the likelihood (*a probability between 0 and 1*) of the benefit occurring by its potential magnitude (*on a three-, five- or seven-point scale*).

    iii. **Risk-Benefit Ratio -** Compute the overall Risk Benefit Ratio as follows: *Risk Benefit Ratio = Total Risk Score / Total Benefit Score.*

4. **Risk-Benefit Assessment:** Assess the level of the risk-benefit ratio. Higher values indicate that the study should be reconsidered.

5. **Risk Mitigation:** Outline measures that will be taken to mitigate the risks identified.

Overall Risk-Benefit Analysis

1. **Risks:** Outline any risks that the researcher, research assistants, data, equipment, infrastructure, and environment, among others, are likely to

manifest in any stage of the study, such as data collection, data processing and analysis, data storage, and dissemination stages of the work.

2. **Benefits:** Outline benefits that the researcher, research assistants, data, environment, and the community / general public in your study may experience directly, indirectly, or 3rd parties, immediately or in the longer term.

3. **Risk-Benefit Analysis Computation:** Assess the risks identified as follows:

    i. **Risk Scoring:** Compute a risk score by multiplying the likelihood (*a probability between 0 and 1*) of the risk occurring by its potential severity (*on a three-, five- or seven-point scale*).

    ii. **Benefits Scoring:** Compute the benefits score by multiplying the likelihood (*a probability between 0 and 1*) of the benefit occurring by its potential magnitude (*on a three-, five- or seven-point scale*).

    iii. **Risk-Benefit Ratio -** Calculate the overall Risk-Benefit Ratio: *Risk-benefit ratio = Total Risk Score / Total Benefit Score.*

4. **Risk-Benefit Assessment:** Assess the level of the risk-benefit ratio. Higher values indicate that the

study should be reconsidered.

5. **Risk Mitigation:** Outline measures that will be taken to mitigate the risks identified.
6. **Handling Adverse Events** - Outline measures that will be taken to handle any adverse events arising from the manifestation of the risks identified.

PROFESSIONAL, LEGAL, AND REGULATORY REQUIREMENTS

Outline all permits, approvals, materials transfer agreements, Intellectual Property agreements, and other regulatory approvals that will be sought for the study.

RESEARCHER CREDENTIALS

1. Highlight the specific credentials, competencies, and skills required for the study and the corresponding education, research experience/ track record, work experience, and training possessed by the investigator/s in these competency and skill areas.
2. Highlight the specific technical/scientific roles to be played by every team member in the proposed study. The investigators' CVs should be provided for verification.

CONFLICT OF INTEREST

1. Disclose any direct or indirect personal, family, friendships, commercial, or social interests that are in a position to compromise the judgments, decisions, or actions of any investigator, co-investigator, or participant in a manner that has the potential to influence the study outcomes.
2. Explain how any identified conflicts of interest will be managed or mitigated, such as through recusal from certain aspects of the research, independent oversight, or other strategies.

REPORTING AND DISSEMINATION

1. **Audience:** Provide details on all relevant stakeholders, such as study participants, researchers, government, community, and businesses, to whom the study findings will be disseminated.
2. **Content:** Provide details on the specific results to be disseminated to each identified target audience.
3. **Avenues:** Provide details on avenues, forums, or platforms that will be used to disseminate the study's findings.

ETHICAL ISSUES

Comment on how the proposed study addresses the following ethical principles: respect for persons, Kindness, Non-maleficence, and Justice.

REFERENCES

Provide all references cited in the proposal and format them according to discipline-specific requirements.

APPENDICES

Provide the Budget, work plan, approvals granted, Informed consent form, and data collection tools. Inclusion of vulnerable population form (if applicable), and any other applicable documents

A NOTE ON PROPOSAL REVIEW

This guideline can be used to develop guidelines or a checklist for the scientific and ethical evaluation of proposals.

Its key value lies in providing a comprehensive list of items and issues that can be used to develop a checklist to check if required items have been included in the proposal.

However, assessing the quality of the responses to the various sections still requires the keen eye of a competent reviewer.

Summary

This guide provides concise pointers on what is expected of a research proposal regarding scientific and ethical soundness.

It focuses on scientific aspects, such as the problem, literature review, and methodology. The methodology section details issues relating to sampling, participants, data management, risk-benefit analysis, and researcher competencies.

It is to be applied in context, depending on the requirements of the relevant discipline or organisation for which a proposal is being prepared.

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Essential Guidelines for Writing Scientifically and Ethically Sound Research proposals is designed to assist researchers, academicians, and professionals in preparing high-quality research proposals. It is concise yet comprehensive and covers pertinent scientific and ethical issues. The guideline provides expectations regarding scientific considerations, such as the preliminaries, objectives, research questions, hypothesis, justification, significance, limitations, assumptions, the scope of a study literature review, and choice of research design. The methodology section of the guideline outlines considerations on primary and secondary data collection, sampling, informed consent, assent, privacy and confidentiality, data management, data analysis, and risk-benefit analysis. It further highlights aspects of research proposals that often need to be improved in most proposal guidelines, such as professional, legal, and regulatory requirements, researcher credentials, qualifications and competencies, conflict of interest, and dissemination.

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