

20  
23

# ROADMAP:

## Harmonization of Governance Strategies for National Research Ethics Committees beyond Health Emergencies



BCA-WA-ETHICS II



BCA-WA-ETHICS II is part of the EDCTP 2 programme, supported by the European Union under grant number CSA2020ERC-3079

# ***Roadmap for the Harmonization of Governance Strategies for National Research Ethics Committees during Health Emergencies and Beyond***

## **Copyright Statement:**

© 2023 University of Zaragoza by BCA-WA-ETHICS II project. This document, Roadmap for the Harmonization of Governance Strategies of National Research Ethics Committees during Health Emergencies and Beyond, is open access and free to use provided appropriate citation is given. All rights reserved.

The BCA-WA-ETHICS II project is a part of the EDCTP-2 Programme supported by the European Union under grant number CSA2020ERC-3079.

This roadmap has been guided and compiled under the stewardship of the main author, ***Farah Nabil***, BCA-WA-ETHICS II project manager at the University of Zaragoza, Spain.

We would also like to extend our deepest gratitude to the following individuals who have made significant contributions to the authorship of this roadmap:

*Ahamani De Olukobi Josias*

*Aminata Suzanne Diop*

*Àngel Gasch Gallén*

*Abib Ndiaye*

*Birama Apho Ly*

*Binet Wewe*

*Flore Armande Gangbo*

*Julie Mahouekpo*

*Lucrèce Zounon Bassa*

*Lasseni Konaté*

*Magloire Okry*

*Maria González Hinjos*

*Mariam Keita*

*Marius Kedote*

*Mercury Shitndo*

*Mohamed Cisse*

*Mohamed Touré*

*Morenike Oluwatoyin Ukpong*

*Oumy Ndiaye*

*Ousmane Diouf*

*Rhanda Adean Adechina*

*Samba Laobé Diatta*

*Sakina Habou*

*Yacouba L. Diallo*

Their expertise and dedication have been instrumental in the creation of this comprehensive roadmap. We appreciate their invaluable inputs and tireless efforts in the pursuit of harmonized governance strategies for National Research Ethics Committees during health emergencies and beyond.

**Proposed Citation:**

Nabil, F., Gasch Gallén, À., González Hinjos, M., Ndiaye, O., Ndiaye, A., Shitindo, M., Keita, M., Mahouekpo, J., Diop, A.S., Gangbo, F.A., Okry, M., Diouf, O., Zounon Bassa, L., Diallo, Y.L., Cisse, M., Touré, M., De Olukobi Josias, A., Konaté, L., Diatta, S.L., Habou, S., Kedote, M., Adean Adechina, R., Wewe, B., Ukpong, M.O., & Ly, B.A. (2023). Roadmap for the Harmonization of Governance Strategies of National Research Ethics Committees during Health Emergencies and Beyond. University of Zaragoza, BCA-WA-ETHICS II project.

# Table of contents

## **I. Introduction**

## **II. Presentation and Summary of Lessons Learned and Best Practices**

## **III. Actions and Strategies**

- a. Autonomy and Financial Independence for NRECs
- b. Strengthening Leadership and Governance Capacity of NRECs
- c. Establishment of Networks with Research Stakeholders and the Health System
- d. Integration of Gender and Sex Dimensions in NRECs Governance and Management
- e. Implementation of Online NREC Management Tools
- f. Implementation of a Quality Management System for NRECs

## **IV. Risk Management and Mitigation**

## **V. Conclusion**

# **I. Introduction**

## **A. Background and Context**

The second phase of the Building Capacity in Bioethics in West Africa (BCA-WA-ETHICS-II) project is a continuation of an initiative to develop the capacity of National Research Ethics Committees (NREC) and affiliated ethicists in West Africa. This regionally significant project is funded by the European & Developing Countries Clinical Trials Partnership (EDCTP) and continues to strengthen capacities for gender mainstreaming in health research ethics.

Amid the COVID-19 pandemic, the project has broadened its scope to encompass general research ethics capacity-building in emergency health situations. This adjustment came from the recognition of the urgent need to reinforce the ethical review process for health research, particularly clinical trials associated with health emergencies. The ultimate goal is to create a harmonized ethical review process across the West African sub-continent, enhancing the quality and equity of healthcare research in the region.

The BCA-WA-ETHICS-II project incorporates various strategic elements, including online training programs on gender mainstreaming, audit preparedness, research ethics, and the AVAREF tools for clinical trial protocol processing. These trainings are designed to fill identified gaps in research ethics capacities, improving the abilities of both the West African National Ethics Committee (WANEC) and West African ethics committee members.

Furthermore, BCA-WA-ETHICS-II seeks to foster effective networking among West African ethics committees, the West African Health Organization, and the World Health Organization. This networking element aims to advance the development of harmonized standard operating procedures and encourage the adoption of the AVAREF Tools for Processing Clinical Trial Applications.

In terms of regulatory support, a significant aspect of the project is evaluating the impact of COVID-19 on the functioning of West African National Research Ethics Committees. This

analysis will support preparations for future health emergencies and promote the integration of AVAREF tools among the National Ethics Committees of Benin, Mali, and Senegal.

Ultimately, the BCA-WA-ETHICS-II project aims to drive forward the harmonization of research ethics governance strategies in the face of health emergencies and beyond. The learnings from this initiative, including its broadened scope in response to COVID-19, form a solid foundation for this roadmap.

## **B. Importance of Harmonizing Research Ethics Governance and NREC Governance in Light of Health Emergencies and Beyond**

The harmonization of research ethics governance and National Research Ethics Committee (NREC) governance in health emergencies is not just advantageous; it is critical for ensuring a prompt, effective, and ethical response in times of crisis. The COVID-19 pandemic has underscored the importance of such harmonization across the West African sub-continent and globally.

### ***1. Ensuring Rapid and Ethical Responses***

Health emergencies require swift decision-making and action. Harmonized governance structures can streamline these processes, reducing the time it takes to initiate crucial research projects, such as clinical trials for new treatments or vaccines. But speed should not compromise ethics; therefore, it is equally important to have agreed-upon standards to ensure research activities respect the principles of autonomy, beneficence, non-maleficence, and justice.

### ***2. Facilitating Cross-Border Collaboration***

In a globalized world, diseases don't recognize borders. A health crisis in one country can quickly spread to others. Therefore, harmonization can facilitate cross-border collaboration in research activities and ethics reviews, encouraging shared understanding and common objectives. This could expedite the ethical review process for multi-country studies, fostering the generation of timely and relevant data to guide the response to health emergencies.

### **3. Promoting Equity in Research and Care**

A harmonized approach can contribute to equity in health research and care. In the absence of harmonized standards, countries with less developed health research infrastructures may face challenges that impede ethical review processes or leave them vulnerable to unethical practices. Harmonization of research ethics governance ensures every country adheres to the same high standards, thereby promoting equity.

### **4. Building Trust in Science and Health Systems**

Harmonization can also play a key role in building public trust in science and health systems. Consistent, transparent, and ethical practices in research governance build confidence in research outcomes and the public health measures they inform. In a health emergency, this trust is critical for public acceptance and adherence to necessary interventions.

### **5. Preparing for Future Health Emergencies**

Health emergencies, like the COVID-19 pandemic, are stark reminders of the importance of preparedness. A harmonized governance structure provides a robust framework that can be quickly activated when a crisis strikes, minimizing the lag time between the identification of a health threat and the initiation of the research needed to combat it.

Overall, the harmonization of research ethics governance and NREC governance is imperative for ensuring the ethical, efficient, and effective response to health emergencies, today and in the future. This roadmap provides a path to achieving this goal, drawing on the lessons learned from the BCA-WA-ETHICS-II project and other initiatives.

## **C. Purpose of the Roadmap**

The primary objective of this roadmap is to provide a clear, comprehensive guide to harmonizing the strategies of governance of NRECs in the context of health emergencies and beyond. Building on the experiences and insights gained from the BCA-WA-ETHICS-II project, this roadmap seeks to:

1. **Guide Harmonization:** Provide a structured, step-by-step approach to facilitate the harmonization of research ethics governance strategies across the West African region, with a particular emphasis on ensuring an efficient and ethically sound response to health emergencies.
2. **Consolidate Best Practices:** Highlight and consolidate the best practices identified during the BCA-WA-ETHICS-II project and other relevant initiatives, offering a repository of actionable, evidence-based strategies for improving research ethics governance.
3. **Strengthen Collaboration:** Foster enhanced cooperation and understanding between different NRECs, research stakeholders, and health organizations, aiding in the creation of a cohesive network that can respond swiftly and effectively to health emergencies.
4. **Enhance Capacities:** Propose strategies for developing the capacities of NRECs and affiliated ethicists, focusing on areas such as gender mainstreaming, audit preparedness, and the ethical review process during health emergencies.
5. **Reduce Gender and Health Inequalities:** Advocate for the implementation of research ethics governance strategies that actively work to diminish gender and health disparities. This includes ensuring that all countries conform to the same high standards and that research participants of all genders and health statuses are treated with respect, dignity, and fairness. The aim is to make health research and care more inclusive and equitable, reflecting the diverse needs and experiences of the population.
6. **Prepare for the Future:** Assist in the preparation for future health emergencies, by providing a robust framework for ethics governance that can be readily activated and adapted in response to various crisis scenarios.

The aim is for this roadmap to serve as a valuable tool for all stakeholders involved in research ethics governance in the West African region, guiding them towards a more harmonized,



effective, and ethically sound approach in the face of health emergencies and in their everyday operations.

#### **D. Overview of the 4<sup>ème</sup> Congrès Scientifique de BCA-WA-ETHICS**

The 4th BCA-WA-ETHICS Congress: The Management of NRECs During Health Emergencies took place from the 25th to the 28th of April, in Benin. Due to its international significance, it was also made accessible virtually. The congress brought together 36 experts in research ethics, quality management, and gender mainstreaming, representing a diverse range of countries, including Benin, Senegal, Niger, Nigeria, Ivory Coast, Mali, Kenya, Switzerland, and Spain.

Throughout the congress, attendees had the opportunity to share experiences, lessons learned, and best practices regarding the management of NRECs during health emergencies.

During the congress, the importance of several key areas was underlined by the participants. These included the need to develop robust strategies to counter misinformation, especially crucial during health emergencies, as it can significantly hinder response efforts. The call for strengthening the ethical evaluation and governance of research during health crises was also emphasised, necessitating comprehensive guidelines, standard operating procedures, and quality management systems. The practical value of online tools like RHInnO Ethics was recognized for enhancing the efficiency and quality of NRECs' work. Participants also highlighted the importance of integrating gender dimensions into the governance and management of research ethics to ensure inclusivity. Moreover, discussions focused on the unique challenges posed by the COVID-19 pandemic, spotlighting how NRECs adapted to continue their essential work during such a health crisis.

The congress concluded with a shared understanding among participants of the urgent need to improve the capacity and preparedness of NRECs in the face of health emergencies. The insights and recommendations gathered from this event provide a foundation for the roadmap we are outlining.

## II. Presentation and Summary of Lessons Learned and Best Practices

### A. Summary of Findings

- ***Session 1: La gestion des comités d'éthique pendant la COVID-19 : leçons apprises***

The management of ethics committees during the COVID-19 pandemic presented unprecedented challenges. Rapidly evolving research and public health situations required the committees to adapt swiftly to effectively oversee and guide ethical considerations. The necessity for clear and timely communication among committee members and with researchers became evident.

- ***Session 2: Expériences de mise en place d'un système de management de la qualité***

Experiences shared about implementing quality management systems in ethics committees stressed the importance of an ongoing commitment to improvement. These systems require well-structured data management, efficient processes, and consistent training to maintain high-quality standards. It was found that such systems play a pivotal role in promoting accountability and performance measurement.

- ***Session 3: Renforcement des capacités de leadership et de gouvernance des Comités d'éthique***

This session emphasized the significance of strong leadership and governance capabilities in ethics committees. The discussion stressed the need for leaders who possess a comprehensive understanding of research ethics, combined with strong decision-making and transparency attributes. The session highlighted that leaders and governance bodies should be well-prepared to handle ethical dilemmas and effectively communicate decisions.

- ***Session 4: Mise en place de réseaux avec les acteurs de la recherche et le système de la santé***

The importance of establishing and maintaining networks with key research stakeholders and health systems was discussed. These relationships promote a more comprehensive approach to ethical oversight, ensuring ethics are embedded throughout research processes and healthcare delivery. They also encourage greater mutual understanding, collaboration, and exchange of expertise.

- ***Session 5: Autonomie et indépendance financière des CNER***

The autonomy and financial independence of NRECs were discussed extensively. Financial independence helps in preventing potential conflicts of interest, ensuring unbiased and uninfluenced ethical decision-making. Various strategies were discussed to ensure financial sustainability and independence, such as establishing funding partnerships, creating endowments, and securing governmental or institutional support.

- ***Session 6: Renforcement d'outils en ligne de gestion des Comités d'éthique***

The session explored the importance of robust online tools for managing Ethics Committees. These tools aid in streamlining operations, promoting effective communication, ensuring comprehensive record-keeping, and maintaining transparency. The participants discussed the benefits and challenges of various tools, highlighting the need for proper training and system maintenance.

- ***Session 7: Intégration des dimensions sexe et genre dans la gouvernance et la gestion de l'éthique de la recherche***

The integration of gender and sex dimensions into the governance and management of research ethics was underscored. This approach ensures that ethical considerations are inclusive and fair. Participants discussed strategies for implementing this integration, emphasizing the importance of ongoing education and awareness in breaking down gender biases in research.

## **B. Key Takeaways from the Congress**

1. **Strong Leadership and Governance:** The critical role of strong leadership and good governance in Ethics Committees was stressed. Leaders must have a comprehensive understanding of research ethics and excellent decision-making skills.
2. **Financial Independence:** The necessity for NRECs to achieve financial independence for unbiased and uninfluenced decisions was emphasized, along with strategies to achieve this goal.
3. **Collaboration:** Building networks with key stakeholders in research and health systems is crucial for comprehensive ethical oversight and collaborative problem-solving.
4. **Adaptability:** The COVID-19 pandemic highlighted the need for ethics committees to be flexible and adaptable in the face of rapidly changing situations.
5. **Online Tools:** Robust online management tools can significantly improve the operations of Ethics Committees, promote effective communication, and maintain transparency.
6. **Consideration of Gender and Sex Dimensions:** Integrating gender and sex dimensions into research ethics governance and management is vital for ensuring fairness and inclusivity.
7. **Quality Management Systems:** The implementation of a quality management system can greatly enhance the performance and accountability of ethics committees in health research.

## **III. Actions and Strategies**

### **A. Autonomy and Financial Independence for NRECs**

#### **I. Lessons Learned from the Congress**

The congress emphasized the necessity of the NRECs attaining financial autonomy and independence. The crucial lesson drawn was the understanding that these bodies must operate as Independent Administrative Authorities (AAI) to ensure integrity, diligence in their functions, and consistency in their decision-making processes.

## **II. Action Plan & Recommendations**

### **Long-Term Vision and Objectives**

The ultimate objective is to make the NRECs financially independent and transform them into Independent Administrative Authorities (AAI). This transformation will fortify the Committees' integrity and diligence in their operations and decisions, ensuring they can operate continuously and efficiently.

### **Key Stakeholders and Their Roles**

The stakeholders and their respective roles are:

- **Ministerial Authority:** Advocate for the Ethics Committee to the supreme authority, emphasizing the Committee's vital role in the health system.
- **President of the Ethics Committee:** Work closely with the Minister of Health to secure a budgetary line for the Committee. Collaborate with a special commission to advocate for partnerships with entities willing to finance research ethics.
- **Permanent Secretariat:** Ensure the regular functioning of the Ethics Committee's activities, and that the budgetary lines are available, mobilized, and allocated to the Committee.
- **Technical and Financial Partners:** Support resource mobilization efforts and contribute to advocacy actions.

### **Timeline and Phases**

- **Short-term (1-11 months) - Mobilization and Initial Planning:** This initial stage is all about building a solid foundation for the project by mobilizing potential partners. These partners could range from other health-focused institutions, NGOs, and even the private sector. Collaboration with these diverse groups will ensure a broader perspective and a more comprehensive approach to health crises. During this phase, the President of the Ethics Committee has a crucial task to perform: submitting a financial action plan to the Minister of Health. This step is vital to securing governmental support and resources for the project. The financial plan should detail the funds required for strengthening leadership and governance capacity and how these funds will be allocated and used effectively. This process will ensure transparency, build trust among stakeholders, and provide a roadmap for the financial management of the project.
- **Medium-term (11-60 months) - Follow-ups, Cooperation, and Resource Mobilization:** In the medium term, the focus is on implementation and building upon the foundation laid in the short-term phase. This phase will include ensuring regular follow-ups with authorities to maintain the visibility of the project and to handle any potential issues in a timely manner. Another key aspect of this phase is to bolster cooperation among the involved parties. Strengthening these relationships will further consolidate the united front required to effectively manage health emergencies. This increased cooperation can be achieved through regular meetings, shared training exercises, and frequent updates on progress. Continuing to mobilize resources during this phase is also critical. The financial viability of the project should be a constant consideration, with fundraising initiatives and potential revenue streams being continuously explored. Importantly, during this phase, the revenue generated from protocol submission fees should be integrated into the operational budget, providing a steady source of funds to support project activities.
- **Long-term (≥ 61 months) - Consolidation and Quality Management:** The long-term phase is focused on consolidating the achievements made and ensuring the project's sustainability. Working with technical and financial partners during this stage is essential

to evaluate the success of the project, identify areas for improvement, and strategize on how to maintain momentum. One of the key tasks during this phase is to establish a quality management system that functions seamlessly. This system should ensure high standards in all activities associated with the NREC and IRBs. A well-functioning quality management system will promote consistency, improve efficiency, and facilitate continuous improvement. In conclusion, this phase is about ensuring the project's longevity and that the benefits brought about by the strengthened leadership and governance capacity continue to make a positive impact on health crisis management in the long run.

### **Key Milestones and Deliverables**

- Legal establishment of the Ethics Committee's status.
- Operational budget for the Ethics Committee.

### **Potential Challenges, Risks, and Mitigation Strategies**

The potential for institutional instability and blockage is a notable risk that could hinder progress. This can be mitigated by proactive advocacy, relationship building with key stakeholders, and strengthening institutional structures and processes.

Human, financial, and logistical resources are required for executing this priority.

The successful execution of the strategy to achieve autonomy and financial independence for NREC hinges on an array of human, financial, and logistical resources.

### **Human Resources**

- **Leadership:** Key individuals, such as the President of the Ethics Committee and the Permanent Secretary, play a critical role in the execution of this strategy. Their leadership, along with the commitment of the Ethics Committee members, is pivotal in driving the initiative forward.

- **Administrative and Operational Staff:** To ensure smooth operations, support staff will be needed for tasks such as budget management, coordination of meetings, and liaising with stakeholders.
- **Experts and Consultants:** Depending on the needs, it may be necessary to hire external consultants or experts in areas such as legal processes (to establish the Ethics Committee as an Independent Administrative Authority), financial planning, and fundraising.

#### **Financial Resources:**

- **Budget Line:** The President of the Ethics Committee should work closely with the Minister of Health to secure a budget line. This budget will serve as the initial funding source to kickstart the operational processes and activities of the Ethics Committee.
- **Protocol Submission Fees:** In the medium-term, revenue from protocol submission fees will be integrated into the operational budget. This will serve as a sustainable source of income to fund the Ethics Committee's activities.
- **Partner Funding:** Advocacy for partnerships with entities willing to finance research ethics will be instrumental in securing additional funds.

#### **Logistical Resources**

- **Communication Tools:** Efficient communication channels are essential for coordinating activities, keeping all parties informed, and fostering strong relationships with stakeholders.



- **Meeting Spaces:** Suitable venues for regular meetings, trainings, and activities are necessary. Depending on the current health conditions, it may also be essential to invest in digital meeting platforms to facilitate remote participation.
- **Legal Documentation:** The process of transforming the NRECs into Independent Administrative Authorities requires legal procedures that will need the preparation and management of multiple legal documents.
- **Operational Equipment:** Computers, printers, and other office equipment will be needed for daily operations. In addition, materials for training sessions, such as projectors and stationery, are necessary.

These resources combined are crucial to meeting the strategic objective of making the NRECs financially independent and transforming them into Independent Administrative Authorities. The accurate estimation, procurement, and management of these resources will be a key factor determining the success of this transformation.

## **B. Strengthening Leadership and Governance Capacity of NREC**

### **I. Lessons Learned from the Congress**

From the congress, it was learned that improving leadership and governance capacity is a key factor in improving the effectiveness of the National Ethics Research Committees (NREC). This includes the ability to manage health emergencies and disaster situations at all levels, and paying attention to Institutional Ethics Committees (IRB). Several aspects of capacity building were identified as priorities:

- Strengthening leadership/governance capacity
- Communication capacity enhancement
- Health crisis and disaster management capacity enhancement
- Capacity building in advanced methods

## **II. Action Plan & Recommendations**

### **Long-Term Vision and Objectives**

The vision is that NRECs will be competent in leadership and management for health crises and disasters, and the IRBs will also be strengthened in these aspects. By 2030, health research ethics committees across the 15 member countries of the ECOWAS (Economic Community of West African States) will have opportunities for leadership and governance capacity building.

### **Key Stakeholders and Their Roles**

The key stakeholders include the National Ethics Committee, Institutional Ethics Committees, researchers and sponsors, communities, political decision-makers, international institutions, civil society, and NGOs. Each stakeholder has specific roles and responsibilities.

### **Timeline and Phases**

- **Short-term (1-11 months) - Mobilization and Foundation Building:** The initial phase of this project is centered on mobilizing potential partners and developing a solid groundwork for the project. The potential partners can be domestic and international bodies, health organizations, non-profit organizations, and even corporations that have an interest in health research ethics. Mobilizing a diverse group of partners will ensure a holistic approach towards managing health emergencies and disasters. At this stage, the President of the Ethics Committee plays a pivotal role by submitting a financial action plan to the Minister of Health. This action plan should provide a comprehensive breakdown of the financial requirements for the project, articulating how these funds will be efficiently allocated to strengthen the leadership and governance capacities of the NREC and IRBs. This step is vital for gaining the support of the government, ensuring the transparency of the process, and setting a clear financial roadmap for the project. In essence, the short-term phase will lay the foundation for the project, establishing the relationships, structures, and financial strategies required for success.

- **Medium-term (11-60 months) - Expansion, Fine-tuning and Resource Mobilization:**  
During the medium term, the emphasis is on follow-ups, cooperation, and the continued mobilization of resources. Regular engagement with authorities is crucial to maintain transparency and deal with any potential issues promptly. Strengthening the collaboration among all involved parties during this phase is essential for consolidating a unified approach to managing health emergencies. Regular meetings, shared training, and frequent updates on progress can help bolster cooperation and facilitate the exchange of ideas and strategies. Resource mobilization remains a key focus during this period. Ongoing fundraising efforts should be maintained, and additional revenue streams explored. The revenues generated from protocol submission fees will be integrated into the operational budget during this phase. This integration will provide a stable source of funds to sustain the various activities of the project and strengthen the NREC and IRBs.
- **Long-term (≥ 61 months) - Consolidation, Quality Management and Sustainability:**  
The long-term phase is all about consolidation and sustainability. Here, the focus is on reviewing and consolidating the achievements made during the project with technical and financial partners. Regular evaluations and assessments are critical during this phase to measure the project's success and identify areas that need improvement. A key goal during this phase is to establish a quality management system. This system should ensure that high standards are maintained in all activities related to the project. It should help promote consistency in operations, improve efficiency, and facilitate continuous improvement in the handling of health emergencies and disasters. The long-term plan is designed to ensure that the capacity of the NRECs and IRBs to manage health crises and disasters effectively is not just improved, but the improvements are sustainable and continue to contribute positively beyond the lifespan of this project. This phase will ensure that the changes brought about by this project become part of the NREC and IRBs' daily operations and culture, ensuring long-term impact and improvement.

## **Human Resources**

These include members of the Ethics Committees who will be extensively trained to efficiently handle health emergencies and disasters. A capable team dedicated to logistical management will also be essential to ensure the smooth operation of the project. Moreover, the motivation of the permanent secretariat, who plays a key role in administrative duties, will be vital for the project's success.

## **Financial Resources:**

- **Training of Ethics Committee members:** The training will be vital in equipping the committee members with the necessary skills and knowledge to lead and govern during health emergencies. This cost will cover trainer fees, materials, venue, and other related expenses.
- **Transport reimbursement:** Given the likely frequent meetings and trainings, a budget to cover transport costs for committee members for each session will be necessary. This will help ensure that all members can attend all relevant activities regardless of their location.
- **Motivation of the permanent secretariat:** Adequate financial motivation for the permanent secretariat is key to maintaining their engagement and commitment to the project.
- **Efficient logistical management:** Logistical management will require funds to ensure the seamless organization of meetings, trainings, and other activities related to the project.

The estimated annual budget for these operations is around 50 million FCFA. However, this estimate could vary based on each Ethics Committee's unique needs and the specific costs that will be incurred in different regions or countries.

## **Logistical Resources**

In addition to human and financial resources, logistical resources are essential for the successful implementation of the project. These resources ensure that the activities related to the strengthening of the leadership and governance capacity of the NRECs are organized and coordinated effectively. Logistical resources include:

- **Training Venues:** Suitable venues for training sessions, meetings, and other gatherings are necessary. These spaces should be conducive to learning and accessible to all participants.
- **Equipment and Materials:** Essential equipment and materials for training sessions, such as projectors, computers, stationery, and instructional materials, should be provided. Furthermore, the necessary software for virtual meetings or trainings should be procured and installed, considering the possibility of remote or hybrid meetings due to potential health emergencies or disasters.
- **Transport and Accommodation:** If necessary, transportation for participants to training locations and accommodation for those travelling from distant locations might be required.
- **Communication Tools:** Efficient tools for communication among stakeholders, such as emails, collaboration platforms, teleconferencing tools, and possibly even physical mail, will be required for seamless information flow.

By integrating these human, financial, and logistical resources, the project will be well-equipped to achieve its objectives of strengthening the leadership and governance capacity of the NRECs and IRBs.

## **C. Establishment of Networks with Research Stakeholders and the Health System**

### **I. Lessons Learned from the Congress**

The congress emphasized the significance of enhancing knowledge and understanding of research ethics among all stakeholders involved in NRECs and IRBs. Recognizing the dynamism and complexity of research ethics, the congress identified areas that require continual learning and development:

- Understanding research ethics principles and application
- Understanding of international and regional ethical guidelines
- Knowledge enhancement about specific ethical issues
- Cultivating a culture of research integrity and ethical conduct

### **II. Action Plan & Recommendations**

#### **Long-Term Vision and Objectives**

The vision is for CNERs and CEIs to have comprehensive knowledge and understanding of research ethics by 2030. This will enhance their capacity to ensure ethical conduct in health research, facilitating their ability to contribute to health improvement across the 15 member countries of the ECOWAS (Economic Community of West African States).

#### **Key Stakeholders and Their Roles**

Stakeholders include National Ethics Committee, Institutional Ethics Committees, researchers, communities, political decision-makers, international institutions, civil society, and NGOs. Each stakeholder plays a vital role in the understanding and promotion of research ethics.

#### **Timeline and Phases:**

- **Short-term (1-11 months) - Awareness and Foundation Building:** The initial phase aims at creating a widespread awareness about research ethics and its principles among the key stakeholders, which includes the NRECs, IRBs, researchers, sponsors,

communities, political decision-makers, international institutions, civil society, and non-governmental organizations. This is achieved through a series of activities like seminars, workshops, and training sessions. These events would be designed to provide an overview of the basic tenets of research ethics, outlining the essential ethical guidelines and principles that should be adhered to in research. At this stage, the NREC plays a crucial role by developing a comprehensive ethical training program that covers the fundamental principles and guidelines of research ethics. The NREC is also responsible for ensuring that all stakeholders understand the importance of ethical considerations in research and are equipped with the necessary tools and information to apply these principles in their respective roles.

- **Medium-term (11-60 months) - Deepening Understanding and Building Capacity:** The focus during this stage shifts to a more in-depth exploration of research ethics. This period is characterized by advanced training programs that delve deeper into ethical issues, looking at complex scenarios and cases that might arise in the course of research. The medium-term phase also involves the dissemination of international and regional ethical guidelines. The objective is to ensure that all stakeholders are aware of and understand these guidelines, and know how to apply them effectively in their work. NRECs play a pivotal role in this phase by curating a repository of these guidelines. This repository will serve as an easily accessible reference point for all stakeholders, providing them with the information they need to adhere to ethical standards in their research activities.
- **Long-term (≥ 61 months) - Consolidation, Evaluation, and Sustenance:** This phase involves the consolidation of all the training and capacity-building initiatives undertaken during the previous stages. The objective is to ensure that all the knowledge and skills acquired by the stakeholders are effectively integrated into their everyday activities. The long-term phase also involves an evaluation of the project's impact. This assessment will help identify the strengths and weaknesses of the initiative, providing valuable insights that can be used to improve future initiatives. The evaluation process should be

rigorous and comprehensive, using both qualitative and quantitative methods to assess the impact of the training programs on the stakeholders' understanding and application of research ethics. The long-term phase also focuses on the sustenance of the knowledge enhancement process. To achieve this, a culture of continuous learning and improvement should be promoted. This can be achieved by establishing annual refresher courses and updates on recent ethical issues, ensuring that all stakeholders remain updated on the latest developments and best practices in research ethics. This approach will ensure that the principles of research ethics continue to be adhered to, even as the field evolves and new ethical challenges arise.

### **Human Resources**

This includes committee members who will undergo training, experts who will facilitate the training programs, and a dedicated team for coordinating and managing the project activities.

### **Financial Resources**

- **Curating and running training programs:** This includes the payment of facilitator fees, provision of training materials, and other related expenses.
- **Creating and maintaining a repository of ethical guidelines:** This would involve costs related to the design, development, and maintenance of an online platform or database.
- **Annual refresher courses and updates:** Funds will be needed to organize these courses and provide updates on recent ethical issues.

The estimated annual budget for these operations is around 35 million FCFA, subject to the unique needs of each Ethics Committee and the specific costs to be incurred.

### **Logistical Resources**



- **Training Venues:** Suitable venues are necessary for hosting training sessions and workshops.
- **Equipment and Materials:** Essential training equipment and materials, like projectors, computers, stationery, and instructional materials, are needed.
- **Communication Tools:** Efficient communication tools for coordination and information dissemination among stakeholders are required.

By leveraging these resources, the project can effectively achieve its objectives of enhancing knowledge and understanding of research ethics among NRECs and IRB members.

## **D. Integration of Gender and Sex Dimensions in NRECs Governance and Management**

### **I. Lessons Learned from the Congress**

The Congress emphasized the critical role of intersectional gender analysis in health research. It highlighted how gender interacts with other axes of inequality, affecting the experiences of various groups, including men, women, and non-binary individuals. The Congress illuminated the importance of integrating intersectionality in research ethics and how it contributes to upholding ethical principles, ensuring just and equitable distribution of research benefits. The call for institutionalizing gender equality plans, conducting regular gender audits, and formulating gender-sensitive Standard Operating Procedures (SOPs) - all with an intersectional lens - was also made clear.

### **II. Action Plan & Recommendations**

## **Long-Term Vision and Objectives**

The long-term vision is to achieve successful integration of intersectional gender and sex dimensions in the governance and management of research ethics across all health research institutions. The objective is to build gender-responsive and intersectionality-informed research ethics committees. These committees will prioritize diversity, equity, and inclusion in their operations, institutionalize gender equality plans, conduct regular gender audits, and operate under gender-sensitive SOPs, all considering the interplay of multiple social categories.

## **Key Stakeholders and Their Roles**

The key stakeholders include the Research Ethics Committees (RECs), researchers, healthcare professionals, government institutions, civil society organizations, media, and international health organizations. Each stakeholder plays a unique role in promoting ethical research that considers intersectionality, creating awareness about health equity issues, supporting inclusive research, and contributing to gender-responsive and intersectionality-informed health research governance.

## **Timeline and Phases**

- **Short-term (1-11 months) - Awareness and Capacity Building:** During this initial phase, it is vital to raise awareness and build capacity on intersectional, gender-responsive research ethics among stakeholders. This can be achieved by conducting a series of awareness-raising seminars and training sessions, targeting research ethics committees, researchers, healthcare professionals, government institutions, civil society organizations, and international health organizations. The aim is to ensure all key players comprehend the importance of intersectionality and gender-responsive approaches in research ethics. Additionally, this phase should see the development of gender-sensitive Standard Operating Procedures (SOPs) to provide clear guidelines on incorporating intersectional gender perspectives in day-to-day research ethics practices. The institutionalization of gender equality plans should also commence, outlining strategies and concrete actions to promote gender equality in all

aspects of research ethics. Gender audits should be initiated to evaluate the current state of gender equality and intersectionality in research ethics.

- **Medium-term (11-60 months) - Deepening Understanding and Expansion:** During this phase, it is recommended to deepen the understanding of intersectional, gender-responsive research ethics among stakeholders and broaden the reach of these principles. This can be accomplished through advanced training sessions, discussions, and workshops focusing on the nuances of intersectionality and gender-responsive approaches in research ethics. Efforts should be made to expand the gender equality measures implemented during the short-term phase. Refining the gender-sensitive SOPs based on feedback and learnings from the initial implementation, advancing the institutionalization of gender equality plans, and conducting regular gender audits should be the core actions. Regular audits would help evaluate the effectiveness of these initiatives and drive future strategy based on data-driven insights, as well as identify gaps and challenges in embedding intersectionality and gender-responsive approaches.
- **Long-term (≥ 61 months) - Consolidation, Evaluation, and Sustainability:** This phase should focus on consolidating the knowledge and practices gained, evaluating the overall impact of the gender equality measures implemented, and ensuring the sustainability of these initiatives. Continuous learning about intersectionality and gender-responsive research ethics should be encouraged. Sustainability of these efforts would rely heavily on regular intersectional gender audits to provide a comprehensive assessment of progress and identify areas for improvement. Insights from these audits would be vital for refining strategies and maintaining the momentum of promoting intersectional, gender-responsive research ethics. In addition, it would be beneficial to reassess and revise gender-sensitive SOPs and gender equality plans, drawing from the lessons learned and experiences gained throughout the project. This constant cycle of learning, evolving, and improving is key to the ultimate goal of integrating intersectional gender and sex dimensions in the governance and management of research ethics.

## **Human Resources**

This includes members of RECs and a dedicated team to manage logistics and other operational aspects of the project. Gender and intersectionality specialists will guide the process of institutionalizing intersectional gender equality.

## **Financial Resources**

- **Training programs:** Costs associated with trainers, venues, materials, and other related costs for training on intersectionality and gender-responsive research ethics.
- **Gender audits:** Costs for conducting regular intersectional gender audits to assess the effectiveness of gender equality measures.
- **Development of gender equality plans and gender-sensitive SOPs:** Resources will be needed for the formulation, implementation, and monitoring of intersectional gender equality plans and SOPs.
- **Project management:** This includes administrative costs, logistics, and salaries for the project management team.

## **Logistical Resources**

- **Training Venues:** Suitable locations for conducting training sessions and meetings.
- **Equipment and Materials:** Essential tools and materials needed for the training sessions, such as projectors, computers, stationery, and software for virtual meetings.
- **Gender Audit Tools:** Necessary tools and frameworks for conducting intersectional gender audits and implementing gender equality plans.

- **Communication Tools:** Efficient tools for communication among stakeholders to ensure seamless information flow.

With these resources, the project aims to effectively integrate intersectional gender and sex dimensions in the governance and management of research ethics.

## **E. Implementation of Online NREC Management Tools**

### **I. Lessons Learned from the Congress**

The 4th BCA-WA-ETHICS underscored the need for reinforcing an online management tool for NRECs. Emphasis was placed on improving the effectiveness, efficiency, transparency, and accessibility of ethics committees. Key takeaways included the importance of adapting to technological and structural changes while ensuring quality ethical and scientific review.

### **II. Action Plan & Recommendations**

#### **Long-Term Vision and Objectives**

The vision centers on adapting the operation of Research Ethics Committees (RECs) to technological and structural changes while ensuring a quality ethical and scientific review that respects principles of transparency and accountability. The primary objectives include enhancing the efficiency of the operation of ethics committees, promoting standardization, and harmonizing the ethics review process.

#### **Key Stakeholders and Their Roles**

- **REC Board:** Responsible for implementing, monitoring, and ensuring quality review.
- **Researchers:** Tasked with appropriating the tool, contributing to the platform, and providing feedback on its manageability.

- **Regulatory authorities:** To manage personal data protection, ensure quality standards, and oversight through the tool.
- **Community:** Expected to access and use information, provide feedback about usefulness and published evidences.
- **Policy makers:** To define policies and utilize evidence and feedback.

### **Timeline and Phases**

- **Short-term (1-11 months) - Awareness and Capacity Building:** This initial phase involves the design of the online management tool, where the functionalities and structure of the system are laid out to accommodate the needs of all stakeholders. Testing then follows to troubleshoot and ensure the system is functional, user-friendly, and meets the requirements of the stakeholders. At this stage, stakeholders' feedback will be integral to fine-tune the system to their needs. The pilot phase commences as the system is introduced to a select group of users, which will enable real-world assessment of the tool's performance and the identification of potential improvements. It's recommended that workshops are organized to enhance computer literacy among ethics committee members and researchers and to provide an understanding of the tool's functionality and benefits.
- **Medium-term (11-60 months) - Deepening Understanding and Expansion:** This phase involves a thorough evaluation of the tool based on feedback from the pilot phase and wider implementation. The evaluation aims to assess the system's effectiveness and efficiency in enhancing the operations of ethics committees, and its transparency and accessibility. A key aspect of this stage is scaling up the project, which entails implementing the system on a broader scale, reaching more stakeholders, and integrating the tool into routine operations of ethics committees. Capacity development efforts should continue, and strategies for managing changes should be

deployed to ensure a smooth transition.

- **Long-term (≥ 61 months) - Consolidation, Evaluation, and Sustainability:** This phase involves consolidating the gains made from the implementation of the online management tool and building on the progress for long-term sustainability. Continuous monitoring will be paramount in this stage, with periodic evaluations carried out to assess the tool's impact on ethics committees' operations. This approach will ensure the identification of areas requiring improvement and the implementation of necessary modifications. Sustainability of the tool can be enhanced by ensuring financial autonomy, continuous training, and updating to accommodate changes in technology and the evolving needs of the ethics committees.

#### **Human Resources:**

- **REC Board:** Responsible for the tool's implementation, monitoring, and quality review.
- **Researchers:** Required to familiarize themselves with the tool, contribute to its enrichment, and provide usability feedback.
- **Regulatory Authorities:** Charged with ensuring the tool's use, managing personal data protection, and maintaining quality standards.
- **IT Team:** Comprising of a software designer and an administrator, they will be crucial for the tool's development and maintenance.
- **Policy Makers:** Their involvement will be key in defining policies and using the tool's evidence and feedback.
- **Training Facilitators:** They will be needed to conduct capacity-building exercises and improve the project stakeholders' understanding and use of the tool.

## **Financial Resources**

- **Development, Testing, and Scaling up of the Online Management Tool:** Funds are required for designing, testing, and expanding a robust online tool, which includes costs related to developers, software, and infrastructure.
- **Training Programs:** Resources must be allocated to provide comprehensive training to enhance computer literacy and guide users on the effective use of the new tool.
- **Periodic Evaluations:** Regular evaluations to measure progress, identify issues, and evaluate the impact of the tool necessitate the allocation of resources for designing and executing these assessments.
- **Continual Maintenance and Improvements:** Provisions for regular tool maintenance, troubleshooting, updates, and improvements based on user feedback and evolving technology are essential.
- **Workshops:** Budgeting for workshops will facilitate knowledge sharing among REC boards and serve as training opportunities for new or struggling users.
- **Communication Initiatives:** Sufficient funding is needed for communication initiatives such as informative flyers, mailing lists, open subscriptions, and regular bulletins.

## **Logistical Resources**

- **Server Infrastructure and Computers:** Stable server infrastructure and adequate computers are needed for the online tool's development, operation, and use.
- **Physical and Virtual Venues:** Venues for conducting training, workshops, and meetings are necessary, including physical locations and virtual platforms.



- **Communication Materials:** Resources are needed for creating and distributing communication materials, like flyers and bulletins, that provide information about the online tool and other initiatives.
- **Technology Tools:** Tools for surveys, feedback collection, progress monitoring, and success measurement, such as online survey platforms and data analytics tools, are essential and must be user-friendly for all stakeholders.

With these resources, the aim is to adapt the functioning of the RECs to technological and structural changes while ensuring the quality of ethical and scientific reviews, upholding principles of transparency and accountability.

## **F. Implementation of a Quality Management System for NRECs**

### **I. Lessons Learned from the Congress**

The 4th BCA-WA-ETHICS highlighted the importance of establishing a robust Quality Management System (QMS). Attention was given to enhance the system's effectiveness, efficiency, transparency, and adaptability to monitor and improve the organization's operations. Notable insights involved the necessity of aligning the QMS to ongoing technological and structural advancements, while maintaining a high standard of operational and process quality.

### **II. Action Plan & Recommendations**

#### **Long-Term Vision and Objectives**

The vision is to establish a quality management system that meets customer needs and expectations and continually enhances the system's effectiveness. The objectives include tracking decision-making and its impacts on activities, driving management engagement, and fostering a collaborative mindset geared toward improved practices.

## **Key Stakeholders and Their Roles**

- **Committees:** Responsible for protecting research participants and ensuring that submitted protocols meet scientific, ethical, and regulatory requirements. They expect the system to function adequately.
- **State Decision-Makers:** They oversee the committees' intervention sectors and ensure adherence to regulations. They expect the system to function correctly.
- **Participants and Community:** Provide accurate information and expect fair treatment and justice in research enrolment.
- **Researchers:** Submit protocols following the current regulations and ensure that research is carried out respecting the committees' recommendations. They expect satisfactory results.
- **Technical and Financial Partners:** They provide technical and financial support to the committees and expect satisfactory outcomes and continuous improvement.

## **Timeline and Phases**

- **Short-term (1-11 months) - Awareness and Capacity Building:** This initial phase is crucial for the successful establishment of a QMS. During this period, strategic and operational objectives are thoroughly defined, laying down the foundation for the QMS. This process entails identifying the system's mission, vision, and values, and specifying the measurable objectives that are aligned with these concepts. Simultaneously, a detailed action plan for the QMS is designed, reflecting monthly, quarterly, and annual tasks as per committee activities. This action plan provides a roadmap, outlining the steps necessary to achieve the system's objectives. It includes tasks such as assigning roles and responsibilities, establishing protocols and procedures, defining quality standards, and setting key performance indicators (KPIs) to measure success. Moreover, during this short-term phase, a critical aspect is initiating training programs for committee members and other stakeholders. These programs aim to enhance their

understanding of the QMS and equip them with the skills necessary for its successful implementation and operation.

- **Medium-term (11-60 months) - Deepening Understanding and Expansion:** The medium-term phase is all about operationalizing the QMS and setting in place systematic monitoring mechanisms. Here, process piloting, performance indicators, internal audits, process reviews, and direction reviews are introduced. Process piloting involves overseeing and guiding the various processes under the QMS, ensuring they align with the system's objectives and comply with the established protocols and procedures. Performance indicators are used to measure the effectiveness and efficiency of the QMS processes, providing data for decision-making and improvements. Regular tracking of these indicators helps to identify any gaps or issues in the system promptly. Internal audits are conducted periodically to assess the functioning of the QMS and verify compliance with the set protocols and procedures. These audits provide an opportunity to uncover any non-compliance issues and determine necessary corrective actions. Process reviews are carried out to evaluate the relevance and effectiveness of the existing processes, facilitating continuous improvement. Similarly, direction reviews are undertaken to scrutinize the strategic direction of the QMS and make adjustments as required.
- **Long-term ( $\geq$  61 months) - Consolidation, Evaluation, and Sustainability:** The long-term phase is geared towards maintaining and enhancing the effectiveness of the QMS through continuous improvement. Surveillance audits are conducted at one and two years to check the system's conformity with the established quality standards and its effectiveness in achieving the set objectives. Following the surveillance audits, a renewal audit is performed to reevaluate the entire QMS and verify its continued relevance and effectiveness. This comprehensive review allows for the identification of areas for further improvement and the planning of necessary modifications. The emphasis during this phase is on learning from the system's performance, making strategic improvements, and fostering an organizational culture of continuous

improvement. This iterative process ensures that the QMS remains adaptable to changing needs and circumstances, thus maintaining its effectiveness and sustainability in the long run.

## **Human Resources**

Trained personnel are essential to the implementation and continuous monitoring of the quality management system. The following roles and their responsibilities are identified as critical:

- **Quality Management Officials:** These are individuals who oversee the entire quality management system, ensuring that it aligns with the organization's strategic goals and meets the established standards.
- **Quality Auditors:** They carry out internal audits to assess the conformity of the system's processes with the defined protocols and identify areas for improvement.
- **Process Owners:** They are responsible for managing specific processes within the system and ensuring their effectiveness and efficiency.
- **Training Facilitators:** Their role is to conduct training programs to enhance the understanding and skills of all involved personnel in quality management.
- **IT Specialists:** They support the implementation and maintenance of the necessary technology tools and infrastructure for the quality management system.

## **Financial Resources**

- **Personnel Training:** A significant portion of the budget should be directed towards training programs to equip personnel with the knowledge and skills necessary for

quality management.

- **IT Equipment:** Funds should be allocated for the purchase and maintenance of required IT equipment. This includes software for process management, data analysis, and report generation.
- **Compensation for Quality Management Officials:** Adequate compensation for quality management officials is necessary to attract and retain competent professionals.
- **Quality Assurance Activities:** This includes funds for internal audits, process reviews, surveillance audits, and corrective actions.
- **System Improvements:** Some resources should be set aside for the continual improvement of the quality management system, such as upgrades to IT equipment and software, process enhancements, and training initiatives.

**Logistical Resources:**

- **IT Equipment:** Computers, servers, software, and other IT equipment that meet the requirements of the quality management approach are necessary.
- **Quality Management Infrastructure:** Dedicated space for the quality management team, including offices and meeting rooms, are needed.
- **Training Venues:** Physical or virtual venues will be required for conducting training sessions and workshops.
- **Documentation Systems:** A system for maintaining documentation related to the quality management system, such as policies, procedures, audit reports, and performance data, is essential.

- **Budget Line:** A dedicated budget line for managing, monitoring, and sustaining the quality approach is critical to ensure proper allocation of financial resources.

With these resources, the objective is to fine-tune the functioning of the Quality Management System (QMS) to align with strategic and operational goals. The focus is on maintaining the highest standards of efficiency and efficacy in the system's processes while upholding the principles of transparency and accountability. Ensuring the system's continual improvement is also a crucial aspect, which supports the organization's adaptability to evolving operational demands and technological advancements.

## IV. Risk Management and Mitigation

Navigating the path to operational and strategic growth in the context of NRECs presents an array of potential risks and challenges. Acknowledging these risks and establishing robust mitigation strategies is essential to achieving the outlined objectives in a smooth and effective manner. The table below enumerates key areas of focus, the potential risks that could be encountered in each of these areas, and practical, specific mitigation strategies designed to address and overcome these potential challenges. The success of the identified strategies relies on the comprehensive understanding and active involvement of all relevant stakeholders, underlining the necessity for collaboration and unified commitment towards the shared vision.

Area	Potential Risks	Mitigation Strategies
<b>Autonomy and Financial Independence for NRECs</b>	1. Insufficient funds limiting operations and innovations	Develop diversified fundraising strategies, including grant writing, corporate sponsorships, and crowdfunding campaigns.

	<p>2. High dependence on external funding sources</p>	<p>Develop an internally driven, sustainable financial model. This may include income-generating activities aligned with the NREC mission and effective financial management practices to minimize costs.</p>
	<p>3. Lack of resources impacting operation and activities</p>	<p>3. Establish a strategic resource allocation plan, prioritizing critical operations and looking for efficiency in processes. Additionally, utilize partnerships and collaborations to share resource burdens where possible.</p>
<p><b>Strengthening Leadership and Governance Capacity of NRECs</b></p>	<p>1. Weak leadership leading to ineffective decision-making</p>	<p>1. Establish leadership development programs focusing on decision-making, strategic planning, and change management.</p>
	<p>2. Poor governance resulting in inefficient operations</p>	<p>2. Implement a robust governance structure with clear roles, responsibilities, and accountability measures. Additionally, periodic governance reviews should be conducted to ensure continuous improvement.</p>
	<p>3. Lack of engagement from</p>	<p>3. Develop engagement strategies such as regular updates, open forums for discussions,</p>

	members and stakeholders	team-building activities, and recognitions for participation and contributions.
<b>Establishment of Networks with Research Stakeholders and the Health System</b>	1. Limited stakeholder engagement inhibiting knowledge exchange and collaboration	Create a stakeholder engagement plan detailing when and how stakeholders should be involved, and what information or input they can provide. This plan should also include strategies to maintain engagement over time.
	2. Inadequate collaboration with the health system	Seek formalized partnerships with health systems and initiate joint projects to demonstrate the benefits of collaboration. Create communication channels between the NRECs and health systems for constant coordination.
	3. Resistance to network establishment due to different priorities or lack of resources	Organize workshops and meetings to highlight the benefits of the network, facilitating open discussions on concerns, and developing joint solutions to resource issues.
<b>Implementation of Online NREC Management Tools</b>	1. Low adaptability to online tools leading to poor utilization	Choose user-friendly online systems with intuitive interfaces and provide comprehensive user guides. Regular user feedback should be taken into account to continuously improve usability.



	<p>2. Inadequate training and support systems</p>	<p>Develop a thorough training program for the online management tools and establish a dedicated technical support team available to assist users. Regular refresher training should be conducted to keep users updated on new features or changes.</p>
	<p>3. Lack of resources to support online tools</p>	<p>Prioritize budget allocation for IT infrastructure and software. Consider cost-effective options like cloud-based solutions. Collaborate with IT partners for possible sponsorships or discounts.</p>
<p><b>Implementation of a Quality Management System for NRECs</b></p>	<p>1. Difficulty in aligning the QMS with the organization's objectives</p>	<p>Conduct workshops with all stakeholders to align the QMS with the strategic objectives of the organization. Regular reviews should be done to ensure alignment over time.</p>
	<p>2. Resistance to the implementation of the QMS due to perceived complexity</p>	<p>Develop a clear communication plan to inform all stakeholders about the benefits and processes of the QMS. Provide adequate training and support during the transition.</p>
	<p>3. Lack of resources for implementing and</p>	<p>Allocate appropriate budget for the QMS implementation, including funds for training, IT equipment,</p>

	maintaining the QMS	quality audits, and continuous improvement. Seek additional funding or resources from external partners if needed.
<b>Integration of Gender and Sex Dimensions in NRECs Governance and Management</b>	1. Lack of gender representation in decision-making	Establish policies that encourage equal representation from all genders in decision-making roles and in the planning and execution of NRECs activities.
	2. Inadequate consideration of gender and sex in policies and processes	Implement gender sensitivity training and integrate gender perspectives in the creation of new policies and review of existing ones.
	3. Resistance to gender mainstreaming due to cultural reasons and conflation with promotion of homosexuality and transgenderism	Undertake a careful, respectful education campaign to explain the true purpose of gender mainstreaming, emphasizing that it is about ensuring equality and fairness rather than promoting specific lifestyles. This can involve workshops, seminars, and informative materials distributed to all members and relevant communities.

## **V. Conclusion**

In summarizing the provided roadmap titled, "Roadmap for the Harmonization of Governance Strategies of National Research Ethics Committees during Health Emergencies and Beyond," the aim has been to address the harmonization of research ethics and governance in response to health emergencies and beyond. The roadmap is a strategic response to the findings and key takeaways from the 4th BCA-WA-ETHICS Scientific Congress, which highlighted the urgency of addressing these issues.

The detailed actions and strategies within this roadmap focus on six main areas: autonomy and financial independence for NRECs, strengthening leadership and governance capacity, establishment of networks with research stakeholders and the health system, integration of gender and sex dimensions in governance and management, implementation of online NREC management tools, and the implementation of a quality management system for NRECs. For each area, we have reviewed the lessons learned from the congress and provided a plan of action and recommendations.

Risk management and mitigation is a critical component of this roadmap, as implementing these changes will come with potential risks and barriers. Detailed mitigation strategies have been outlined to navigate these risks, providing a more secure path towards our objectives.

As we embark on the journey outlined in this roadmap, we also recognize the need for continuous evaluation and adaptation. The roadmap suggests an initial semi-annual review cycle, transitioning to an annual review as the system matures. This approach will ensure the roadmap remains responsive to evolving needs and challenges. The roadmap is not just a guide but a living document, serving as a basis for consistent improvement and adaptation in our collective pursuit of harmonized governance strategies for National Research Ethics Committees, particularly during health emergencies. This continuous evolution will ensure that we can effectively respond to the ever-changing landscape of health emergencies while also ensuring a proactive approach to future challenges and opportunities.