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An Integrated Framework for Scientific and Ethical Review of Research Proposals

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Abstract
Research proposals must adhere to both scientific and ethical standards to ensure the integrity and impact of research endeavours. However, existing guidelines often fall short in providing comprehensive guidance for non-medical disciplines, requiring separate documents for scientific and ethical reviews, and lacking detailed instructions for specific steps such as risk-benefit analysis and the use of secondary data. This study addresses these challenges by developing a detailed, step-by-step guideline for preparing research proposals that seamlessly integrate scientific and ethical reviews. Through a qualitative research design, involving focus group discussions with ethics review committee members and key informant interviews with experts, combined with a comprehensive literature review, this study identified best practices and challenges in the current review process. The proposed guideline offers a structured approach to preparing research proposals, emphasizing clarity in research objectives, methodology, data analysis, and expected outcomes for scientific review. For ethical review, it provides detailed instructions on risk-benefit analysis, informed consent processes, privacy and confidentiality measures, and the ethical use of secondary or archival data. The guidelines were pilot-tested with researchers to ensure their usability and effectiveness, resulting in a refined tool that can standardize the proposal preparation process and improve the quality and integrity of research across various disciplines.

Introduction

Research activities are valued for their ability to address human challenges and are conducted with meticulous care (Nayak & Singh, 2021). The scientific community and the general public are deeply invested in the integrity of research processes due to the potential for misconduct (Macrina, 2014). To mitigate these risks, the scientific community has developed mechanisms for preparing and reviewing research proposals. These mechanisms typically involve two main aspects: scientific review and ethical review. The scientific review process focuses on assessing the validity, significance, and justification of the research problem (Jasper et al., 2014). It examines the availability of SMART research objectives and questions, the depth and breadth of the literature review, the clarity of the theoretical and conceptual frameworks, and the completeness of the study's methodology (Adeoye & Adong, 2023). These elements ensure that the research is well-grounded, feasible, and likely to contribute valuable knowledge to the field.

Ethical review focuses on identifying potential harm to human and animal participants and the environment. Ethical review committees and researchers must implement mitigation measures to protect participants and minimsze harm throughout the research process (Markham et al., 2012). This

review ensures that research activities adhere to ethical standards, thereby maintaining public trust and safeguarding the rights and well-being of participants.

Despite the established nature of scientific review, ethical review practices are still largely under development, particularly in non-medical disciplines (Fouka & Mantzorou, 2011). Most existing ethics review tools and processes are adopted from the medical field, often leading to challenges in applicability and usability for non-medical research (Peute et al., 2020). These adopted tools are only sometimes well-suited to the specific needs of non-medical disciplines, resulting in difficulties for researchers navigating these medically inclined frameworks.

Additionally, the current practice often requires the preparation of two separate documents: a research proposal for scientific review and an application for ethics review. These documents are reviewed by different sets of reviewers, leading to significant overlaps and inefficiencies. This separation is not always clear-cut, as many concerns in scientific and ethical reviews overlap.

The growing importance and prominence of scientific and ethical reviews in research highlight the need for improved guidelines. Specifically, there needs to be more comprehensive guidelines that cater to non-medical fields and combine scientific and ethical aspects into a single, cohesive document for review. This gap in the current framework presents a significant challenge for researchers across various disciplines. In addressing this gap, the research question arises: "*What are the key elements of a general-purpose guideline for research proposals that can ensure both scientific rigour and ethical compliance?*"

Developing such a guideline is crucial to streamline the proposal preparation process, ensuring that all critical scientific and ethical issues are comprehensively addressed. This integrated approach would facilitate more efficient and thorough reviews, ultimately enhancing research quality and integrity across medical and non-medical fields.

Literature Review

Sound Science

Sound science is a cornerstone of credible research, encompassing rigorous methodology, ethical considerations, and the pursuit of objectivity, validity, and reliability. Horváth (2013) emphasises that soundness involves applying tested and justified methods, proper study design, and skilful execution. Siponen et al. (2021) further highlight the importance of ethical considerations, such as minimising harm and maximising benefits.

Across various fields, the principles of sound science are consistently emphasised. In medical research, randomised controlled trials (RCTs) are often considered the gold standard for establishing causality and minimising bias (Recker, 2021). Ethical soundness is paramount in this context, given the direct impact on human health and the necessity of adhering to strict guidelines (Danis et al., 2012). In the social sciences, quantitative and qualitative methodologies can achieve soundness. Krathwohl (2009) underscores the importance of case study research for understanding complex social phenomena and ensuring soundness through triangulation. Ethical considerations in social science research often include informed consent and confidentiality (Sieber & Stanley, 1988).

Environmental science also relies on sound research practices to inform policy decisions. A study by Field et al. (2009) highlights the importance of robust sampling methods and long-term data collection for accurate climate change research. Ethical soundness in this field includes considering the potential consequences of research findings on communities and ecosystems. A combination of experimental and observational methods can achieve soundness in educational research. Slavin (2002) argues for the necessity of rigorous experimental designs, such as randomised trials, to establish the

effectiveness of educational interventions (Sloane, 2008). Ensuring validity and reliability in educational assessments is also crucial for obtaining meaningful results (Jonsson & Svingby, 2007).

While the principles of sound science are common across fields, their application can vary significantly. For instance, while RCTs are a staple in medical research, they may not always be feasible or ethical in social science or educational research. These fields often rely on alternative methods, such as case studies, longitudinal surveys, and mixed-method approaches, to achieve soundness. Ethical considerations also differ across contexts. In medical research, ethical guidelines are often stringent and codified in regulations like the Declaration of Helsinki (Sprumont et al., 2007). In contrast, ethical considerations in social science research might focus more on power dynamics and the potential for harm in more subtle, non-physical ways. In environmental research, ethical soundness includes the broader impact of research findings on policy and public perception.

Research Ethics

Research ethics provide a framework for conducting and disseminating scientific research ethically. These guidelines protect research subjects, participants, and the environment from harm. Fundamental principles include honesty, integrity, objectivity, informed consent, respect for persons, non-maleficence, responsible publication, anonymity, confidentiality, non-discrimination, openness, intellectual property rights, justice, protection of vulnerable persons, and possession of appropriate skills (Agunloye, 2019).

The specific ethical considerations in research vary across fields. In medical research, strict guidelines, such as the Declaration of Helsinki, emphasise informed consent, risk-benefit assessment, and independent ethical review (Sprumont et al., 2007). Randomised controlled trials are often used to ensure scientific rigour and ethical integrity (Shamy & Fedyk, 2018). In contrast, social science research usually involves more subjective data and requires different ethical considerations. Ethical guidelines in this context focus on protecting participant privacy and confidentiality, given the sensitive nature of the information often collected (British Sociological Association, 2020). In qualitative research, maintaining ethical standards involves carefully considering the researcher-participant relationship and ensuring that participants are not exploited or harmed (Aluwihare-Samaranayake, 2012).

Environmental research introduces another layer of ethical complexity, often involving human and animal subjects and entire ecosystems. Ethical guidelines in this field stress the importance of sustainability and minimising environmental harm. The Belmont Report, while initially intended for biomedical and behavioural research, provides principles that are broadly applicable to environmental studies, such as respect for persons, beneficence, and justice (Nicolaides, 2016). Studies like those conducted by Skillington (2019) on climate change underscore the importance of ethical considerations in research that has far-reaching implications for current and future generations.

Ethical considerations in educational research often focus on protecting vulnerable populations, such as children and adolescents. Ethical guidelines from organisations like the American Educational Research Association (AERA) stress the importance of obtaining informed consent from parents or guardians, ensuring voluntary participation, and safeguarding student data confidentiality (Cohen et al., 2017). Studies in this field must balance the need for accurate data with the ethical imperative to protect young participants from potential harm (Sherblom, 2003).

While the fundamental principles of research ethics remain consistent, their application can vary significantly depending on the field. Medical research emphasises rigorous trial design and patient safety; social sciences focus on participant protection; environmental research prioritises sustainability; and educational research safeguards vulnerable populations.

Science and Ethics

The relationship between science and ethics is fundamental. Scientists, being human, are susceptible to errors and ethical lapses. Ethical principles are crucial for ensuring the soundness and integrity of research, including protecting the safety of research participants and the reliability of research results (Dyer, 2013).

In biomedical research, ethical guidelines are rigorously enforced to prevent misconduct. The Declaration of Helsinki outlines ethical principles for medical research involving human subjects, emphasising informed consent, risk minimisation, and independent ethical review (Guraya et al., 2014). However, historical cases like the Tuskegee Syphilis Study demonstrate the importance of these safeguards, as unethical practices can still occur (CDC, 2022).

In contrast, social science research often involves more subjective and sensitive data, posing unique ethical challenges. Maintaining participant confidentiality and navigating power dynamics between researchers and subjects are crucial considerations. The British Sociological Association's Statement of Ethical Practice provides guidelines to protect participants' rights and ensure ethical conduct in social research (Cohen et al., 2017).

Environmental research introduces additional ethical considerations due to its potential impact on ecosystems. Researchers must balance the need for data with the responsibility to minimise environmental harm. Ethical guidelines in this field, such as those discussed by Resnik (2012), emphasise sustainability and the long-term impact of research on the environment. The debate over genetically modified organisms (GMOs) illustrates the ethical complexities in environmental science, where potential benefits must be weighed against ecological risks (Sanvido et al., 2012).

Ethics Review

Ethics review is a crucial component of the research process. It ensures that research is conducted ethically by evaluating its moral grounding and protecting participants' rights and welfare (World Health Organization, 2009). This process helps maintain research integrity and prevent undue risk to participants and society.

The ethics review process typically involves several stages: application, review, deliberation by a review committee, and approval or rejection of the proposal. Once approved, a study is subject to ongoing monitoring and evaluation, culminating in study closure upon completion (Gupta, 2017). Ethics review committees often differentiate between low-risk and high-risk studies, allowing for a more efficient review process and appropriate allocation of resources (Rid et al., 2010). *The review time frame for research proposals can vary.* Routine reviews follow standard procedures, while expedited reviews are reserved for time-sensitive research involving minimal risk or urgent public health needs (Borah, 2020). This flexibility is crucial for timely research, especially during public health emergencies.

International standards and guidelines, such as those provided by the Council for International Organizations of Medical Sciences (CIOMS), guide ethics review processes to ensure consistency and fairness in biomedical research. These guidelines emphasise the importance of informed consent, risk-benefit assessment, and equitable selection of subjects (Meza et al., 2018).

Despite the structured process, ethical reviews in non-medical disciplines can be challenging due to the nuanced ethical considerations involved. Social science and humanities research often raise complex issues such as privacy, consent, and the interpretation of qualitative data. Ethical review committees must adapt their frameworks to address these specific challenges and ensure that ethical principles are upheld across all research fields (Wilson et al., 2018). Furthermore, *the rise of digital research methodologies has introduced new ethical challenges.* Data privacy, informed consent in virtual

settings, and the potential for digital harm require ethics review committees to continually update their guidelines and practices (Tiidenberg, 2018).

Scientific and Ethical Review

Scientific and ethical reviews are intertwined practices that often overlap in research projects. While scientific review focuses on research soundness, ethical review considers fairness and justice (Van den Hoonaard & Hamilton, 2016). Both practices often examine the same sections of a research proposal, such as sampling. For example, a scientific review might focus on the representativeness of a sample for statistical analysis. In contrast, an ethical review would consider participants' inclusion and exclusion criteria (National Commission for Science, Technology and Innovation, 2022).

The National Commission for Science, Technology and Innovation (NACOSTI) in Kenya merged the separate review processes for scientific and ethical review of research proposals. This addressed the potential for overlap and conflict between the two processes. In 2022, NACOSTI expanded the mandate of the Institutional Ethics Review Committees (IERC) to include scientific review, renaming them Institutional Scientific and Ethics Review Committees (ISERC).

Methodology

Study Design

This study employed an exploratory research design to develop comprehensive guidelines for preparing research proposals for scientific and ethical review. The methodology utilised qualitative techniques, including focus group discussions, key informant interviews, and an extensive literature review. The various data collection methods used are as follows:

Focus Group Discussions - A focus group was convened in September 2022, comprising members from various ethics review committees to gain in-depth insights into the existing review processes. This diverse group included seasoned reviewers, committee chairs, and administrative staff, bringing a wealth of experience and perspectives to the discussion. The focus group also reviewed the gaps in existing ethics review tools in light of new scientific and ethics review requirements. The focus group sessions were structured to encourage open dialogue and sharing of best practices and challenges encountered in the review process.

Key Informant Interviews - Key informant interviews were conducted with experts in the field to delve deeper into specific issues identified during focus group discussions. These semi-structured interviews aimed to gather additional insights from individuals with extensive experience in scientific and ethical review processes. The informants were chosen based on their expertise, reputation, and contributions to the field.

Observation - Before and during the study, the investigators also collected data on the process and critical challenges relating to the ethics review process through observations. This was possible given their role as ethics reviewers, who were also actively involved in examining proposals for ethical issues.

Literature Review - A comprehensive literature review was conducted to contextualise the findings from the focus group discussions and key informant interviews. The review included scholarly articles, policy documents, and guidelines from leading research institutions and ethics review boards. The literature was critically analysed to identify common practices, innovative approaches, and gaps in the current scientific and ethical review methodologies. The insights gained from this review were integrated with the expert opinions to enhance the robustness of the proposed guidelines.

Development of Guidelines - The investigators developed draft guidelines for preparing research proposals by analysing findings from focus groups, key informant interviews, and a literature review.

The guidelines were created by merging aspects of two existing sets of guidelines: a proposal development guideline and an ethics review guideline. The final integrated guideline covers all aspects of the research proposal and ethical review.

Guideline Review **-** These guidelines were then subjected to a validation process involving a second round of expert reviews and consultations. Feedback from this validation phase was incorporated to refine and finalise the guidelines. In October 2023, the draft tool was then reviewed by the Scientific and Ethics Review Committee at Kabarak university, subjected to expert review, and tested by students.

Pilot Testing **-** The final step involved testing the proposed guidelines with a sample of researchers preparing proposals for review in October 2023. This phase involved three students and two reviewers. Its objective was to assess the guidelines' usability, clarity, and effectiveness in a real-world setting. Feedback from the pilot testing was used to adjust the guidelines.

Ethical Considerations - Ethical clearance for this study was obtained from the Kabarak University Institutional Scientific and Research Ethics Committee (KABU – ISERC, KABU0/KUREC/001/04/03/22) on March 4, 2022. A data collection permit was also secured from the National Commission of Science Technology and Innovation (NACOSTI/P/22/16789) in compliance with national regulations. These approvals ensured that the study adhered to ethical standards and protected the rights and confidentiality of all participants.

Results

Gaps in Current Ethical Review Processes and Tools

[1] *From Ethics Review to Scientific and Ethical Review* - In 2022, the National Commission for Science, Technology, and Innovation in Kenya expanded the mandate of Ethics Review committees in Kenya to include scientific review. The implication of this change in practice meant that the committees were now required to concern themselves with the entire research proposal and not just the aspects of the methodology that had ethical issues (National Commission for Science, Technology, and Innovation, 2022). It was, therefore, observed that current processes and tools could not address the additional requirement for scientific review.

[2] *Low capacity for identifying and mitigating ethical issues* - It was observed in practice and from the focus group that several issues related to ethical practices were not well addressed in the proposals submitted for review by the committee. The causes for this were determined to be (i) the lack of inclusion of ethical considerations in the guidelines in use for proposal development and (ii) the lack of specific training on these ethical issues for both students and their supervisors.

[3] *Lack of specific guidelines on some aspects of the ethics review* - The proposal guidelines were found to be lacking in guidance on several key areas required by the ethics review process, including data management, risk-benefit analysis, professional and regulatory requirements, researcher qualifications, conflict of interest, reporting and dissemination, and ethical issues.

[4] *Lack of provisions to identify and address ethical issues relating to emerging issues and technologies* – The committee and focus group participants observed increased proposals incorporating emerging technologies like AI, IoT, and blockchain. They noted that current ethics review guidelines lacked guidance on ethical issues related to these technologies and data protection. While the ethics committee addressed data management issues, applicants found these

unclear, especially regarding emerging data protection laws.

[5] *Bias towards medical issues* - The committee and focus group participants observed that the current application guidelines and review tools were adapted from medical ethics committees. This led to a lack of generality in the areas of focus and language, making them unsuitable for reviewing non-medical proposals.

[6] *A disconnect between the proposal examination and ethical review processes* – It was observed that the current process leading to the approval of a research proposal comprised two separate steps: (i) the proposal development and examination step and (ii) the ethics review process. This, coupled with the lack of guidelines on addressing ethical issues during proposal development, resulted in researchers being confronted with ethical issues after their proposals had been approved.

The data collection exercise required a comprehensive guideline addressing scientific and ethical considerations for research proposals. This guideline should apply across various disciplines and guide on addressing ethical concerns related to emerging technologies and issues.

The Integrated Guideline Development Process

The integrated guideline development was a two-step process as follows:

[1] *Guideline Development* – Based on the gaps identified, a draft guideline focused on the methodology section of the proposal development guideline. It included sections on research design, data type, participant considerations, data collection tools and instruments, data management, risk-benefit analysis, professional requirements, researcher qualifications, conflict of interest, reporting and dissemination, and ethical issues.

[2] *Guideline Review* – The draft guideline was reviewed by focus groups, experts, and volunteer applicants. Feedback was received on its comprehensiveness, clarity, and potential for leading to well-written proposals. However, the guideline's length and complexity were noted as potential challenges. The need for capacity building was emphasised. The guideline's inclusion of aspects such as secondary data, data protection, risk-benefit analysis, and researcher qualifications were appreciated. Overall, the guideline was noted to be comprehensive and forward-looking.

The Integrated Guideline

This guideline, presented in Appendix 1, outlines a comprehensive framework for developing research proposals, integrating key elements from traditional proposals and ethical considerations. It includes vital components such as preliminaries, introduction, literature review, methodology, data considerations, ethical aspects, and reporting plans. Specifically, it addresses participant protection, risk-benefit analysis, data management, and adherence to ethical principles. By following this guideline, researchers can ensure their proposals are scientifically sound, ethically responsible, and well-structured.

Discussion

The preliminaries section of a research proposal is crucial for establishing its scientific soundness. A strong title and informative abstract are essential for grabbing attention and showcasing an understanding of the field (Tayie, 2005). A well-formatted proposal with complete preliminaries demonstrates professionalism and attention to detail, which readers and reviewers perceive as a sign of a credible research design. Overall, the preliminaries section lays the groundwork for the proposal's scientific merit by demonstrating an understanding of the field, responsible research practices, and a meticulous approach.

The introduction section of a research proposal is crucial for establishing the context and significance of the study. A well-written introduction should summarise the state of the field and highlight a specific knowledge gap, demonstrating the study's originality and importance (Wright & Michailova, 2023). By clearly defining the problem statement, objectives, hypotheses, and research questions, researchers can establish a clear roadmap for the investigation and ensure a focused and well-directed research approach (Gralla et al., 2016). Justifying the significance of the research by explaining how it aligns with broader goals and its potential benefits solidifies the proposal's scientific merit. Finally, acknowledging limitations and delimitations while defining the scope and assumptions demonstrates transparency and a realistic approach to the research process, ensuring a well-defined research focus (Theofanidis & Fountouki, 2018).

A well-written literature review demonstrates the researcher's ability to critically analyse existing research, identify knowledge gaps, and strategically position their study within the broader scientific context. By outlining the search strategy and conducting a detailed review of the study area, key findings, methodologies, and contrasting viewpoints, researchers can showcase their understanding of the current research landscape and identify areas for further exploration. A well-defined theoretical and conceptual framework strengthens the proposal by clearly understanding the established concepts that inform the study design and the relationships between variables (Wright & Michailova, 2023).

A well-justified research design is essential for a scientifically sound proposal. The chosen design should be appropriate for addressing the research question and demonstrate an understanding of each method's strengths and limitations (Taherdoost, 2022). A detailed plan for integrating quantitative and qualitative data, including participant selection, sampling, data collection, and analysis, is crucial for mixed methods research. Using multiple data sources or methods, triangulation can enhance the research's credibility and ethical soundness by comprehensively understanding the issue under investigation.

The choice of location and study site in primary data collection is crucial for ensuring the data's generalizability and the research's ethical conduct. Explaining the rationale behind the location's choice demonstrates an understanding of the context and strengthens the study's internal validity. Additionally, discussing potential access challenges and addressing ethical considerations related to the chosen location showcases the researcher's ability to plan and anticipate hurdles while maintaining responsible research practices (Denscombe, 2017; Barasa, 2024).

Leveraging secondary data in a research proposal requires careful consideration of its scientific and ethical implications. A well-developed section should justify the use of secondary data, provide details about its source and acquisition, and address issues like generalizability, data usage, and informed consent. This demonstrates a commitment to transparency, ethical conduct, and data quality throughout the research process (Degtiar & Rose, 2023).

A clear data management plan ensures data privacy and confidentiality throughout the study. It demonstrates a commitment to protecting participant information and strengthens the credibility of the research. The plan should detail measures for handling sensitive information, implementing data security safeguards, monitoring data quality and participant well-being, and outlining procedures for data entry, cleaning, storage, archiving, and disposal (Goosen, 2018).

The data analysis section of a research proposal should demonstrate a well-developed plan for extracting meaningful insights. Researchers should clearly outline the procedures and methods for each research objective or hypothesis, ensuring that the analytical techniques match the specific research questions (Thomson & Emery, 2014). Justifying the choice of data analysis software and

providing a detailed analysis plan demonstrates a commitment to responsible data exploration and enhances the research's reproducibility.

A comprehensive risk-benefit analysis is essential for an ethical research proposal. It should outline potential risks for participants, highlight the potential benefits for both participants and society and assess the ethical acceptability of the research. Clear measures to minimise identified risks, such as informed consent procedures and data anonymisation, demonstrate a commitment to participant protection (Membré et al., 2021).

A comprehensive approach to risk identification in a research proposal demonstrates the researcher's ability to anticipate and mitigate potential challenges. This includes considering risks to people, data, equipment, infrastructure, and the environment (Cohen & Palmer, 2004). By expanding the analysis to include benefits beyond participant well-being, researchers can highlight the broader impact of their research on researchers, research assistants, data quality, the environment, and the community at large. Additionally, outlining clear mitigation strategies for all identified risks showcases a proactive approach to minimising potential harms and demonstrates a commitment to responsible research practices.

A well-considered research proposal should include a detailed consideration of professional, legal, and regulatory requirements. Outlining necessary permits, approvals, and agreements demonstrates an understanding of the regulatory landscape and ensures the study is conducted ethically and responsibly. This strengthens the proposal's scientific merit by ensuring its feasibility and reducing the likelihood of delays or disruptions. By addressing specific requirements such as informed consent and data privacy, researchers can demonstrate their commitment to protecting participants and data integrity (Massey et al., 2014).

The team qualifications section of a research proposal should outline the specific credentials, qualifications, and competencies required for the study. By showcasing how the investigators' education, experience, and training align with these requirements, researchers can demonstrate a well-considered plan and a team capable of addressing the research questions and methodological challenges (Levine, 2007). Detailing each team member's specific technical and scientific roles further strengthens the proposal by showcasing a well-coordinated research effort with a clear understanding of the diverse skill sets needed for success.

A well-written research proposal should disclose any potential conflicts of interest to ensure transparency and safeguard the integrity of the research (Buccione et al., 2018). By identifying and managing conflicts, researchers can foster trust with reviewers, minimise bias, and protect participant well-being. This demonstrates a commitment to ethical research practices and strengthens the proposal's credibility.

The dissemination plan section of a research proposal is crucial for demonstrating the broader impact of the research and ensuring its ethical and scientific merit. A well-crafted plan should identify specific target audiences, outline dissemination strategies through peer-reviewed journals or conferences, and consider the potential impact on study participants, researchers, government agencies, and the general public (Grimshaw et al., 2012). By addressing these elements, researchers can showcase the potential for the research to contribute to knowledge advancement, ensure ethical conduct, and maximise the reach and influence of the findings.

Conclusions

A well-structured research proposal is essential for the successful execution of scientific investigations. The preliminaries, introduction, literature review, methodology, data management and analy-

sis, ethical considerations, and professional requirements are crucial components that collectively contribute to the scientific soundness and ethical integrity of the research.

The preliminaries, comprising the title and abstract, provide a concise overview of the research, capturing attention and demonstrating an understanding of the field. The introduction establishes the context, problem statement, objectives, and significance, ensuring the research is well-defined and relevant. A comprehensive literature review demonstrates the researcher's ability to critically analyse existing research, identify knowledge gaps, and position the study within the broader scientific context.

The methodology section outlines the research design, data collection methods, data analysis procedures, and ethical considerations. A well-justified research design ensures that the chosen approach appropriately addresses the research questions. The data management and analysis sections demonstrate a commitment to data integrity, privacy, and ethical handling.

Ethical considerations, including risk-benefit analysis, conflict of interest management, and informed consent, are essential for ensuring participant safety and protecting the integrity of the research. Professional requirements, such as necessary permits, qualifications, and conflict of interest declarations, demonstrate a commitment to responsible research practices. By addressing these key components, researchers can develop scientifically sound and ethically responsible research proposals that lay the groundwork for impactful and credible investigations.

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Appendix I

An Integrated Framework for Scientific and Ethical Review of Research Proposals

This guideline integrates key elements typically found in a research proposal, such as the preliminaries, background, literature, and methodology, with key ethical considerations, such as the protection of participants and risk-benefit analysis.

1. **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.

   i. **Title:** The title should be concise and summarise the study's main ideas in as few words as possible.

   ii. **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 method of disseminating the findings.

   iii. **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.

2. **Introduction**

   The introductory section provides a comprehensive overview of the research proposal.

   i. **Section overview:** Provide a summary of the kind of information the chapter will contain (Word count 200)

   ii. **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.

   iii. Statement of the Problem: The statement of the problem should connect to the background of the study while directly articulating the current situation or context, the specific issue or challenge, the effects or consequences of the problem, the target population or stakeholders affected, the location or setting where the problem exists, the timeframe or duration of the issue, any relevant statistics or data, the importance or significance of the problem, the gap in existing research or knowledge and the purpose of the study or research project.

   iv. **General Objective(s) / Aim(s) / Purpose of the Study:** These mirror the study's title and should also give a clear indication of the output of the study. They should cover the specific objectives in a broad sense.

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

      a) **Qualitative Research -** Provide specific objectives and research questions

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

      c) **Mixed Methods Research -** Provide specific objectives, research questions, and hypotheses. The specific mixed methods design that combines quantitative and qualitative approaches should be clear.

   vi. **Justification/Rationale of the Study:** This section should clearly present the study's rationale and how it fits into global, national, and regional development blueprints.

vii. **Significance of the Study:** This section should clearly outline positive outcomes/gains that will accrue from the study for individuals and/or communities.

viii. **Limitations and delimitations of the Study:** This section should clearly outline potential challenges and weaknesses that may limit the achievement of the study objectives and provide a plan for overcoming them.

ix. **Assumptions of the Study:** This section should present issues or circumstances assumed to be accurate or at least plausible and necessary for achieving the study objectives.

x. **Scope of the Study:** This section should clearly describe how the identified problem will be addressed. Mention the depth of the study in terms of the geographical area, the participants as well as the problem statement

3. **Literature Review**

The literature review critically analyses existing scholarly work on a specific topic. It's essentially an in-depth investigation into what's already known about the research area.

i. **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 in a clear and concise manner

-- the order of the following sections in the literature review may vary from discipline to discipline --

ii. **Empirical review of Literature:** This section should provide in a clear and detailed manner content covering the broad area of the study and the problem; key outcomes of previous research in the area; key research methods or approaches in previous studies; comparisons and contrasts of different points of view, outcome, and approaches in previous research.

iii. **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.

iv. **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.

v. **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.

4. **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. 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.

i. **Research Design:**

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

a) The choice of a research design, depending on the type of research chosen (qualitative, quantitative, or mixed research), should be stated and justified (why it's the most preferred).

b) 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.

ii. **Type of Data:** Two main distinctions are made in this respect: Primary and Secondary / Archival Data

i. **Primary data collection** from natural or legal persons.

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

a) **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.

b) Study Population

1. Describe the study population and the parameter of interest depending on the research design chosen.
2. If a vulnerable population is included, justify why they should be included. For example, they should be included only if it becomes very necessary and all other available options for the study are not forthcoming. The **'Inclusion of Vulnerable Populations form'** must be comprehensively completed. Any untruths regarding their inclusion would result in the rejection of the proposal.

c) Sampling (if applicable)

1. 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.
2. Inclusion and Exclusion Criteria: The criteria that will be used to identify participants are clearly outlined
3. Sampling Method: Describe the approach used to identify a subset of a population from the general population.

d) Census (if applicable)

1. **Inclusion criteria:** Provide the criteria that will be used to identify participants in the census.
2. **Recruitment method:** Outline the process for identifying and/or screening the study participants based on the inclusion and exclusion criteria.

e) **Recruitment Process:** Describe how contact between researchers and prospective participants will be made to inform them of the study.

f) **The Consenting / Assenting Process:** Link to other documents from here, e.g., informed consent form

1. 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.
2. Provide the informed consent/assent form in the proposal appendices.

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

h) **Data Collection Tools and Instruments:** For each tool and/or instrument to be used for data collection, provide the following information;

1. **Type of data collection tool and/or instruments:** Indicate and justify the type of data collection tool and/or instruments.
2. **Variables and Constructs:**
   (a) **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).
   (b) **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 in the study (*related to achieving the study objectives*).
3. **Validity and Reliability**: Provide all the measures that will be taken to ensure the validity and reliability of the tools, instruments, approaches, and/or methods to be used for data collection, e.g., pre-testing, piloting, calibration, settings, or configuration of instruments.

i) **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, and the safety, privacy, and confidentiality of the participants during data collection, including researcher safety.

ii. **Secondary Data**

Secondary, archival, or preexisting 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.

a) **Justification for the use of Secondary Data:** Justify the use of secondary data and why the chosen secondary data set/s

b) **Data Source:** Describe the source of all the preexisting data sets, the usage rights, and conditions for the use e.g., acknowledgements of source and funders

c) **Data Acquisition:** Describe the legitimate process of acquiring the data.

d) **Location of the Study:** Describe the location of the original data collection.

e) **Use of the secondary data set/s**

1. **Study Population:** Describe the study population in the preexisting data and, if applicable, justify the inclusion of vulnerable populations from the preexisting data in the current study.
2. **Sample Size Determination:** Provide the approach used to determine the sample size for the current study from the preexisting data.
3. **Sampling Method:** Describe the sampling technique to select records from the preexisting data.
4. **Variable identification and extraction:** Describe the criteria for selecting the specific variables to be extracted from the preexisting data for use in the current study.
5. **Inclusion and Exclusion Criteria:** Describe the criteria that will be used to identify candidate records from the preexisting data.
6. **Consent:** Provide information on the consent provided by the study subjects in the original data collection and consent for secondary use of the preexisting data.

5. General Considerations

i. **Data Management**

a) **Privacy and Confidentiality:**

Privacy is a multifaceted concept encompassing the right to be free from unauthorised intrusion and the ability to control personal information. 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 preexisting data during its use in the current study.

- If identifier information will be collected or extracted,
- Explain its nature and why it is necessary for the study.
- Explain when and how the data set will be de-identified.

b) **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.

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.

c) **Data Monitoring and Safety Plan**

A data safety and monitoring plan outlines measures to ensure participants' safety and the data's validity and integrity.

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

d) **Data Entry and Cleaning**

Data entry is where raw data is captured and introduced into a digital format. 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.

Provide the procedures for data entry and cleaning.

e) **Data Storage, Archiving, and Disposal:**

Data Storage refers to the methods and technologies used to hold and maintain data for ongoing access and use. 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.

ii. **Data Analysis**

Data analysis involves inspecting, cleaning, transforming, and modelling data to discover useful information, inform conclusions, and support decision-making.

a) Describe and justify the data analysis procedures and methods for each study objective/research question or hypothesis.

b) If a software program will be used in the analysis, describe it and justify the choice.

iii. **Risk-Benefit Analysis**

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

1. **Participant/Subject Risk-Benefit Analysis**
    i. **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.
    ii. **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.
    iii. **Risk-Benefit Analysis Computation:** Assess the risks identified as follows;
        1. **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*).

2. **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*).
3. **Risk-Benefit Ratio -** Compute the overall Risk Benefit Ratio as follows: *Risk Benefit Ratio = Total Risk Score / Total Benefit Score*

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

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

ii. **Overall Risk-Benefit Analysis**

a. **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.

b. **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.

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

1. **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*).
2. **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*).
3. **Risk-Benefit Ratio -** Compute the overall Risk Benefit Ratio as follows: *Risk Benefit Ratio = Total Risk Score / Total Benefit Score.*

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

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

f. **Handling Adverse Events** - Outline measures that will be taken to handle any adverse events arising from the manifestation of the risks identified.

c) **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.

d) **Researcher Credentials, Qualifications & Competencies**

i. 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.

ii. Highlight the specific technical/scientific roles to be played by every team member in the proposed study. The preceding information should be provided in the proposal, and the CVs of all the investigators should be provided for verification.

c) **Conflict of Interest:**

i. Clearly outline 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.

ii. 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.

d) **Reporting and Dissemination:**

i. **Audience:** Provide details on all relevant stakeholders, such as study participants, researchers, government, community, and businesses, to whom the study findings will be disseminated.

ii. **Content:** Provide details on the specific results to be disseminated to each identified target audience.

iii. **Avenues:** Provide details on avenues, forums, or platforms that will be used to disseminate the study's findings.

e) **Ethical Issues** - Comment on how the following ethical principles have been addressed in the proposed study: Respect for persons, Beneficence, Non-maleficence, and Justice

f) **References:** Provide all references cited in the proposal and format them according to discipline-specific requirements.

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

These guidelines have also been published separately as – "Essential Guidelines for Writing Scientifically and Ethically Sound Research Proposals. Moses M. Thiga, Pamela Kimeto, Michael N. Walekhwa, Miriam Muga and Valarie Suge. ISBN 978-9966-26-345-2.