

# Providing a Legal Framework for a National Public Health Institute (NPHI)



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## PREFACE

National Public Health Institutes (NPHIs) are science-based governmental institutions or organizations that promote health by coordinating public health functions and programs to prevent, detect, and respond to public health threats. The importance of NPHIs, their core functions and attributes, and steps for consideration in creating NPHIs are described in the Framework for Development of National Public Health Institutes in Africa, published in 2018 by the Africa Centres for Disease Control.

The Africa CDC is working to establish a new Public Health Order for Africa, in which Member States are empowered to strengthen and protect the public health of their peoples. NPHIs provide the platform to help countries achieve their public health goals.

Creating an NPHI usually involves bringing together functions that previously existed in separate organizational units, sometimes with the addition of functions or units that did not previously exist in the national government. Many NPHIs are largely developed from units within Ministries of Health, which may not have specific legal language that specifies their functions and authorities. Others have their origin in research institutes, some of which are authorized by laws. Regardless of the organizations or parts of organizations that comprise the new NPHI, a legal framework that clearly defines what the NPHI will do and how it will operate is an important step to providing the clarity of mission, governance, leadership, and finance that contribute to success.

Developing a legal framework for an NPHI is not easy. The process requires extensive participation of many parts of government and key stakeholders, and political will and commitment of leadership at the highest levels. Because the legal document that establishes and defines

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the NPHI represents a long-term commitment on the part of government, it requires a vision for the future and the foresight to address current public health needs and those of the future.

Africa CDC and African Union Member States are committed to improving the health of the people of Africa. Having comprehensive NPHIs supported by strong legal foundations is an important aspect of this process.

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## INTRODUCTION

The Framework for Development of National Public Health Institutes in Africa was published by the Africa CDC in 2018. This landmark document describes the importance of national public health institutes (NPHIs) for achieving the vision and mission of the Africa CDC. National public health institutes provide the platform for integrating and coordinating public health functions within countries. Africa CDC is focusing on five strategic pillars that are essential for public health in Africa:

- Surveillance and disease intelligence
- Emergency preparedness and response
- Laboratory systems and networks
- Information systems
- Public health research

NPHIs are essential for ensuring the implementation of these pillars.

Increasingly, countries are recognizing that a legal framework – whether a law, decree, regulation or other binding document or documents – is an important support for the NPHI to conduct its activities effectively and efficiently. The purpose of this document – Providing a Legal Framework for an NPHI – is to describe the types of legal mechanisms countries are using to establish NPHIs or enhance the stature of existing NPHIs and the issues typically addressed. It also describes processes countries have used to place NPHIs on sound legal footing, and some of the typical challenges and facilitating factors encountered. It includes detailed descriptions of content that countries might want to include in their documents and case studies from five countries with varied experiences creating NPHIs by decree, law, or regulation.

## WHAT IS MEANT BY A LEGAL FRAMEWORK?

A legal framework for an NPHI is a document or series of documents, agreed-to by the highest levels of government, that formally establishes a new or existing NPHI. This means that the NPHI has a distinct identity, with such elements as its functions, whether it reports to the Ministry of Health, is governed by a Board, or reports to both, and parameters related to its leadership being clearly defined.

Sometimes, the legal framework is comprised of several documents. For example, there may be a high-level document – such as a decree – that establishes the NPHI and provides an overview of mission, functions, and leadership positions and a statute or other document that defines the overall structure of the institute and provides specific authorities to the NPHI, e.g., to develop sub-national organizational components. These may require approval by the legislature or by the Council of Ministers. There are also internal regulations and other documents that can be approved at the ministerial level.

## POTENTIAL BENEFITS OF PROVIDING A LEGAL FRAMEWORK FOR AN NPHI

Countries develop laws, decrees, regulations, or other legal bases for NPHIs for different reasons. Examples include to create the NPHI as a new organization that exists outside existing organizations such as the Ministry of Health, provide specific authorities to the NPHI, or allow for funding mechanisms and channels that differ from the usual systems.

Some potential benefits of having a legal framework for an NPHI include:

- Provide clarity about the NPHI mission, roles, and responsibilities. Having a legal framework ensures continuity of the NPHI over time.
- Provide specific authorities to the NPHI. Examples include:
  - Working with or coordinating across sectors. For example, some NPHIs are given authority as the International Health Regulations focal point or to coordinate multisectoral leadership groups that include not only leadership for human health, but also agriculture, veterinary, environmental, and other interests.
  - Allowing data collection from sub-national levels and the private sector. Surveillance and investigation of public health problems can be facilitated when the NPHI is explicitly empowered to collect data and other information from all levels of government and from organizations that are not part of government.
  - Providing for special authorities in extenuating circumstances. This includes being able to quarantine or isolate individuals during extraordinary health events if essential for protecting the public's health and to circumvent regular controls on hiring and procurement during emergencies.
- Ensure continuity of leadership when political changes occur. For example, legal documents often describe terms for NPHI Directors and Deputy Directors, which often do not overlap the duration of terms for elected officials.

## POTENTIAL BENEFITS OF PROVIDING A LEGAL FRAMEWORK FOR AN NPHI

- Provide a strong basis for NPHI funding. For example, NPHIs can be authorized to obtain their budgets directly from the Ministry of Finance instead of being part of the Ministry of Health budget request. They may also authorize creation of foundations that can receive private funds to support the mission of the NPHI and allow NPHIs to collect fees for services rendered.



# TOPICS COMMONLY ADDRESSED IN LAWS, DECREES, OR REGULATIONS PROVIDING A LEGAL FRAMEWORK FOR NPHIS

## Domains to consider when developing a legal framework for an NPHI

**I. Establishment** – The legal instrument establishes the NPHI

**II. Functions** – The legal instrument describes the core functions of the NPHI, including authorities needed to achieve them.

**III. Leadership** – The legal instrument establishes the leadership structure of the NPHI.

**IV. Oversight and Advisory Boards** – The legal instrument establishes NPHI oversight and advisory boards.

**V. Accountability and Reporting** – The legal instrument establishes accountability and reporting mechanisms.

**VI. Financial Resources and Their Use** – The legal instrument authorizes funding and addresses certain aspects related to the use of funds.

**VII. Effective Date** – The legal instrument establishes an effective date.

**VIII. Repeal, Amendment, or Transfer of Prior Authorities**

The contents of NPHI legal framework documents and the level of detail will vary by country. At a minimum, most legal documents will include a statement of establishment of the NPHI, a description of the functions, and information about the governance structure. Appendix A describes some of the legal domains and attributes often addressed in the legal documents establishing an NPHI. The domains described in detail in Appendix A are shown in the Box.

Below are examples of topics that have been included in NPHI legal framework documents. Most of these domains are described in Appendix A in more detail.

### • Definitions

Many legal frameworks will include definitions of terms used in the framework.

### • Establishment

This section often includes an overview of the legal document -- topics such as the purpose of the Act, Decree, or Regulation; and, if relevant, establishment of the NPHI as a corporate body (e.g., for parastatal organizations) or as an autonomous government institute. It may include provisions for the NPHI to establish sub-national, e.g., regional centres.

### • Governance of the NPHI and relationship to the Minister of Health

An important issue is whether the NPHI is a line agency, reporting to the Minister of Health, or exists as a parastatal, or has aspects of both. Some issues related to these decisions are discussed in the IANPHI Best Practices Series document: “Legal Mandates and Governance for NPHIs” ([http://www.ianphi.org/\\_includes/documents/Legislation%20BP%20Guidance%20%20.pdf](http://www.ianphi.org/_includes/documents/Legislation%20BP%20Guidance%20%20.pdf)). If the organization has oversight by a Board of Directors,

## TOPICS COMMONLY ADDRESSED IN LAWS, DECREES, OR REGULATIONS PROVIDING A LEGAL FRAMEWORK FOR NPHIS

### **NPHI Core Functions (CFs)**

- CF 1.** Population Health and Health-Related Indicators
- CF 2.** Public Health Laboratory and Surveillance Systems, and Emergency Preparedness and Response
- CF 3.** Disease Prevention and Health Promotion
- CF 4.** Advocacy, Communication and Social Mobilization
- CF 5.** Policies and Plans that Support Individual and Community Health Efforts
- CF 6.** Health Protection and Support for Regulation and Enforcement
- CF 7.** Evaluation and Promotion of Equitable Access to Services
- CF 8.** Public Health Workforce Development
- CF 9.** Evaluation, Prevention, and Control of Public Health Issues in Clinical Settings
- CF 10.** Research in Public Health

the composition and terms of that Board and other aspects related to its functioning are often included in the legal document.

Regardless of NPHI governance, the relationship to the Minister of Health is usually discussed. If the NPHI is a line agency, the Director of the NPHI will usually report to the Minister of Health or a senior Ministry official. If the NPHI is a parastatal organization and reports to a Board of Directors, the Ministry of Health is usually represented among Board members and may chair the Board, and the Minister may be provided certain authorities, for example, to receive NPHI data or reports.

### • **Functions of the NPHI and related authorities**

The NPHI functions are often based on or similar to the Africa CDC NPHI Core Functions, for example, conducting surveillance and public health research. The Core Functions described in the Framework for Development of National Public Health Institutes in Africa, published by the Africa CDC, are shown in the Box.

Many NPHIs have responsibility for public health emergency preparedness and response. The legal document creating the NPHI may include authorization for cross-cutting efforts, such as coordination of multisectoral committees.

Some NPHIs have authorities that are only relevant during extreme emergencies, such as the authority to quarantine or isolate individuals or groups of individuals or to utilize alternative channels for hiring and procurement.

Particularly if the legal framework will move functions from the Ministry of Health or other government organizations into the NPHI, it may be helpful to explicitly state which

## TOPICS COMMONLY ADDRESSED IN LAWS, DECREES, OR REGULATIONS PROVIDING A LEGAL FRAMEWORK FOR NPHIS

functions will be moved and which will be retained elsewhere.

- **Role in relation to subnational levels and private entities**

The legal framework may provide for or specify authorities and limits related to sub-national levels of the public health system or private organizations. For example, NPHIs are sometimes given explicit authority to collect data for surveillance from subnational levels and private health-care providers, and to collect information with personal identifiers as part of outbreak investigations. They may also be allowed to take on responsibilities that are devolved to sub-national levels during major emergencies that could have national or international impacts. NPHIs may be able to enter into contracts or other legally-binding documents, second or receive staff, share facilities, and otherwise collaborate and coordinate with private organizations.

- **Leadership of the NPHI**

Various terms are used to describe the leader of the NPHI, including Director, Director-General, President, and Chief Executive Officer. The legal documents establishing the NPHI often include information about the required competencies of the Director and Deputy Director of the NPHI, how they will be selected, and their terms of service.

- **Oversight and advisory boards, and other bodies supporting the work of the NPHI**

The legal framework may mandate or otherwise authorize certain committees and boards designed to inform and support the work of the NPHI. For example, the framework can call for a scientific advisory board and can provide guidance on membership, functions and activities.

## TOPICS COMMONLY ADDRESSED IN LAWS, DECREES, OR REGULATIONS PROVIDING A LEGAL FRAMEWORK FOR NPHIS

- **Requirements for NPHI reporting and accountability**

Annual reporting may be required, both on activities and on finances including audits.

- **Financial resources**

The legal framework provides clarity on sources of NPHI funding. It usually allows for appropriations from the national budgets and may articulate the process that the NPHI will use to submit its budget, e.g., through the Ministry of Health or working directly through the Ministry of Finance. It may authorize the NPHI to raise funds through providing services, selling publications, or other activities, and may allow for it to accept funds from public or private entities, national or foreign. Sometimes it will allow the creation of a foundation specifically to raise funds that support the NPHI's mission, or partnership with organizations that can raise such funds.

The legal framework may also address issues related to the use of resources. Besides addressing purchase of equipment and supplies, purchase or renovation of property and buildings, and contracting, it may include provisions that provide the NPHI with flexibility related to human resources. This can include payment of salaries, authority to second staff to other organizations or participate in staff exchanges, and authority to provide staff with long-term training opportunities.

- **Date the legal document goes into effect**

The effective or commencement date (i.e., the date the legal document has force of law) will be stipulated and any prerequisites for the legal document to go into effect will be made clear.

## TOPICS COMMONLY ADDRESSED IN LAWS, DECREES, OR REGULATIONS PROVIDING A LEGAL FRAMEWORK FOR NPHIS

- **Legal documents that will be repealed, explicit transfers of functions and resources**

Because NPHIs are often built on pre-existing organizations, there may be existing legislation, rules, or regulations that may not be aligned with the new legal framework. These may need to be repealed or modified. If human, financial, or other resources are to be transferred, the terms for these transfers may be addressed. The legal framework may also explicitly state what functions are being transferred, e.g., from the Ministry of Health, and what functions are remaining in other organizations.

## IDENTIFYING CONFLICTS WITH EXISTING LEGAL DOCUMENTS

An important step in developing a legal framework for an NPHI is to identify existing legal documents that may conflict with the new one. For example, creating an NPHI includes moving functions, staff, property, and other resources from the Ministry of Health or other organizations to the NPHI. If these are assigned by law or decree elsewhere, the NPHI legal framework should include explicit language addressing the change. Another example that may require explicit modification of pre-existing laws or decrees is the authorization for an NPHI that is a line agency in the Ministry of Health to submit its budget directly to the Ministry of Finance.

## CHOICE OF LEGISLATIVE OR EXECUTIVE BRANCH APPROACHES FOR ESTABLISHING NPHIS

Countries have used different approaches to establishing legal bases for their NPHIs. Some, for example, Ethiopia and Mozambique, have used processes that mainly involved the Executive Branch of government, typically requiring approval of a Council of Ministers and the President. Others, such as Liberia, have legislation, passed by the Legislative Branch. Even if the NPHI is established through a law, there may be a need for additional, more detailed regulations and other legal documents, usually created in the Executive Branch, to provide the detail required for the NPHI to function.

Theoretically, a legal framework for the NPHI that passes through the Executive Branch only may be easier to dismantle than one that passes through a legislature. However, creating a legal framework that requires legislative approval may take longer and may be delayed due to political shifts, particularly if the process takes a long time. Both Executive and Legislative Branch approaches have been used successfully in Africa.

## BALANCE BETWEEN DETAIL AND SPECIFICITY

One of the challenges in drafting a legal document establishing an NPHI is developing a document that is specific enough to provide the necessary framework for the NPHI, but not so specific that it will soon become outdated. For example, providing extensive detail about organizational structure may help in estimating costs for the NPHI and clarify how it will function, but as responsibilities are added or additional units created, amendments may be needed. Passage of amendments through the legislature or Council of Ministers is usually time-consuming and can be difficult. Therefore, many countries opt for a more general foundational document, which is supplemented by additional, more detailed documents that are more easily approved and modified. This approach allows the NPHI to adapt as needs change.



## FACILITATING FACTORS AND TYPICAL CHALLENGES IN CREATING A LEGAL FRAMEWORK

Regardless of the legal mechanism used, support from the highest levels of government is essential. Because authorities and other aspects included in legal documents that create or empower an NPHI have implications for the Ministry of Health and other agencies, the support of the Minister of Health and other high-level officials from other Ministries is essential.

Developing a legal framework for an NPHI requires extensive discussion and negotiation, with stakeholder involvement from the earliest stages. This includes stakeholders both in and outside of government. Taking the time to ensure all critical stakeholders have input and that their concerns are heard helps build support for the NPHI. Creating an NPHI may be facilitated by the broad thinking and government-wide consultations that occur during periods of health system or government-wide reform.

Legal documents for NPHIs often consolidate functions that had previously been dispersed among multiple organizations. Accomplishing consolidation with minimal disruption of well-functioning efforts is essential.

Consolidation means that some organizations may need to relinquish control of activities, personnel, and resources. Discussions about what the NPHI will include can be difficult. Having an agreed-to vision and stakeholder support for the NPHI and its potential impact on public health can help resolve some of the initial disagreements.

The importance of high-level leadership and support cannot be overstated. High-level support is essential to ensure decisions are made that keep the vision for public health in mind, rather than the interests of specific individuals or organizations. This is discussed in more detail in the *Framework for Development of National Public Health Institutes*.

## FACILITATING FACTORS AND TYPICAL CHALLENGES IN CREATING A LEGAL FRAMEWORK

Particularly if the legal framework will permit the NPHI to use alternative administrative mechanisms to those used by the Ministry of Health, e.g., using alternatives to hiring through the civil service system, there may be concerns about how expensive the NPHI will be. For example, some parastatal organizations allow for higher salaries and more flexible procurement systems than are available through the Ministry of Health. However, the flexibility and options for funding provided by a parastatal may prove beneficial in the longer term. A business plan can be helpful in facilitating discussion about cost and financial issues. The IANPHI Best Practices Series includes a discussion of “Building a Business Case for NPHI Creation” ([http://www.ianphi.org/\\_includes/documents/Business%20case\\_BP%20](http://www.ianphi.org/_includes/documents/Business%20case_BP%20)).

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**Fig. 1- Domains to consider when developing a legal framework for an NPHI**

**I. Establishment** – The legal instrument establishes the NPHI.

**II. Functions** – The legal instrument describes the core functions of the NPHI, including authorities needed to achieve them.

**III. Leadership** – The legal instrument establishes the leadership structure of the NPHI.

**IV. Oversight and Advisory Boards** – The legal instrument establishes NPHI oversight and advisory boards.

**V. Accountability and Reporting** – The legal instrument establishes accountability and reporting mechanisms.

**VI. Financial Resources and Their Use** – The legal instrument authorizes funding and addresses certain aspects related to the use of funds

**VII. Effective Date** – The legal instrument establishes an effective date.

**VIII. Repeal, Amendment, or Transfer of Prior Authorities**

### APPENDIX A. MENU OF CONSIDERATIONS FOR AN NPHI LEGAL FRAMEWORK

This Appendix describes eight legal domains, or major categories, frequently included in the legal instruments establishing NPHIs. Under seven of these domains are listed attributes – further detail about what might be included in the domains. Note that in some cases the attributes provide options, not all of which will be relevant. For example, attribute 1.2 establishes the NPHI as a parastatal entity, and attribute 1.3 establishes it as a line agency in the Ministry of Health. The NPHI should choose which if any of the options is most appropriate.

This list is not meant to be exhaustive. Which elements are included in an NPHI's legal documents, how they are organized, the order in which they appear, and the exact language used will depend on the NPHI and the country context.

Importantly, the information contained in Appendix A is not intended as a model legal instrument. Examples of the specific language used by existing NPHI creation documents are in the laws, decrees, and regulations in Appendix C and in legal documents found at <http://www.ianphi.org/resources/toolkit/nphilegislation.html>.

Note that many NPHIs have multiple documents that comprise their legal framework. The focus of this Appendix is on a higher-level document, such as might be passed by the national legislature or Council of Ministers. Some issues addressed here and other more detailed content (e.g., related to specific day-to-day operations of the NPHI) are often addressed in documents requiring Ministerial or other lower-level approvals, allowing for easier change as the country's needs or the NPHI itself changes.

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**Fig. 2- Legal domains and attributes for establishment of an NPHI\***

**Domain 1: The legal instrument establishes the NPHI\*\***

- 1.1 – The legal instrument establishes an NPHI
- 1.2 – The legal instrument establishes the NPHI as a parastatal entity
  - 1.2.1 – The legal instrument articulates a reporting structure
  - 1.2.2 – The legal instrument describes functions and operations
    - 1.2.2.1 – The legal instrument describes the scope of duties
    - 1.2.2.2 – The legal instrument includes limitations on authorities
- 1.3 – The legal instrument incorporates or establishes the NPHI within the existing Ministry of Health organization
  - 1.3.1 – The legal instrument articulates a reporting structure
  - 1.3.2 – The legal instrument describes functions and operations
    - 1.3.2.1 – The legal instrument describes the scope of duties
    - 1.3.2.2 – The legal instrument includes limitations on authorities

\* **Legal domains** correspond to the major areas of law

\*\* **Attributes** provide more detail about what could be covered in the legal instrument

## DEFINITIONS

Legal frameworks establishing NPHIs often include definitions to clarify the meaning of terms included in the legal instrument. This section provides the accepted definitions for terminology used throughout the legal instrument, including terms that do not have a standardly accepted meaning. If a term is used anywhere in the legal instrument, it should be used consistently throughout.

### I. Establishment

In some legal documents, an early statement establishes the NPHI. Usually the legal framework will define the NPHI as a line agency, reporting to the Minister of Health; a parastatal entity; or an organization that has aspects of both. This may come at the beginning of the legal document, as part of the establishment of the NPHI, or later. Some issues related to governance of NPHIs are discussed in the IANPHI Best Practices Series document: “Legal Mandates and Governance for NPHIs” ([http://www.ianphi.org/\\_includes/documents/Legislation%20BP%20Guidance%20%20.pdf](http://www.ianphi.org/_includes/documents/Legislation%20BP%20Guidance%20%20.pdf)).

### II. Functions

Functions commonly addressed in creating a legal framework for an NPHI include public health research, surveillance, laboratory services, public health emergency management, and use of evidence to formulate policy recommendations. These are usually consistent with the functions described in detail in the Framework for Development of National Public Health Institutes in Africa, published in 2018 by the Africa CDC. Sometimes, NPHI establishment documents provide extensive detail about the NPHI’s functions. For example, a document might include over ten statements related to the role of the NPHI in laboratory-related efforts. Other times, for example, if the

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role of the NPHI is expected to expand substantially or a transition period to full NPHI functioning is expected, the functions are left more general, so that amendments will not be needed. Some broad legal considerations related to the function of an NPHI include:

1. Breadth of topics and functions covered by the NPHI.

Many NPHIs in Africa begin with a focus on communicable diseases. However, they often are expanding to address non-communicable diseases, injury, and violence. In addition, NPHIs often have responsibilities related to certain common functions like surveillance, research, laboratory, and public health emergency management, among others.

2. Authority to collect, protect, and share data, specimens, and other information.

The ability of NPHIs to collect data and specimens from subnational levels and private-sector entities, e.g., for surveillance, is often facilitated by having legal authority to do so. Language may also be included about requirements, restrictions, and protections related to human subjects and restrictions or requirements for protection or sharing of information or specimens. The legal instrument may also include restrictions on specific kinds of data, and additional requirements for data security and data sharing. It may include language about ownership of intellectual property generated by work conducted within the NPHI or supported using NPHI resources.

3. Authority to lead multi-sectoral efforts.

Many NPHIs have responsibility for public health emergency preparedness and response and have authorizing language allowing them to develop interagency committees, conduct exercises, and do other cross-cutting activities to reduce the impact of emergencies.

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**Fig. 3- Legal domain and attributes related to the functions of an NPHI**

**Domain 2: The legal instrument describes the core functions of the NPHI**

**2.1** – The legal instrument designates administrative roles and functions

**2.1.1** – The legal instrument includes authority to manage funds or distribute funds to others

**2.1.2** – The legal instrument grants rule making or regulatory authority to the NPHI

**2.2** – The legal instrument designates roles and functions for laboratory systems

**2.2.1** – The legal instrument establishes a public health laboratory or laboratory network

**2.2.1.1** – The legal instrument describes diagnostic testing capacity at national, regional, district, or community levels

**2.2.1.2** – The legal instrument describes collection of laboratory data

**2.2.1.2.1** – The legal instrument includes data sharing requirements

**2.2.1.3** – The legal instrument allows for specimen collection

**2.2.1.3.1** – The legal instrument includes provisions for regulation of specimen collection

**2.2.1.3.2** – The legal instrument includes provisions for regulation of specimen transport

**2.2.1.3.3** – The legal instrument includes provisions for regulation of specimen storage

**2.3** – The legal instrument designates roles and functions for surveillance systems

4. Use of data to guide policy. Although responsibility for policymaking tends to remain with the Minister of Health, the NPHI is often stated to have a role in conducting and financing research, synthesizing information for policy purposes and recommending evidence-based policies to the Minister.

5. Laboratories. If the NPHI has a central or national laboratory, the functions of that laboratory may be articulated. These may include providing reference or specialty laboratory services, managing a national laboratory network, and supporting laboratory quality throughout the country.

6. Special authorities during public health emergencies.

Many NPHIs have authorities that are only relevant during extreme emergencies, such as the authority to quarantine or isolate individuals or groups of individuals or to utilize alternative channels for hiring, procurement, or regional collaboration. Sometimes, being able to act on these authorities requires development of criteria for action and concurrence by the Ministry of Health.

### III. Leadership and Control

The legal document usually indicates the title for the leader of the NPHI. Typical titles are Director, Director-General, President, and Chief Executive Officer, but may vary depending on structure. In some cases, processes for appointment and qualifications may be specified down to the level of Department Directors or may identify specific positions (e.g., EOC Director). The IANPHI “Best Practices Series: Recruiting an NPHI Director” describes some considerations regarding duties and qualifications of an NPHI Director ([http://www.ianphi.org/\\_includes/documents/Director%20BP%20Guidance%20.pdf](http://www.ianphi.org/_includes/documents/Director%20BP%20Guidance%20.pdf)). Specific considerations include:

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**2.3.1** – The legal instrument permits activities for the prevention and control of infectious diseases

**2.3.1.1** – The legal instrument permits data collection on infectious diseases

**2.3.1.2** – The legal instrument includes provisions for data privacy and security

**2.3.1.3** – The legal instrument includes diagnostic capacity for detection and identification of infectious diseases

**2.3.1.4** – The legal instrument allows for systematic, ongoing collection of data for public health purposes

**2.3.1.5** – The legal instrument includes provisions for mandatory reporting within the country

**2.3.1.6** – The legal instrument includes provisions for international reporting

**2.3.2** – The legal instrument permits activities for prevention and control of non-communicable diseases

**2.3.2.1** – The legal instrument permits data collection on non-communicable diseases

**2.3.2.2** – The legal instrument includes diagnostic capacity for detection and identification of non-communicable diseases

**2.3.2.3** – The legal instrument allows for systematic, ongoing collection of data for public health purposes

**2.3.2.4** – The legal instrument includes provisions for the development of health indicators

**2.3.2.5** – The legal instrument includes provisions for reporting within the country

**2.4** – The legal instrument permits activities for epidemiologic investigation

1. Qualifications of the NPHI leadership. The legal framework often includes information about the required competencies of the Director, Deputy Director, and potentially other positions of the NPHI. This usually includes requirements related to education, public health practice, and management experience. If included in the document, requirements should strike a balance ensuring the candidate has the experience and skills to lead the NPHI while being broad enough to allow for the recruitment of diverse candidates.
2. Selection and approval process. The legal framework describes how the Director, and other senior positions will be selected, including who will make the appointment (e.g., the President, on the recommendation of the Board of Directors).
3. Tenure. When director and deputy terms of service are specified (often as four- or five-year, renewable terms), the stability of the NPHI is increased, as leadership and direction are less subject to political considerations, which is important for a science-based organization like an NPHI.
4. Removal from office. Clarifying what constitutes grounds for removing an NPHI Director and the process for doing so, including who makes the final decision, also contributes to reducing the risk of politicizing this position.

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**2.5** – The legal instrument permits activities for a public health emergency response function within the NPHI

**2.5.1** – The legal instrument allows for emergency preparedness activities

**2.5.1.1** – The legal instrument authorizes the development of public health response plans and/or procedures

**2.5.1.2** – The legal instrument authorizes establishment of an Incident command structure for public health emergencies

**2.5.1.3** – The legal instrument authorizes public health emergency response training

**2.5.2** – The legal instrument makes provisions for public health surveillance during times of emergencies

**2.5.3** – The legal instrument provides for coordination and communication between and among sectors during public health emergencies

**2.5.3.1** – The legal instrument includes provisions related to multi-sectoral communication

**2.5.3.2** – The legal instrument designation of a focal point for communication

**2.5.4** – The legal instrument describes certain powers related to public health emergency response

**2.5.4.1** – The legal instrument makes provision for the declaration of a public health emergency

**2.5.4.2** – The legal instrument establishes procedures to enable quarantine of individuals or infectious agents during times of emergency

**2.5.4.3** – The legal instrument establishes procedures to enable isolation of individuals or infectious agents during times of emergency

**2.6** – The legal instrument designated roles and functions for disease prevention

### IV. Oversight and Advisory Boards

Legal frameworks for National Public Health Institutes, particularly those that are parastatal entities, may include provisions for oversight by a Board of Directors. In addition, NPHIs may also be required to establish boards with specific regulatory, oversight, or advisory functions. In these cases, other matters related to the authorization, selection of members, and aspects related to the operation and business of a Board of Directors or other regulatory, oversight, or advisory boards may be included. An institutional review board is an example of a board with an oversight and regulatory function. Advisory boards without regulatory or oversight functions, such as scientific advisory boards, may also be established to provide advice, but they do not have responsibilities related to governance. Legal considerations related to establishment of boards can include:

1. **The composition of the board.** Legal guidelines pertaining to the composition of the board may speak to the relationship to and participation by high-level leadership from the Ministry of Health as well as other governmental entities. There may be requirements to include board members from academia or other sectors as well as provisions for non-voting or “ex-officio” member designation and participation.
2. **A process for member selection.** The legal framework may stipulate certain processes or requirements for the selection of oversight or advisory board members, or it may designate authority to others to develop and/or oversee processes for the selection of board members.
3. **Tenure of members.** The legal framework may stipulate terms of service. In practice, terms of service may be staggered, and such practice could be reflected in the legal document.



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and health promotion

**2.6.1** – The legal instrument authorizes behavioral health and communication activities

**2.6.2** – The legal instrument requires policy development for health promotion and for the prevention and control of disease

**2.6.3** – The legal instrument specifies creation of a health promotion function

**2.7** – The legal instrument designates the roles of and functions for workforce development

**2.7.1** – The legal instrument requires identification of public health workforce needs

**2.7.2** – The legal instrument authorizes public health workforce training activities

**2.7.3** – The legal instrument describes other workforce capacity building activities

**2.8** – The legal instrument establishes roles and functions for public health research and development

**2.8.1** – The legal instrument authorizes public health research activities

**2.8.2** – The legal instrument authorizes public health monitoring and evaluation activities

**Fig. 4 – Legal domain and attributes related to leadership and control of an NPHI**

**Domain 3: The legal instrument establishes the leadership structure of the NPHI**

**3.1** – The legal instrument establishes the role of NPHI Director

**3.1.1** – The legal instrument describes processes for appointment, resignation, or removal or addresses tenure

4. The role of boards. In authorizing boards or similar entities, the legal framework may specify the role in oversight, governance, or advisory functions. Governance boards may also have authority to review or approval of budgets or budget proposals, have broad or specific functions to promulgate regulations, and may have responsibilities for ensuring safe and ethical conduct in the operationalization of key public health activities such as research.

5. Issues related to functioning. A legal framework may address issues including periodicity of board meetings, whether allowance or payments to board members are permitted, requirements for recordkeeping, how board decisions are to be made, and what constitutes a quorum.

## V. Accountability and Reporting

Whether reporting to a Minister or a Board or both, the NPHI generally will be responsible for reporting on topics such as its activities, future plans, and finances, typically on an annual basis. Many NPHIs are subject to annual auditing, and some are required to make certain information publicly available.

## VI. Financial Resources and Their Use

NPHI legal frameworks can authorize funding, set parameters for the use of funds, and establish certain budgeting and managing practices. The framework may also include parameters for the use of funds for hiring of staff, staff transfers, and secondments. Broad legal considerations include:

1. Allowable sources of funding. Legal frameworks can authorize funding, either from the state's budget, through the ability to raise funds from other sources or through

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**3.1.2** – The legal instrument describes the role, duty, and authority of the Director

**3.1.2.1** – The legal instrument describes limitations on authority of the Director

**3.1.3** – The legal instrument establishes professional qualifications or other competencies for the NPHI Director

**3.2** – The legal instrument establishes the role of NPHI Deputy Director

**3.2.1** – The legal instrument describes processes for appointment, resignation, or removal or addresses tenure

**3.2.2** – The legal instrument describes the role, duty, and authority of the Deputy Director

**3.2.2.1** – The legal instrument describes limitations on authority

**3.2.3** – The legal instrument establishes professional qualifications or other competencies for the NPHI Deputy Director

**3.3** – The legal instrument establishes the role of technical or administrative department leads— Details would depend on the way the NPHI is organized.

**3.3.1** – The legal instrument establishes the position of Director for each of the Departments of the NPHI

**3.3.1.1** – The legal instrument describes processes for appointment, resignation, or removal or addresses tenure

**3.3.1.2** – The legal instrument describes the role, duty, and authority of the Director

**3.3.1.2.1** – The legal instrument describes limitations on authority of the Director

**3.3.1.3** – The legal instrument establishes professional qualifications or other competencies for this position

both. Appropriations from the state's budget may be authorized up to a certain amount, or for a certain period of years. The ability to raise funds through other sources, such as through the collection of fees or through the receipt of gifts may also have similar time or resource limits.

2. Who can provide funding. Explicit language may be included that allows the NPHI to accept funds from public or private entities (e.g., development assistance and gifts). Language may also be included to determine whether funds can be accepted from foreign institutions or organizations.
3. Budget submission and approval process. The legal framework may describe how proposed budgets are to be submitted and approved, e.g., through the Ministry of Health or working directly through the Ministry of Finance.
4. Bank accounts. The NPHI may be required to keep its funds in the national bank or may be given the flexibility to use any reputable bank. The legal framework may specify that the NPHI can keep and use its interest income.
5. Use of funds. The legal framework may describe how funds can be used. For instance, specific language may be seen authorizing use of funds for purchasing supplies and equipment; paying staff salaries and other benefits; supporting staff secondment and transfers; purchasing, leasing, selling and/or renovating facilities; entering into contracts; and making awards to recipients; among others.

### VII. Effective Date

Depending on the country's processes for formalizing legal documents, language may be included about processes required prior to the legal framework entering into effect, for example, publication in a specific national government

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**Fig. 5 – Legal domain and attributes related to oversight and advisory boards**

**Domain 4: The legal instrument establishes NPHI oversight or advisory boards**

**4.1 – The legal instrument establishes a board of directors**

**4.1.1 – The legal instrument articulates a role or purpose for the board**

**4.1.1.1 – The legal instrument designates oversight functions**

**4.1.1.1.1 – The legal instrument provides the board with authority to approve budgets or budget proposals**

**4.1.1.1.2 – The legal instrument provides powers to the board related to NPHI leadership positions**

**4.1.2 – The legal instrument sets guidelines for the composition of boards**

**4.1.2.1 – The legal instrument identifies sectors for mandated representation on the board**

**4.1.2.2 – Representation from various Ministries, e.g., Ministry of Agriculture or Education, is mandated**

**4.1.2.3 – Representation from law enforcement is mandated**

**4.1.2.4 – Representation from the academic sector is mandated**

**4.1.2.5 – Representation from the private sector and/or civil society is mandated**

**4.1.3 – The legal instrument stipulates how the board’s membership is determined**

**4.1.3.1 – The legal instrument describes how board members are to be selected or designates authority for determining**

document. In addition, the authorization may be indefinite or for a certain number of years.

### VIII. Repeal, Amendment, or Transfer of Prior Authorities

Because NPHIs are often built on pre-existing organizations, there may be legislation, rules, or regulations that conflict with the new legal framework. These may need to be repealed or modified. Language included in the legal framework can cover such issues as:

1. Transfer of rights, obligations, and resources from a pre-existing organization. For example, staff being transferred from a pre-existing organization may be required to sign employment contracts with the NPHI and complete orientations or training required by the new organization.
2. Repeal of provisions from previous legal documents. If specific authorities provided to the NPHI were explicitly part of the legal mandate of another organization, changes must be made to harmonize the previous legal mandate with that of the NPHI. If the NPHI is being created as a parastatal and employees will not be under civil service, language should be included that makes this change explicit.

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nomination and selection of members to an entity

**4.1.3.2** – The legal instrument sets board member tenure

**4.1.4** – The legal instrument establishes parameters for the board operation and conduct of business

**4.1.4.1** – The legal instrument establishes Board convening periodicity

**4.1.4.2** – The legal instrument recognizes or creates requirements related to decision making, recording keeping, or public engagement

**4.2** – The legal instrument enables other boards or bodies (e.g., institutional review boards, scientific advisory boards, etc.)

**4.2.1** – The legal instrument specifies the function of other boards

**4.2.1.1** – The legal instrument grants oversight functions

**4.2.1.2** – The legal instrument grants advisory functions

**4.2.2** – The legal instrument makes provisions related to the makeup of the board and/or the selection and tenure of its members

**4.2.3** – The legal instrument makes provisions related to the conduct of business of other boards or bodies

### Fig. 6 – Legal domain and attributes for accountability reporting

#### Domain 5: The legal instrument establishes reporting mechanisms

**5.1** – The legal instrument establishes reporting mechanisms

**5.1.1** – The legal instrument requires reporting on a regular recurring basis

**5.1.1.1** – The legal instrument requires annual reporting

**5.1.2** – The legal instrument specifies content that is to be reported

**5.1.2.1** – The legal instrument requires regular updates from departments or from programs

**5.1.2.2** – The legal instrument requires reporting of financial expenditures

**5.1.2.3** – The legal instrument requires reporting of significant research findings

**5.1.2.4** – The legal instrument mandates reporting of population-level health data

**5.1.2.5** – The legal instrument mandates development of and reporting on health indicators

### Fig. 7 – Legal domain and attributes for authorization of resources (financial and human)

#### Domain 6: The legal instrument authorizes resources

**6.1** – The legal instrument authorizes funding for NPHI activities

**6.1.1** – The legal instrument establishes an authorized funding ceiling (maximum amount)

**6.1.2** – Funding authorizations are time bound

**6.1.3** – The legal instrument specifies financial data that are to be reported

**6.2** – The legal instrument designates allowable sources of funding

**6.2.1** – The legal instrument authorizes appropriations from the state's budget

**6.2.2** – The legal instrument authorizes the receipt of gifts

**6.2.2.1** – The legal instrument designates prohibited sources of gift funds

**6.2.3** – The legal instrument

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establishes a mechanism or mechanisms for the collection of fees

**6.2.4** – The legal instrument authorizes receipt of development aid or awards from foreign entities

**6.3** – The legal instrument allows for collection and use of income earned from interest

**6.4** – The legal instrument establishes certain financial management requirements

**6.4.1** – The legal instrument establishes financial accounting requirements

**6.4.2** – The legal instrument requires use of certain banks

**6.5** – The legal instrument sets parameters for budget development and submission

**6.6** – The legal instrument authorizes how funds can be used

**6.6.1** – The legal instrument allows for funds to be used to purchase equipment and supplies

**6.6.2** – The legal instrument allows for funds to be used to purchase commodities

**6.6.3** – The legal instrument allows for funds to be used to pay salaries and/or other benefits

**6.6.3.1** – The legal instrument allows for funds to be used to cover transfer of staff

**6.6.3.2** – The legal instrument allows for funds to be used to hire new staff

**6.6.3.3** – The legal instrument allows for use of funds to cover costs associated with seconded staff

**6.6.4** – The legal instrument allows for funds to be used to lease, purchase or renovate real property

**6.6.5** – The legal instrument allows the NPHI to enter into contracts

**6.6.6** – The legal instrument allows the

NPHI to make financial awards to other parties

**6.7** – The legal instrument contains restrictions on the use of funds

### Fig. 8 – Legal domain and attributes related to the effective date and period of authorization

#### Domain 7: The legal instrument establishes an effective date

**7.1** – The legal instrument states when the authorizations contained within it goes into effect

**7.1.1** – The legal instrument states a specific date

**7.1.2** – The legal instrument links the effective date to an action (e.g. 180 days after enactment)

**7.2** – The legal instrument sets an expiration date for authorities contained therein

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### APPENDIX B. STEPS FOR CREATING A LEGAL FRAMEWORK FOR AN NPHI

To develop and gain approval of a sound legal framework for an NPHI requires a thoughtful process and considerable investment of time and technical resources. If the legal framework is being crafted at the same time the NPHI is being created, the steps listed in Appendix C of the Africa CDC’s document “Framework for Development of National Public Health Agencies in Africa” are also an important reference.

Creating a legal framework for an NPHI requires support at the highest levels in order to ensure that resources are available to develop drafts and hold needed meetings, to gain support from stakeholders, and to shepherd the needed documents through the process required for high-level government approval. Typically, the commitment of the Minister of Health and often the President are critical to successfully completing the legal framework.

The process for creating a legal framework for an NPHI is often iterative, providing repeated opportunities for input and modification. The following provides an outline of some of the steps that may help to ensure a successful outcome, that is, a well-crafted, widely accepted legal framework for the NPHI. Some of these steps are one-time activities; others will need to be repeated or implemented continuously. The timing and sequencing of steps will vary by country.

#### Identify leadership and staff support for developing the legal framework

A senior person or group of people who have the respect of key participants and technical and managerial skills should be identified to lead establishment of the legal

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framework. This person will help maintain the momentum to complete the process, ensure a quality document is created, and build support from stakeholders in and outside of government. Besides the person who will lead the effort, assistance is likely to be needed from a range of people with different skills and experiences.

### **Develop a plan for establishing the legal framework**

Part of the initial planning process for establishing the legal framework for an NPHI should include laying out the critical steps (many of which are described below) and actions, including a timeline and identification of who will be responsible for each activity. Such a plan can be used for communications purposes, to measure progress, and to ensure critical steps aren't left out.

An early activity in the planning is researching the required legal process, including approvals needed, supporting documentation, and the sequence and expected timing for obtaining the required approvals. Existing laws that may be relevant to the legal framework must be identified to ensure that any potential conflicts are identified and taken into consideration.

As progress is made towards creating and gaining support for the legal framework, the plans, timelines, and responsible individuals may need to be updated.

### **Involve stakeholders early and often**

This step includes mapping of key stakeholders whose cooperation and support will be important to developing and gaining approval of the legal framework. Stakeholders include both individuals inside the Ministry of Health and

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other parts of government that will be impacted by legal establishment of the NPHI, as well as outside partners and other organizations. Involvement of influential partners such as the WHO may be helpful.

Stakeholder engagement is an ongoing process and should include communication and coordination to increase awareness of and support for the legal framework. Plans for regularly communicating about changes that will be happening, learning from the perspectives and experiences of others, and incorporating stakeholder ideas and concerns are important.

### **Determine the preferred NPHI governance structure**

An important issue is whether the NPHI is a line agency, reporting to the Minister of Health, or exists as a parastatal, or has aspects of both. Some issues related to these decisions are discussed in the IANPHI Best Practices Series document: “Legal Mandates and Governance for NPHIs” ([http://www.ianphi.org/\\_includes/documents/Legislation%20BP%20Guidance%20%20.pdf](http://www.ianphi.org/_includes/documents/Legislation%20BP%20Guidance%20%20.pdf)).

If the organization has oversight from a Board of Directors, the composition and terms of that Board and other aspects related to its functioning are often included in the legal document. In some cases, the NPHI is established as a line agency, since sometimes that can be done more quickly; in some countries, an NPHI is first established as a line agency while a legal framework creating a parastatal organization is being developed.



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### **Clarify the approval mechanism for establishing the legal framework**

The appropriate legal authority (or legal authorities) for establishing the legal framework is different in different countries, and also may differ based on whether or not the NPHI will be a line agency in the Ministry of Health. In some cases, the legal framework for the NPHI will be established through legislation, in some cases through executive order, and in some cases through some kind of administrative rulemaking or regulation. Where there are options for establishing the legal framework, factors such as speed, flexibility, and long-term stability may support one approach over another.

### **Identify legal documents that will need to be revoked or changed when the NPHI is established**

It is important to assess whether existing legislation, decrees, rules, regulations, etc. potentially overlap or conflict with the proposed legal framework. For example, if the functions being assigned to the NPHI are currently legally assigned to the Ministry of Health, the relevant existing legal frameworks need to be modified. If the NPHI is being given new responsibilities related to One Health or International Health Regulations, legal documents in the departments that address issues related to animal health, agriculture, or environmental health will need to be reviewed and perhaps modified.

If people, property, and material goods that are currently assigned to one organization are to be transferred, this may need to be addressed formally. If NPHIs are responsible for outbreak and emergency response, government rules related to confidentiality of information about individuals (e.g., patient records) and sharing of specimens, including

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internationally, may also need to be assessed. Existing legal documents may also need to be changed to ensure the NPHI can fulfill international obligations, for example, related to the International Health Regulations.

### **Determine what additional rules and regulations will be required to further define the NPHI's functions and operations**

Often, the legal framework document that establishes the NPHI is relatively brief. Many additional rules and other legally binding documents may be needed to provide the detail about what the NPHI will do and how it will function. The NPHI's activities may also be informed by other legislation or decrees not specifically designed for the NPHI, for example, laws that impact food safety or laws designed to address government-wide issues in emergency response.

### **Draft the legal framework**

Once the appropriate research is completed and input received, a legal framework can be drafted. Examples of legal frameworks from a number of African countries are included in Appendix C of this framework and at <http://www.ianphi.org/resources/toolkit/nphilegislation.html>.

### **Provide opportunities for review of the drafts of the documents that comprise the legal framework**

The early and final draft(s) of the legal document(s) essential to establishing the legal framework should be reviewed widely internally and by a range of stakeholders, since once it is legally binding, changes will be difficult. Stakeholder engagement sessions may be a useful way of ensuring that these documents reflect the priorities and are responsive to the needs and interests of a wide range of stakeholder

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groups and may ensure acceptance of and support for the resulting legal framework.

### **Complete other steps or processes required for rule-making**

In some countries, especially if a parastatal organization is being formed, there may be a requirement for a business case to be developed. Often proposed rules need to go through a series of formal announcements and comment periods.

### **Conduct the remaining steps to achieve approval**

Once the legal document(s) needed to establish the legal framework are in final form they will need to be submitted to the relevant authorities for approval. In addition, steps should be taken to ensure successful implementation of the legal framework. This may include assessment of additional standards of practice, policies, or guides to assist with NPHI functionality, as well as an assessment of any additional legal authorities necessary to ensure NPHI functionality.

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### APPENDIX C. CASE STUDIES OF CREATING LEGAL FRAMEWORKS FOR NPHIS, AND THE RESULTANT LAWS, STATUTES, DECREES, OR REGULATIONS

#### C1. Guinea-Bissau Case Study, Decree-Law, and Statutes

## CASE STUDY

### Case Series on Providing a Legal Framework for a National Public Health Institute: The Guinea Bissau Experience

#### National Public Health Institute of Guinea Bissau (INASA)

Guinea Bissau's National Public Health Institute (INASA) was formally established on August 26, 2010. The creation of INASA was the culmination of over a decade of effort that had been interrupted by war and political shifts.

#### Critical Aspects of the INASA Decree-Law and Statutes

INASA is defined as having its own juridical personality – it is financially, technically, legally, and administratively autonomous. It is governed by a General Council, a collective body that has authority to approve INASA's annual plans, accounts, budget, and activity reports. It “works under the tutelage of the Ministry of Health.”

INASA has “patrimonial autonomy,” which means it controls its property. For example, it can create regional centers. The President of INASA is named by the Council of Ministers, in response to a proposal by the Minister of Health. The only stated requirement is that the President have a doctorate in medicine or a related field.

Financial resources come from three major sources: appropriations from the state budget, revenues from services, and donations and grants from other institutions. Among INASA's responsibilities are developing a national research agenda and conducting research, providing recommendations for prevention measures to the Ministry of Health, providing laboratory reference services, and workforce training.

#### Legal Mechanism Used

INASA was established by Decree-Law No.12/2010, passed by the Cabinet Council and signed into law by the

## CASE STUDY

President. The statutes of INASA describe key aspects of the organization, such as its functions and governance. These went into effect with passage of the Decree-Law and publication in the Official Bulletin of Guinea Bissau.

### Lessons Learned in Creating the Decree-Law

- High-level political support was critical for INASA's formation. The frequent turnover of Ministers delayed INASA's creation for many years.
- INASA was created by merging several pre-existing and fragmented groups and functions, not all of which had been in the Ministry of Health. Developing a plan that would achieve the desired outcomes and addressed the resistance to INASA among some parties required extensive negotiation and hard work. For example, the National School of Public Health, which trained public health workers, midwives, laboratory technicians, and other public health workers, had been under the Ministry of Education. Although it became part of INASA, many of its existing ways of operating were left intact.
- The support of other NPHIs in developing INASA was critical. Having a Lusophone NPHI – Fiocruz – involved was particularly helpful. Fiocruz and Mozambique's INS helped develop the first strategic plan and the statutes of INASA, respectively.
- While the President of INASA is appointed by the Council of Ministers for a term of five years, the basis under which the President can be removed is not stated, which means that decisions can be made to change leaders on political or other grounds.

We thank Drs. Augusto Paulo Silva and Amabelia Rodrigues for their assistance in developing this case study. Dr. Silva had been Secretary of State/Deputy Minister of Health in Guinea Bissau and a long-time champion of creating an NPHI, and Dr. Rodrigues was the first President of INASA.

# **NATIONAL INSTITUTE OF PUBLIC HEALTH (INASA)**

## **CHAPTER I NATURE, TASKS AND COMPETENCIES**

### **ARTICLE 1 (Definition)**

1. The National Institute of Public Health hereinafter referred to as INASA, is a scientific institution of planning and implementation of the National Health Policy and the National Policy for Education in the health sector.
2. INASA is an institution with its own juridical personality, endowed with technical, administrative, financial and patrimonial autonomy, with headquarters in Bissau, being able to create regional centres under its dependence.
3. INASA works under the tutelage of the Ministry of Health
4. The following constitute financial resources of the National Institute of public health:
  - a) Budget appropriations from the State Budget, pursuant to article 41 of the decree establishing it;
  - b) Revenues generated by its own services;
  - c) Donations and grants from personalities or foreign, national or international institutions;

### **ARTICLE 2 (Attributions)**

#### **INASA general attributions are:**

- a) Coordinate and oversee the definition of National Research Agenda for health and implementation throughout the national territory;
- b) Carry out scientific research on the health issues that contribute to the reduction of morbidity and mortality of the population and disseminate their results;
- c) Recommend to the MoH prevention measures for disease control relevant to public health, measures to be met by the public, private and community sector;
- d) Provide laboratory reference services to the National Health Service programs in the prevention and control of communicable and non-communicable diseases;
- e) provide scientific and technical training in the areas under its competence;
- f) contribute to the development and evaluation of programs and appropriate technologies relevant to public health;

- g) based on agreements of collaboration with the Directorates-General of the MoH, particularly with the Directorate-General for Prevention and Health promotion, carry out studies concerning the evaluation of health programs, proposing eventual revisions and improvements for decision-making;
- h) Encourage multidisciplinary and multi-sectoral research activities and promote the strengthening of the national research capacity in health sciences.
- i) Provide qualified advice and consultancy to the programs of prevention and control of diseases, to normative and technical bodies of INASA management;
- j) Develop epidemiological research, clinical, health services and in biological and social sciences applied to the health of the mother and child;
- k) Promote research, teaching activities and technical cooperation and technological development aimed at the preservation of the environment;
- l) participate in the formulation and implementation of National Health Policy and the National Policy for education in the area of health
- m) Propose communication strategies for health in collaboration with other health-promoting institutions

### **Article 3 (Goals)**

The objectives of INASA are namely:

- a) Generate, absorb and disseminate scientific and technological knowledge in health to provide strategic support to the national system of health and contribute to the improvement of the quality of life of the population and for the full exercise of citizenship;
- b) Promote and carry out health research under the basis of the priorities set by the National Research Agenda;
- c) Encourage research in health system as an instrument for the definition of health policy
- d) Form and train human resources for health, science and technology;
- e) Ensure the multisectoral and multidisciplinary scientific research, through related research institutions and other bodies of recognized technical competence

### **Article 4 (Competence)**

For the fulfillment of its tasks, it is up to INASA to:

- a) Investment of interest to carry out the prevention and control of diseases relevant to public health, including communicable and non-communicable diseases;
- b) Develop, standardize or assess technologies applied to prevention and disease control;



- c) Serve as a reference laboratory to programs for disease control and prevention, including the obligatory notification in public and private institutions;
- d) Implement studies in partnership with other national and international institutions, about problems of common interest in public health and develop reference laboratory functions;
- e) Carry out Intra-and extra-mural activities of scientific and technical training, postgraduate, to levels of higher and average technical and professional education and participate in undergraduate training of mid-level and higher levels of education in training institutions;
- f) Promote e coordinate national development activities of research in health science, particularly through institutional strengthening and scientific upgrading of national technicians;
- g) Coordinate with national and international scientific institutions, as well as international agencies for development support in order to promote technological transfer of knowledge, training and the upgrading of national researchers and technicians;
- h) Edit the magazine and the Guinean health collection and organize health visits and other actions aimed at the production and dissemination of scientific information.
- i) Facilitate access by health professionals and the public in general to scientific and technical information across the Organization and development of specialized services.

**CHAPTER II**  
**Organic System**  
**Section I**  
**Structures**

**Article 5**  
**(Bodies)**

INASA has the following structure:

- a) General Council
- b) Board of Trustees
- c) President of INASA
- d) Scientific Council
- e) Supervisory Board

**Section II**  
**COMPETENCE AND FUNCTION OF INASA's STRUCTURES**

**Subsection I**  
**Article 6**  
**(General Council)**

1. The General Council of INASA is a collective body with deliberating powers on INASA general policy;
2. The General Council is composed of the:
  - a) President of the General Council
  - b) President of INASA;
  - c) President of the Scientific Council;
  - d) Director of the Centre for Management and Institutional Development;
  - e) Director of the Centre for Epidemiology and Community Health (Bandim Health Project);
  - f) Director of the National Laboratory of Public Health;
  - g) Director of the Centre for Tropical Medicine;
  - h) Director of the Centre for Information and Communication for health;
  - i) Director for the National Health School;
  - j) Representative of Universities in the country;
  - k) Representative of the National Studies and Research Institute
  - l) Representative of the National Institute for Education Development;
  - m) Representative of the National Institute of Statistics;
  - n) Representative of the National Biodiversity Institute;
  - o) Representative of the National Institute of Agricultural Research;
  - p) Representative of the National of Applied Technological Research;
  - q) Representative of the Centre of Applied Fishing Research;
  - r) Representative of the Youth Institute;
  - s) Representative of the Institute of Women and Child;
  - t) Coordinator of Communicable Diseases Program;
  - u) Coordinator of Mother and Child Health Program;
  - v) Coordinator of the Environmental Health and Non Communicable Diseases;
  - w) Coordinator of Health System Development Program
3. The coordinators listed in subparagraphs t, u, v, and w are the INASA.
4. The president of General Council will be a Ministry of Health Staff preferably technician in the health area, appointed by decree of the Minister of Health, for a period of 3 years.
5. The general council meets in regular session twice a year and extraordinarily walk by its chairman, or the chairman of INASA, with at least half of its members.

6. The deliberations of the General Council are taken by consensus or, where that is not possible, by an absolute majority of the members present.
7. Members of the Executive Board participate in discussion and voting, except when it comes to voting on proposals submitted by the governing council to the General Council.

## **Article 7 (General Council Functions)**

### **Are the functions of General Council:**

- a)** Consider and approve annual plans and program of INASA;
- b)** Approve annual accounts and activities reports;
- c)** Consider and approve annual budget of INASA;
- d)** Require external evaluation of the institution and pin down its goals;
- e)** Decide on changes in organic structure, according to the development and needs of the institution, and consider the proposals for the creation of research units and assigning laboratorial reference functions.
- f)** Consider and approve the regulation of professional careers and the staff establishment of INASA;
- g)** Elect, upon proposal of the President, the Chairman of the Supervisory Board;

## **Article 8 (President of General Council)**

The President of the General Council shall inform, whenever necessary, the Ministry of Health about the general situation of INASA and to this effect, presenting it the program, plan, budget and annual accounts report, approved by the general council, and other information deemed important for better oversight by the ministry.

**Subsection II**  
**Article 9**  
**(Governing Board)**

1. The Governing Board of INASA is composed of:
  - a. President of INASA;
  - b. President of Scientific Council;
  - c. Director of Central Management and Institutional Development;
  - d. Director of Center of Tropical Medicine;
  - e. Director of Center of Epidemiology and Community Health/PSB (Bandim Health Project);
  - f. Director of National Public Health Laboratory;
  - g. Director of Health Information and Communication for Health;
  - h. Director of National Health School.
  
2. At the discussion and approval of the Governing Board program, annual plan and budget, it will take part, the National Public Health Laboratory, The Centre for Tropical Medicine, The School of Health and the National Center of Epidemiology and Community Health/PSB.

**Article 10**  
**(Competence)**

Is the competence of the Governing Board of INASA, under the direction of President:

- a. Preparing the program, the annual plan and budget and the annual accounts and activities reports and present them to the General Council for discussion and approval;
- b. Decide on the signing of agreements and protocols of cooperation with other national and international organizations.

**Article 11**  
**(Appointment of Direction)**

1. President of INASA is named in the Cabinet Council on a proposal by the Minister of Public Health, among doctorates in medicine or related fields.
2. The remaining board members are appointed by the Minister of Public Health, at the proposal of the President INASA by a hazard of five years.

**Subsection III**  
**Article 12**  
**(Competence of President of INASA)**

1. The President of INASA is the governing body of the institute, being responsible for the direction and coordination of all activities of institution.
2. Also incumbent upon the President INASA:
  - a. Preparing the proposal of the program, annual plan and budget and present it to the Governing Board;
  - b. Exercise disciplinary authority over all personnel of INASA;
  - c. Propose to the General Council changes to the organizational structure of INASA;
  - d. Perform all other duties not covered in the competencies of other organs, namely the General Board and the Supervisory Board.
3. For the preparation of the program, annual plan and budget, the President of INASA prompts a mini-program plan and budget for each of the following units:
  - a. National Public Health Laboratory;
  - b. Center of Tropical Medicine;
  - c. National Health School;
  - d. Center of Management and Institutional Development;
  - e. Centre of Epidemiology and Community Health;
  - f. Center for Information and Communication for Health.

**Subsection IV**  
**Article 13**  
**(Competence of Scientific Council)**

1. The President of the Scientific Council, directs and coordinates the scientific activities of the Ethics Committee of the Centers and Research Units and Service Units.
2. The Scientific Council comprises de following services:
  - a. Coordination of Communicable Diseases;
  - b. Coordination of Environmental Health and Non-Communicable Diseases;
  - c. Coordination of Health Systems;
  - d. Centre of Epidemiology and Community Health / PSB;
  - e. Center for Tropical Medicine;
  - f. National School of Health;
  - g. National Laboratory of Public Health;
  - h. Center of Management and Institutional Development.
3. Is the competence of Scientific Council:
  - a. Appreciate, reviewing and monitoring protocols for scientific research;
  - b. Promote opportunities for the discussion of research results and technical-scientific subjects;
  - c. Appreciate technical and scientific development and staff training programs;
  - d. Appreciate technical and scientific cooperation programs with national and foreign institutions;
  - e. Organize Days of Health and other similar events.

4. The INASA exercise even through the Scientific Council, a power of superintendence over the following technical and scientific units, as part of its program and plan
  - a) Center of Epidemiology and Community Health ( Bandim Health Project)
  - b) Nacional Laboratory of Public Health ( Laboratorio Nacional de Saude Publica)
  - c) Center of Tropical Medicine
  - d) Center of Information and Communication in Health
  - e) Center of Management and Institutional Development

**Subsection V**  
**Article 15**  
**Financial Council**

The financial department composed of President, Vice-President, Secretary, assistant secretary and two other members.

**Article 16**  
**(Competency)**

1. Responsibilities of Financial Department
  - a) Appreciate the functionality of financial management
  - b) Check the budget of expenses
  - c) Dispatch the report about expenses and activities to Main Department
2. On any occasion requests, will be given to the supervisory board details about the financial management, access to books or any accounting records.

**Chapter III**  
**Advisory and technical bodies**

**Article 17**

INASA consists of adviser organ, the National Ethics Committee for Health

**Article 18**  
**( Ethic Committee)**

The National Ethics Committee for Health responsibilities:

- a) Encourage researchers for biomedical field and the general public about the principles and values that command research on humans and animals, as well the nature of ethical problems that are attached to them also the solutions that must be considered.
- b) Judge on proposed research protocols for their researchers to ensure the protection of communities, humans and even animals for experimentation when subjected to biomedical research or other.
- c) Cooperate with the National Bioethics Committee for Health in their activities.

**Article 19**  
**(Independence and functionality)**

The Ethics Commission is independent in its deliberations, and its composition and functioning in own fixed rules proposed by the scientific council and approved by the governing board.

**Chapter IV**  
**(Final Provisions)**

**Article 20**

INASA will developed and submitted to the approval of the ministry of health, within six months after the promulgation of this Diploma, rules of their organs.

**Article 21**  
**(Subsidiary rules)**

The doubts arising in interpretation, and the application of this statute shall be resolved by order of the minister of health.



**Article 22**  
**(Transitional provision)**

While the National Research Council for Health and the National Council of bioethics are being created, their functions and tasks will be ensured by INASA.

## APPENDICES

### APPENDIX C. CASE STUDIES OF CREATING LEGAL FRAMEWORKS FOR NPHIS, AND THE RESULTANT LAWS, STATUTES, DECREES, OR REGULATIONS

#### C2. Liberia Case Study and Law

## CASE STUDY

### Case Series on Providing a Legal Framework for a National Public Health Institute: The Liberia Experience

#### National Public Health Institute of Liberia (NPHIL)

The National Public Health Institute of Liberia (NPHIL) was officially established by the NPHI Act of 2016, which was signed into law by the President in January 2017. This law was passed quickly, to address the weaknesses in public health observed during Liberia’s response to the 2014-2015 Ebola outbreak. The process used to develop the law and its content and garner support is described in the IANPHI “Case Study: Creating the National Public Health Institute of Liberia” ([http://www.ianphi.org/\\_includes/documents/Legislation%20BP%20Case%20Study\\_Liberia%20.pdf](http://www.ianphi.org/_includes/documents/Legislation%20BP%20Case%20Study_Liberia%20.pdf)).

#### Critical Aspects of the NPHI Act to Establish NPHIL

The Act establishes NPHIL as a “corporate body with perpetual existence and a common seal.” NPHIL may conduct business and has responsibilities similar to how other corporations operate. It is governed by a Board of Directors, which includes Ministers of Health, Finance and Development Planning, Justice, and Agriculture; the University of Liberia; and six non-statutory members. The Board functions, tenure of members, requirements for meetings, and other aspects of Board functioning are included in the Act.

The law specifies the functions of the NPHIL, some of which derive from transferring public health and biomedical research functions, property, and staff from the Ministry of Health to NPHIL. It includes provisions related to both communicable diseases and non-communicable conditions, e.g., injuries. The role of the Minister is defined to include policies and practices related to the health sector, formulation of policies related to public health, and recommending an annual research agenda for Liberia’s health priorities to NPHIL. Requirements, functions, and terms of the Director General and two Deputy Directors General are also specified, as are issues related to

## CASE STUDY

financing and budget.

By establishing the NPHIL as a parastatal organization rather than a line agency, NPHIL will have the autonomy needed to respond quickly to public health emergencies.

### Legal Mechanism Used

NPHIL was formally established by a law. With support from the Minister of Health and the President, the legal drafting and approval process took only a little over a year.

### Lessons Learned in Creating the Law

- In Liberia, the support of the President and other high-level officials was important for creating a parastatal agency and also sped what is usually a time-consuming process.
- Two factors that facilitated passage of the Act were the sense of urgency following the Ebola crisis and that other changes to the law governing the Ministry of Health were being made at the same time, e.g., transferring the Department of Social Welfare to a newly created ministry.
- The involvement of influential partners, like WHO, US CDC, and IANPHI, was helpful. A step-wise approach, with extensive stakeholder involvement, including from legislators, helped ensure buy-in. Some issues, such as moving research and the reference lab to the NPHIL, were contentious and required extensive discussion.
- NPHIL started to function as an NPHI before the law was passed, providing an early demonstration of its usefulness.
- Based on his experience, Dr. Nyenswah encourages all countries in Africa to create NPHIs. He suggests that Africa CDC, WHO, and US CDC speak with one voice to affirm the importance of establishing NPHIs.

We thank Dr. Tolbert Nyenswah, Director of NPHIL, for his assistance in developing this case study.

**An Act to Establish the National Public Health Institute of  
Liberia**



**AN ACT TO ESTABLISH THE NATIONAL PUBLIC  
HEALTH INSTITUTE OF LIBERIA**

REPUBLIC OF LIBERIA

## **AN ACT TO ESTABLISH THE NATIONAL PUBLIC HEALTH INSTITUTE OF LIBERIA**

**WHEREAS**, the Legislature is authorized under Chapter 10, Article 89 of the 1986 Liberian Constitution to enact legislations to create agencies and commissions of government as may be necessary for the effective operation of the government;

**WHEREAS**, there have been profound insurgences of infectious diseases which threatened the life of all the people of Liberia as evidenced by the recent unprecedented outbreak of Ebola Virus Disease (EVD) in West Africa which exposed weaknesses in Liberia’s national health care system and highlighted the need for the establishment of a public health institution in Liberia to support national health delivery services;

**WHEREAS**, it has now become incumbent upon Liberia as a nation to create an institution to collaborate with and strengthen the Ministry and other Institutions in the Health Sector to heighten the infection prevention and control efforts of the of the Government of Liberia;

Now therefore it is hereby enacted by the Senate and House of Representatives of the Republic of Liberia, in Legislature assembled:

### **PART I: PRELIMINARY PROVISIONS**

#### Section 1.1: Short Title

This Act shall be cited as “the NPHI ACT OF 2016.”

#### Section 1.2: Repeal and Amendment

Immediately upon the passage of this Act:

- a. “The act establishing the National Research Institute of Liberia (commonly known as Liberia institute for Biomedical Research (LIBR))” is hereby repealed.
- b. Section 30.2 (d, e, o) of the 1972 Executive Law, Title 12 of the Liberian Code of Law revised is hereby amended transferring public health and biomedical research functions of the Ministry of Health to NPHIL.

#### Section 1.3: Definitions

Unless otherwise stated in this Act, the following terms shall have meanings as follows:

- a. "Abandonment of duty" as defined by the Decent Work Act of 2015
- b. "Board" means the Board of Directors of NPHIL.
- c. "Consulting and service fees" means fees earned for services provided by NPHIL.
- d. "Conviction" means determination of guilty by a court of competent jurisdiction of crimes related to fraud, bribery, perjury, misrepresentation, corruption, plagiarism or other felonious crimes
- e. "Deputy Director General" means the person appointed under Section of this Act.
- f. "Director General" means the administrative head of NPHIL appointed under Section 15 of this Act.
- g. "Foundation" means an independent, fundraising body to be established by the Board as referred to in Section 18.
- h. "Grossly inefficient" as defined by the Decent Work Act of 2015
- i. "Indirect costs/institutional charges" means a fixed percentage levied by NPHIL on all research grants.
- j. "Institute" means the NPHIL
- k. "Minister" means the Minister of Health.
- l. "Ministry" means the Ministry of Health.
- m. "NPHIL" means the National Public Health Institute of Liberia.
- n. "Operational research" means non-medical research that supports logistical and health management decisions
- o. "Response" is the rapid, coordinated detection and control to outbreaks.
- p. "Surveillance" epidemiological practice by which the spread of disease is monitored in order to establish patterns of progression
- q. "Intellectual property" means any property as defined by the Patent, Copyright and Trademark Law of Liberia, Title 24

## **PART II: THE NATIONAL PUBLIC HEALTH INSTITUTE OF LIBERIA**

### Section 2.1: Establishment of the National Public Health Institute of Liberia

- a. There is hereby established the National Public Health Institute of Liberia as a corporate body with perpetual existence and a common seal. It may sue and be sued in its own name and subject to the provision of this act; performs such other acts as corporate bodies may lawfully perform.
- b. The Institute shall be an autonomous agency of the government but for the sake of proper coordination of the health services shall share scientific information reports with and have sectorial reporting accountability to the Ministry of Health.
- c. The Institute may in the performance of its function acquire and hold movable and immovable property and may enter into contracts or any other transactions that a state-owned enterprise may enter into.

## Section 2.2: Composition

The NPHIL shall be comprised of following six departments:

- a. Department of Training and Capacity Building
- b. Department of Infectious Diseases and Epidemiology
- c. Department of Laboratory and Public Health Diagnostics
- d. Department of Environmental and Occupational Health
- e. Department of Public Health and Medical Research and Development
- f. Department of Administration

## Section 2.3: Objective of the National Public Health Institute of Liberia

The overall objective of NPHIL is to improve the health status of the population of Liberia in collaboration with relevant agencies and institutions of government. The specific objectives are as follows:

- a. Contribute to the development and sustainability of public health workforce
- b. Develop, enhance, and expand the surveillance and response platforms
- c. Develop and strengthen the laboratory system and public health diagnostics
- d. Develop, enhance, and expand processes and structures to protect environmental and occupational health
- e. Expand, conduct, and coordinate public health and medical research to inform Liberian public health policies

## Section 2.4: Functions and Operation of the National Public Health Institute of Liberia

- a. NPHIL shall perform the following:
  - i. coordinate, develop, and maintain surveillance systems to collect, analyze, and interpret health data to guide health interventions;
  - ii. use surveillance data to advise on setting health policies, priorities, and planning;
  - iii. use public health information for monitoring and evaluation of policies and interventions;
  - iv. coordinate reference laboratory and laboratory referral services;
  - v. provide leadership and direction to counties and local authorities on disease and injury surveillance and outbreak response;
  - vi. promote cooperation between Liberia and other countries with regard to the epidemiological surveillance and management of diseases and injuries, including strengthening cross border and regional public health efforts;
  - vii. strengthen capacity of the health workforce in health surveillance to reduce the burden of disease and injury;



- viii. strengthen epidemiology and surveillance of communicable and non-communicable diseases;
- ix. prevent diseases and workplace illnesses and injuries
- x. promote environmental responsibility
- xi. enforce environmental and public health laws, policies, and regulations
- xii. advise the Minister on strategies to improve the health of the population;
- xiii. support the health response and provide recommendations to government on control measures for disease outbreaks and mitigating health risks and hazards;
- xiv. collaborate with relevant government departments and government agencies to implement communication strategies on public health issues and outbreak response;
- xv. provide technical support to all spheres of government and other regulatory bodies on disease surveillance, prevention, and control;
- xvi. conduct research to inform policy and guidelines on public health and develop processes for dissemination of research findings to key stakeholders;
- xvii. strengthen advocacy, social mobilization and partnerships related to public health research;
- xviii. provide training and technical information on health issues to health professionals, government and regulatory bodies;
- xix. maintain accredited reference and specialized laboratories for pathogen detection, disease and injury surveillance and monitoring, outbreak response and the provision of scientific evidence to prevent and control infectious diseases;
- xx. set up Institutional Review Board on public health and medical research
- xxi. coordinate activities relevant to national specimen biobank
- xxii. Recommend the quarantine and isolate of persons who have a communicable disease constituting a public health threat
- xxiii. Recommend the declaration of public health emergency and disease outbreaks based on available public health data

b. NPHIL may:

- i. liaise with any other regulatory authority or institution and exchange information with and receive information from any such authority or institution in respect of matters of common interest or public health concern;
- ii. cooperate with persons and institutions undertaking basic research in Liberia and in other countries by the exchange of scientific knowledge and the provision of access to the resources and specimens available to NPHIL;

- iii. Participate in joint research operations with government departments, tertiary institutions, museums, scientific institutions and any other persons ;
- iv. Produce and sell by-products.
- v. Collaborate with the Ministry of Agriculture and other appropriate agencies of Government in maintaining data and giving advice to Government on the population dynamics of its wildlife reserves, their biotic interactions and their socioeconomic, biomedical, and cultural significance, with the view of protecting the reserves from indiscriminate removal or abuse in the context of One Health.
- vi. Perform such other functions as may from time to time be required by or consented to by the Board.
- vii. Promulgate and issue regulations governing NPHIL in the field of public health research in Liberia.

### **PART III: GOVERNANCE AND CONTROL**

#### Section 3.1: Role of the Minister

The Minister shall:

- a. Continue to exercise the functions and responsibilities provided for in the Act establishing the Ministry and the Public Health Law, except as altered by the amendments identified in Section 1.3 of this Act.
- b. Subject to the exercise of functions, powers and authority of the NPHIL pursuant to this Act and other applicable laws, the Ministry shall undertake such functions and responsibilities as are appropriate for the attainment of adequate, affordable and accessible health care delivery system in Liberia, and in particular the Ministry shall have the capacity and responsibility under this Act to:
  - 1. provide policy advice to the Government of Liberia on matters relating to the health sector on both domestic and international matters;
  - 2. develop policy of general application to the health sector;
  - 3. encourage and promote the provision and availability of quality, accessible and affordable health services for the people of Liberia;
  - 4. represent the health policy interests of Liberia in international health organizations;

5. support the establishment of a regulatory environment that facilitates the improvement of health services in Liberia; and
  6. Take such other actions as are needed to co-ordinate Government policies and programs affecting the health sector generally.
- c. Have the authority to formulate policies related to public health.
  - d. Have the authority to recommend annual research agenda for Liberia's health priorities to NPHIL.

### Section 3.2: Board of Directors

There is hereby established a Board of Directors which shall be the governing body of NPHIL and which shall consist of eleven members. The Board shall be comprised of five (5) statutory members and six (6) other members appointed by the President.

### Section 3.3: Composition of the Board

The Board shall consist of:

- a. The Minister of Health;
- b. The Minister of Finance and Development Planning;
- c. The Minister of Justice;
- d. The Minister of Agriculture;
- e. The University of Liberia; and
- f. Six (6) other non-statutory members one of whom shall be the Chair who shall have a minimum of a master's degree in public health, public policy, medicine, health administration, or research-related disciplines and a minimum of three years' work experience and must be a person of integrity.

### Section 3.4: Functions of the Board

The Board shall:

- a. Consider and approve annual plans and programs of NPHIL.
- b. Vet and appoint the Deputy Director Generals and Directors of all Departments.
- c. Vet and recommend at most three (3) persons for the position of the Director General for appointment by the President.
- d. Approve annual budgets, strategic and operational plans.
- e. Ensure contracts, agreements, and memorandums of understanding with third parties, contractors, and agencies are consistent with applicable laws.
- f. Decide in changes in the organic structure of NPHIL according to the development and needs of NPHIL.

- g. Establish the NPHIL Foundation.
- h. Receive and approve reports from the Director General on the progress of NPHIL.
- i. Draft, adopt, and enforce bylaws for the Board.
- j. Ensure the proper implementation of this Act.
- k. Approve the salary structure of the Director General and the Deputy Director General

### Section 3.5: Tenure of the Board

- a. The President will appoint the non-statutory members of the Board, and they will serve for a term of three (3) years. All non-statutory Board members will be eligible for re-appointment once.

- b. Resignation, Suspension, Removal

- i. Resignation

- 1. Any member of the Board may voluntarily resign by submitting a letter of resignation to the President.
    - 2. A member who has two unexcused absences within the period of one year will be considered to have resigned his position on the Board.
    - 3. If a statutory member has two unexcused absences within the period of one year, the Board will take appropriate action against such statutory member.

- ii. Suspension

No member of the Board of Directors shall be suspended except upon the recommendation of a vote by two-thirds majority of the members of the Board to the President, provided, however, that a Board Member shall be suspended for cause.

- iii. Removal

A member of the Board shall be disqualified or removed if:

- 1. Convicted of any crimes by a competent tribunal consistent with due process of law; or
    - 2. The member is no longer able to perform the duties due to physical or mental incapacity, as certified by at least two qualified medical doctors or psychiatrists; or
    - 3. It is discovered that a member has at any time been convicted of an offense involving dishonesty, whether in Liberia or elsewhere; or
    - 4. The member ceases to be a resident of Liberia.

### Section 3.6: Board Meeting

- a. Time of Meeting: The Board should meet at least once every three (3) months to conduct business of the Institute.
- b. Venue: The Board shall meet at a place that is designated by the Chairman, provided that it is in Liberia.
- c. Leadership: The Chairman of the Board shall preside at meetings. At the first ever meeting of the Board, members of the Board shall elect a Vice Chairman, who will preside in the absence of the Chairman.
- d. Quorum: Simple majority of Board members present at a meeting of the Board shall constitute a quorum, provided both statutory and non-statutory members are present.
- e. Decision: A vote of a simple majority present at a meeting shall be required for a decision, except as to those decisions for which a two-thirds majority of members is required by this Act.

### Section 3.7: Committees of the Board

The Board may constitute external advisory group and relevant committees comprising of members of the Board and technical experts from time to time as the need arises.

## **PART IV: THE DIRECTOR GENERAL AND DEPUTY DIRECTOR GENERALS**

### Section 4.1: Appointment of the Director General

The President shall, upon the recommendation of the Board of Directors, appoint the Director General.

### Section 4.2: Qualifications of the Director General

The Director General must have the following qualifications:

- a. a minimum of a master's degree in public health or a doctorate degree in biomedical sciences
- b. a minimum of five years of progressive technical work experience in a scientific or public health research setting of which a minimum of 2 years of management experience
- c. a person of integrity
- d. a demonstrated track record of successful grant applications

- e. a minimum of five (5) public-health related, scientific publications in peer-reviewed journals

#### 4.3: Functions of the Director General

The Director General shall:

- a. Be the administrative head of NPHIL and carry out the day-to-day functions of NPHIL.
- b. Report to the Board.
- c. Appoint qualified, competent and suitable persons as employees below the rank of Deputy Directors, pursuant to organizational structure of NPHIL.
- d. Be responsible for delivering on the agreed mandate of NPHIL as determined by the Board in the terms of this Act.
- e. Formulate and develop internal rules and directives for an efficient and effective administration of the institute.
- f. effectively organize and maintain staffs
- g. be responsible for effective placement of staffs Utilization of staffs and resources to achieve maximum operational results.
- h. Sign on behalf of the entity all memoranda of understanding, contracts, and agreements with key stakeholders consistent with Public Procurement and Concession Commission Act and all other applicable laws thereto.
- i. be responsible for the issuance of guidelines in regards to the manner which claims shall be handled
- j. Advise the Ministry on health-related challenges in Liberia.
- k. prepare the annual budgets, strategic and operational plans, and submit to the Board for approval
- l. serve as the Secretary of the Board
- m. exercise all powers in conformance of any such duties as may be delegated or assigned by the Board
- n. ensure the proper implementation of this Act

#### 4.5: Tenure of the Director General

The Director General shall serve for a term of five (5) years. He or she will be eligible for re-appointment once.

- i. Resignation

The Director General may voluntarily resign by submitting a letter of resignation to the President, provided that he or she gives two months notices prior to the date of his or her resignation.

ii. Suspension

The Director General shall be suspended for by the President for cause upon the recommendation of a vote by two-thirds majority of the members of the Board.

iii. Removal

The Director General shall be removed if:

1. Found to be grossly inefficient;
2. Found to be corrupt;
3. Convicted of any crime by a competent tribunal consistent with due process of law; or
4. No longer able to perform the duties due to physical or mental incapacity, as certified by a qualified psychiatrist or medical doctor; or
5. It is discovered that a member has at any time been convicted of an offense involving dishonesty, whether in Liberia or elsewhere, and sentenced to imprisonment without the option of a fine; or
6. No longer a domicile in Liberia.

#### Section 4.5: Appointment of the Deputy Directors General

The Board shall appoint two Deputy Directors General, one for Technical Services and one for Administration.

#### Section 4.6: Tenure of the Deputy Director Generals

The Deputy Directors General shall each serve for a term of four (4) years. They shall each be eligible for re-appointment once.

#### 4.7: Qualifications of the Deputy Director General of Technical Services

The Deputy Director General of Technical Services shall have the following qualifications:

- a. a minimum of MD, PHD, DRPH with experience in in public health.
- b. a minimum of five years' work experience in a scientific or public health research setting

- c. a person of integrity
- d. a demonstrated track record of grant applications
- e. a minimum of 5 public-health related, scientific publications in peer-reviewed journals

#### 4.8: Qualifications of the Deputy Director General of Administration

The Deputy Director General of Administration must have the following qualifications:

- a. a minimum of a master's or advanced degree or its equivalent in business administration, law or related disciplines
- b. a minimum of five years' work experience in a financial or administrative capacity
- c. a person of integrity
- d. a demonstrated track record in management of grants

#### 4.9: Functions of the Deputy Director General for Technical Services

The Deputy Director General for Technical Services shall:

- a. serve as chief scientist for the NPHIL
- b. act in the absence of the Director General
- c. report to the Director General
- d. serve as supervisor for all technical or science departments pursuant to organizational structure of NPHIL
- e. be responsible for delivering on the agreed mandate of NPHIL as determined by the Board in the terms of the technical aspects of this Act
- f. perform all other functions as assigned by the Director General

#### Section 4.10: Functions of the Deputy Director General for Administration

The Deputy Director General for Administration shall:

- a. act as Director General in the absence of both the Director General and Deputy Director General of Technical Services
- b. report to the Director General
- c. serve as supervisor for the financial and administration departments pursuant to organizational structure of NPHIL
- d. be responsible for delivering on the agreed mandate of NPHIL as determined by the Board in the terms of the administrative aspects of this Act
- e. perform all other functions as assigned by the Director General



#### 4.11: Resignation, Suspension and Removal of Deputy Directors General

a. Resignation

The Deputy Directors General may voluntarily resign by submitting a letter of resignation to the Board.

b. Suspension

The Deputy Director Generals shall be suspended by a vote of two-thirds majority of the members of the Board for cause.

c. Removal

A Deputy Director General shall be removed if:

1. Found to be grossly inefficient;
2. Found to be corrupt;
3. Convicted of any crime by a competent tribunal consistent with due process of law; or
4. No longer able to perform duties due to physical or mental incapacity as certified by at least two qualified medical doctors or psychiatrists; or
5. It is discovered that a member has at any time been convicted of an offense involving dishonesty, whether in Liberia or elsewhere, and sentenced to imprisonment without the option of a fine; or
6. No longer a domicile in Liberia.

### **PART V: FINANCIAL PROVISIONS**

#### Section 5.1: Funding

a. The NPHIL shall be funded through:

- i. Budgetary allocation.
- ii. Fees from sale of research products.
- iii. Grants and donations.
- iv. Indirect costs/institutional charges on all grants.
- v. Consulting and services fees.
- vi. Cooperative agreements with other governments.
- vii. Intellectual property including patents.
- viii. NPHIL Foundation,
- ix. Investment and
- x. any other lawful means

- b. All funds to be generated by NPHIL as listed in a(i-viii) of this Section shall be retained by NPHIL for the purpose of defraying its expenses.

#### Section 5.2: Annual Budget

- a. The Director General shall prepare and submit to the Board for approval an annual budget for the ensuing year which the Board shall approve and subsequently submit to the Minister of Finance and Development Planning.
- b. The budget must include details of NPHIL income and expenditure for the current and two subsequent years including actual from the past year. The budget must include detailed and comprehensive estimates of the current year's known and anticipated income and expenditure and a projection of income and expenditure for the next financial year as well as the following year along with carried forward balances or as required under the budget law.

#### Section 5.3: Procurement

The operation of the NPHIL shall be in accordance with the Public Procurement and Concessions Commission Act, as amended and reinstated in 2010.

#### Section 5.4: Accounts and Audit

- a. NPHIL shall keep up-to-date and accurate accounting and financial records, which shall conform to laws, applicable statutes and regulations.
- b. Subject to the Board's approval, NPHIL will open and maintain accounts with the Central Bank of Liberia and any other reputable local bank for purpose of carrying out its affairs.
- c. The Director General shall submit the account of NPHIL to the Board who shall from time to time commission audit(s).
- d. NPHIL is subject to the audit of the General Auditing Commission.

#### Section 5.5: Report

- a. The Director General shall submit quarterly and annual report consisting of financial and programmatic information to the Board for onward submission to the President and to the Legislature.
- b. The Director General shall submit other reports as may request by the Minister from time to time on specific issues, programs, or periods.
- c. The Director General is required to report to the Minister, President and Legislature within a period of forty-eight hours significant findings from studies that may inform or influence policy decisions.

## **PART VI: MISCELLANEOUS PROVISIONS**

### Section 6.1: Intellectual Property

Ownership of intellectual property generated by persons employed by NPHIL during the course of their engagement with NPHIL shall vest in the Institute of the Republic of Liberia.

### Section 6.2: Confidentiality

- a. All patent related research information or findings, processes, research, techniques, or plans shall be kept confidential, except as provided herein.
- b. All information receive by the relevant parties herein shall be kept confidential
- c. Members of the Board of Directors, the Director General, officers, employees, and staffs of NPHIL shall treat all information obtained in the course of their employment and/or engagement with NPHIL strictly confidential, not to be disclosed to any third party, and shall not use it for any other purpose other than for the purpose of this Act.
- d. NPHIL shall ensure that its officers, employees, and all associates treat partners' information as confidential.

Any breach of the above confidentiality provision shall be punishable according to law.

## **PART VII: TRANSITIONAL PROVISIONS**

### Section 7.1: Transfer of Property

As of the effective date of this Act, all properties and assets of the Emergency Operations Center, National Reference Laboratory, and Disease Prevention and Control Unit of the Ministry of Health, and the National Research Institute (also referred to as the Liberia

Institute for Biomedical Research), the Division of Environmental and Occupational Health of the Ministry of Health, shall be transferred to the NPHIL.

#### Section 7.2: Transfer of Employees

- a. As of the effective date of this Act, employees of the Emergency Operations Center, National Reference Laboratory, and Disease Prevention and Control Unit of the Ministry of Health, and the National Research Institute (also referred to as the Liberia Institute for Biomedical Research), Division of Environmental and Occupational Health Services of the Ministry of Health shall be transferred to NPHIL subject to the Civil Service requirements.
- b. Any person transferred to NPHIL shall:
  - i. Sign the Professional Ethics and Code of Conduct of NPHIL prior to assuming duties or within thirty (30) working days after the effective date of the Act;
  - ii. Sign the Employee Handbook of NPHIL prior to assuming duties or within thirty (30) working days after the effective date of the Act;
  - iii. Be subject to the Human Resource Management Manual of NPHIL, the Professional Ethics and Code of Conduct of NPHIL and related regulations and to the administration of NPHIL;
  - iv. No longer be a civil servant; and
  - v. Sign employment contracts with NPHIL in line with the Decent Work Act
- c. All transfers relating to the commencement of the NPHIL shall be completed within twelve (12) months as of the effective date of this Act.

**ANY LAW TO THE CONTRARY NOTWITHSTANDING**

## APPENDICES

### APPENDIX C. CASE STUDIES OF CREATING LEGAL FRAMEWORKS FOR NPHIS, AND THE RESULTANT LAWS, STATUTES, DECREES, OR REGULATIONS

#### C3. Mozambique Case Study and Decree

## CASE STUDY

### Case Series on Providing a Legal Framework for a National Public Health Institute: The Mozambique Experience

#### Mozambique National Institute of Health (INS)

The National Institute of Health of Mozambique (INS) was established in 1976 as a division within the Preventive Medicine Directorate of the Ministry of Health (MoH). In 1983, the INS became a distinct institution within the MoH, with limited autonomy. This changed in 2017, with the passage of Decree 57/2017.

#### Critical Aspects of the new INS Legal Framework

The 2017 Decree provides the INS with autonomy and assigns it additional public health responsibilities, while also increasing its operational efficiency. For example, the INS budget is now negotiated directly with the Ministry of Finance. In addition, the INS is now authorized to establish sub-national divisions. With more operational autonomy, INS will be better able to rapidly respond to outbreaks, have improved efficiency in conducting nation-wide surveys, and have increased capacity for grant management and oversight.

Under the Decree, the Director-General and Deputy Director-General are appointed by the Prime Minister for renewable terms of five years, which helps ensure institutional stability. The INS must establish strong collaboration and coordination with the MoH, as the INS is technically supervised by the Minister of Health.

INS funding derives from a number of sources, but still depends heavily on external funding through bilateral or multilateral funding mechanisms, as well as through competitive grants.

#### Legal Mechanism Used

The legal framework for the INS is the Decree passed by the Council of Ministers and signed by the Prime Minister, which is the approach used to establish public institutes in

## CASE STUDY

Mozambique. The Decree includes high-level parameters, such as the INS mission, INS functions, and qualifications and terms for leaders of the INS. Statutes passed by an Inter-Ministerial Commission, chaired by the Prime Minister, provide more detail, for example, about the functions of the directorates.

### Lessons Learned in Creating the Decree

- INS' reputation and visibility were critical for garnering support. The INS already had a solid national and international reputation, due to its achievements in fields such as research, surveillance, outbreak investigations, reference laboratory services, and education.
- The support of the Minister of Health was essential for the passage of the Decree.
- The INS had developed a strategic vision and was working to achieve it before the Decree was passed. (Fiocruz provided critical assistance in developing INS' vision and plans.) INS leadership recognized that more autonomy would help the INS to be a more nimble, efficient organization. When the political situation was favorable, the INS was poised to take advantage of the opportunity to redefine itself; it had clearly articulated plans and clear messages about how changing its status would be good for public health.
- In developing its framework, the INS consulted with NPHIs from around the world, Directorates within the MoH, and other Ministries in Mozambique to ensure a solid and robust organizational and functional structure, as well as alignment with national legislations. For example, consultation with the Ministry of Finance was essential for budgetary issues, with the Ministry of State Administration to ensure consistency of the organizational structure with national legislation, and with the Ministry of Science and Technology to ensure alignment with national policies and strategies on Science and Technology.

We thank Dr. Eduardo Samo Gudo Jr., Deputy Director-General at INS, for his assistance in developing this case study.

## Summary

Council of Ministers:

**Decree No. 57/2017:**

Redefines the nature, attribution, and competencies of the National Institute of Health in order to intensify the coordination, management, and realization of health research.

**Resolution No. 46/2017:**

Approves the Social Action Policy and Implementation Strategy and revokes Resolution No. 12/98 of April 9.

## COUNCIL OF MINISTERS

### Decree No. 57/2017

#### of November 2<sup>nd</sup>

There being the need to redefine the nature, attribution, and competencies of the National Institute of Health to intensify the coordination, management, and realization of health research, under provision 1 of article 82 of Law No. 7/2012, of February 8, the Council of Ministers decrees:

#### Article 1 (Nature)

The National Institute of Health, abbreviated as (INS) is the entity for the management, regulation, and oversight of activities related to the generation of scientific evidence in health to guarantee better health and well-being, endowed with legal personality, with administrative and technical-scientific autonomy.

#### Article 2 (Scope and Headquarters)

1. The INS has its headquarters in the Province of Maputo, in the District of Marracuene, and carries out its activities throughout the national territory.
2. With the authorization of the Minister who oversees the health area, after hearing the Minister who oversees the area of finance and the Provincial Government, the INS may create and extinguish delegations or other forms of representation in any part of the national territory.

#### Article 3 (Guiding Principles)

Within the scope of its activities, INS is guided by the following specific principles:

- a) Excellence and continuous self-evaluation;
- b) Respect for human rights;
- c) Respect for codes of ethics and professional deontology;
- d) Transparency and accountability;
- e) Promotion of participatory management and innovation capacity;
- f) Universality and equity;
- g) Collective solidarity;



- h) Promotion of multi-sectoral and transdisciplinary exchange;
- i) Appreciation of national professionals, as well as national biological and cultural heritage.

#### Article 4 (Attributions)

The powers of the INS are:

- a) Preparation of policy and strategy proposals in the area of health research, ensuring their correct implementation, monitoring and periodic evaluation.
- b) Promotion of the development of health research at different levels of care to ensure a better definition of Health Policy and program management in order to provide a timely and effective response to health problems.
- c) Conducting clinical, biomedical, pharmacological, epidemiological, socio-anthropological and health-related research, based on national priorities.
- d) Contribution to the development, evaluation, and promotion of the use of appropriate health technologies.
- e) Contribution to the prevention and control of endemic and epidemic diseases, and to the management of special Public Health events.
- f) Contribution to the development of human resources, in particular in the technical-professional and scientific areas specific to Health.
- g) Carrying out the quality control of laboratory analyses through a laboratory reference system.
- h) Dissemination of information of a technical-scientific nature, for the scientific community, health workers, and the public in general.
- i) Implementation of Health Observations to document the Health Status of the Population and its Determinants.
- j) Formation of partnerships with other national and international institutions for the execution of research, training, and public health activities.

#### Article 5 (Competencies)

In order to fulfill its attributions, it is incumbent upon the INS to:

- a) Coordinate and oversee the definition of the national health research agenda and the application of it throughout the national territory;
- b) Promote and coordinate national health research development activities, in particular through institutional strengthening, the scientific training of national technicians and the monitoring of the research environment in the Health System;
- c) Develop clinical, biomedical, pharmacological, epidemiological, and socio-anthropological research, based on national priorities.
- d) Develop and conduct research in Health Systems as an instrument for the definition of health policies;
- e) Develop and guarantee multi-sectoral and transdisciplinary research, through related research institutions and other bodies of recognized competence.
- f) Promote funding for scientific research activities;
- g) Assess the health situation and its determinants;
- h) Develop and evaluate technologies applied to disease prevention and control;

- i) Contribute to laboratory diagnosis in the face of epidemic outbreaks;
- j) Carry out quality control of laboratory analyses through a laboratory reference system;
- k) Ensure biosafety aspects related to the operation of reference laboratories;
- l) Conduct postgraduate and continuing education courses for health personnel in coordination with the Ministries that oversee the areas of Education and Higher Education;
- m) Collaborate with teaching institutions in the training of health care personnel at medium and higher levels in coordination with the Ministry that supervises the area of Education.
- n) Cooperate with national and foreign scientific institutions and international development support agencies to promote technology transfer for the formation and training of national researchers and technicians;
- o) Promote actions of technical-scientific dissemination inherent in public health.

#### Article 6 (Tutelage)

1. The INS is supervised by the Minister who oversees the area of Health.
2. The guardianship includes, in particular, the power to authorize and approve the following acts:
  - a) Approval of INS Internal Rules;
  - b) Homologation of programs, activity plans, and annual reports;
  - c) Creation of forms of local representation;
  - d) Inspection of INS bodies, services, and documents;
  - e) Others resulting from the Law.

#### Article 7 (Directorate General)

1. The INS is headed by a Director General, assisted by a Deputy Director General, both appointed by the Prime Minister, on the proposal of the Minister overseeing the area of Health.
2. The Director-General and the Deputy Director-General shall serve for a renewable term of five (5) years.

#### Article 8 (Competencies of the Director General)

It is incumbent upon the Director General of INS to:

- a) Define the general direction of management and direct the activities of the INS, with the vision of realizing its attributions, reporting to the Minister of guardianship.
- b) Direct the activity of the external relations of the INS;
- c) Represent the INS in and out of court;
- d) Submit to the Minister of guardianship the plan and annual report of activities;
- e) Superintend the management of the human and financial resources of the INS;
- f) Appoint, dismiss, and discharge the heads of the central body, regional delegations, and other forms of local representation;
- g) Carry out the other duties assigned to him by the Minister of guardianship.

#### Article 9 (Competencies of the Deputy Director General)

The Deputy Director General shall:

- a) Under the guidance of the Director General, ensure technical and scientific coordination and integration of INS activities;
- b) Assist the Director General in the performance of his duties;
- c) Substitute for the Director General with his impediments, in accordance with the precedence he has defined;
- d) Exercise any other powers delegated to him by the Director General.

#### Article 10 (Bodies)

The INS has the following bodies:

- a) The Governing Board is the advisory and management body of the INS;
- b) The Consultative Council is the consultation and coordination body of the INS;
- c) The Technical-Scientific Council is the multi-sectoral consultation body of the Directorate General of the INS;
- d) The Institutional Scientific Committee is an advisory body to the Directorate General of INS, regarding the technical-scientific development of the institution;
- e) The Institutional Ethics Committee is a technical body that looks after the ethical aspects of the technical-scientific activities of the INS;
- f) The Institutional Biosafety Committee is a technical body that looks after the biosafety aspects of the technical-scientific activities of the INS.

#### Article 11 (Funding)

The following constitute the funding of the INS:

- a) Appropriations from the State Budget;
- b) Proceeds from the provision of services;
- c) Proceeds from the sale of publications edited by INS;
- d) Subsidies, donations, covenants, or liberalities attributed by any public or private entities, national or foreign;
- e) Any others resulting from the activity of the INS or that are legally awarded to it.

#### Article 12 (Expenses)

The following constitute expenses of the INS:

- a) Charges relating to operations;
- b) Costs resulting from the training and management of staff;
- c) Costs of acquiring, maintaining, and conserving goods, services, or facilities necessary for operations and the exercise of attributions.

#### Article 13 (Personnel)

The INS personnel are governed by the legal regime of the public function, but it is permissible to conclude labor contracts that are governed by the general regime, whenever this is compatible with the nature of the function to be performed.

#### Article 14 (Organic Statute)

It is the responsibility of the Ministry that oversees the area of Health to submit to the competent body the approval of the Organic Statute of the INS within a period of sixty (60) days from the date of publication of this Decree.

#### Article 15 (Implementation)

This Decree shall enter into force on the date of its publication.

Approved by the Council of Ministers on September 5, 2017.

Published.

The Prime Minister, *Carlos Agostinho do Rosario*.

#### **Resolution No. 46/2017**

**of November 2<sup>nd</sup>**

There being the need to redefine a normative legal framework that institutionalizes the general lines, philosophy, and strategy of the State in the field of social action in the country, according to item f) of No. 1 of Article 204 of the Constitution of the Republic, the Council of Ministers determines:

Article 1. The Social Action Policy and Implementation Strategy, which is an integral part of this Resolution, is hereby approved.

Article 2. Resolution No. 12/98, of April 9, is revoked.

Article 3. This Resolution shall enter into force on the date of its publication.

Approved by the Council of Minister on August 1, 2017.

Published.

The Prime Minister, *Carlos Agostinho do Rosario*.

## APPENDICES

### APPENDIX C. CASE STUDIES OF CREATING LEGAL FRAMEWORKS FOR NPHIS, AND THE RESULTANT LAWS, STATUTES, DECREES, OR REGULATIONS

#### C4. Nigeria Case Study and Law (Copy of Law pending, awaiting publication)

## CASE STUDY

### Case Series on Providing a Legal Framework for a National Public Health Institute:

#### The Nigeria Experience

#### Nigeria Centre for Disease Control (NCDC)

The NCDC was established in 2011 to improve Nigeria's preparedness to handle public health challenges and to optimize the use of public health resources. The value of having an NPHI was demonstrated during the 2014 response to the Ebola outbreaks. In 2017, a legal framework for NCDC was passed by the national legislature. It was signed by President Buhari in 2018. Because Nigeria is so large and populous, a decision was made to create a parastatal organization, which would be more nimble than a line agency within the Ministry of Health.

#### Critical Aspects of the Nigeria CDC Establishment Bill

The Bill establishes NCDC as a corporate body that has properties consistent with those of other corporations. NCDC is provided a wide range of critical roles. Prominent are issues related to communicable diseases and addressing acute public health threats, including leading Nigeria's implementation of the International Health Regulations. Examples of other functions given to NCDC include providing support to States and Local Governments, developing and disseminating public health research to inform policy and guidelines, and maintaining a network of reference and specialized laboratories. It can demand information, data, clinical samples, and reports on communicable and non-communicable diseases of public health relevance within Nigeria.

The NCDC is governed by a Board, with a Chair appointed by the President, and the Director General/Chief Executive Officer of NCDC serves as Secretary to the Board. The Director General is appointed by the President for a five-year term and is subject to the supervision of the Board and the Minister.

## CASE STUDY

### Legal Mechanism Used

The Nigeria CDC Establishment Bill was approved by the national legislature in 2017 and was signed into law in November 2018. Within the Nigerian lawmaking process, there are no Executive Branch options, such as decrees, as there are in other countries.

### Lessons Learned in Creating the Nigeria CDC Establishment Bill

- The NCDC began functioning in ways consistent with the Bill before it had been signed by the President. Staff were recruited and NCDC began conducting the functions described. Demonstrating effectiveness as an NPHI, even without an official legal framework, increases critical support for the NPHI's functions and for the creation of a legal framework.
- Input from stakeholders was very useful in the development of the Bill. For example, the decision to have NCDC be the International Health Regulations focal point was arrived at following widespread consultations, including with WHO.
- Because amending a law or decree can be very time-consuming, it may be better to leave vague such topics as the organizational structure or details of the Board's functioning so they can be easily modified as the country's or organization's needs change.
- Addressing overlap between functions of the NPHI and that of other organizations requires a great deal of discussion and consultation. Another difficult issue was clarifying at what point responsibility transfers from a previous organization to the newly created NPHI.
- NCDC has had support both from the Minister of Health, but also from the President. Having the President back the NPHI's creation can overcome otherwise difficult roadblocks.

We thank Dr. Chikwe Ihekweazu, Chief Executive Officer of Nigeria CDC, and Oyeronke Oyebanji, Technical Assistant to the Chief Executive Officer, for their assistance in developing this case study.