

Strengthening health research through policy reform: A survey of Sub-Saharan enabling legislation to coordinate national health research systems

Authors and Affiliations

Benjamin Mason Meier, JD, LLM, PhD
Department of Public Policy
University of North Carolina at Chapel Hill
Chapel Hill, North Carolina, USA

Joshua Davis, MPH
Carolina Population Center
University of North Carolina at Chapel Hill
Chapel Hill, North Carolina, USA

Montse Ferrer, JD
Cornell Law School, Ithaca, New York, USA

**Strengthening health research through policy reform:
A survey of Sub-Saharan enabling legislation to coordinate national health research systems**

Background: Clinical research is a critical component in the health agenda of developing country governments, serving as a springboard for the development of sustainable national health research systems to prevent disease and promote health. As countries develop policies to coordinate the multiple institutions governing research and to guide national health research systems—facilitating the benefits of foreign-sponsored research while regulating the research process—it is necessary to understand these bodies and how they are institutionalized through national law.

Methodology/Principal Findings: Through comparative policy analysis, this exploratory research surveys national health research system policies across Sub-Saharan Africa, categorizing health research bodies on the basis of their function in the governance of the national health research system. Identifying a trend toward coordination in health research systems and analyzing legislative efforts to enable national health research coordinating bodies, this study conceptualizes these new institutions for research coordination and discusses the best practices of these enabling laws.

Conclusions/Significance: With developing nations moving toward the codification of authority for national coordinating bodies, this comparative analysis proposes that legislative models be developed to structure national research coordination reforms – enumerating principles of such a model law to authorize coordinating bodies, outlining a template of key provisions to guide the development of enabling legislation, and providing a conceptual base for future research on coordinating institutions. Through multinational efforts to create model processes for foreign-sponsored research, this article concludes that the legislative authorization of such harmonized, predictable, and sustainable coordinating bodies could improve both the quantity and quality of research proposals and serve to heighten the national benefits of research while minimizing individual risks.

Keywords: national health research systems; health research coordinating bodies; public health policy reform; human subjects protection

I. Introduction

Foreign-sponsored clinical research has become a critical component of an expanding public health agenda in the developing world. To meet the requirements of international institutions, nongovernmental organizations, and multinational corporations, developing nations have been pressed to develop institutions to coordinate the review, approval, and monitoring of this research. Establishing governance for national health research systems, nations have sought to enact legislation to authorize these coordinating institutions for research regulation.

Surveying national health research policy across Sub-Saharan Africa, this article examines legislative efforts to enable coordinating bodies for national health research systems, conceptualizing these new institutions for research coordination, analyzing the best practices of these laws, and proposing principles for a model national law to enable health research coordinating bodies. This Introduction provides background on the public health benefits attained through coordination of national health research systems. Given this imperative for coordination, our Methods and Results sections survey current regulatory frameworks for health research governance, discussing distinctions between general and specific legislation to authorize institutions for coordinating health research systems. Analyzing the practices of these legal frameworks for health research coordinating bodies, our Discussion reviews the structures and features that have institutionalized regulatory pathways in strengthening systems for health research.

With this exploratory research finding that nations are moving toward the codification of authority for national health research coordinating bodies, these findings suggest that legislative models be developed to harmonize national research coordination efforts, with this article proposing a model law as an appendix to the present article to outline the key principles arising

out of the development of national legislation. Through ongoing multinational efforts to create uniform processes for foreign-sponsored research, this article concludes that such efficient, predictable, and transparent processes—if applied pursuant to legal authority—could serve to heighten the public health benefits of national health research systems, advocating additional research to clarify the institutional, procedural, and epidemiological outcomes of these coordination efforts

Background: Health research coordination in Sub-Saharan Africa

Clinical research is a critical component of the public health agenda, serving as a springboard for the development of sustainable national health research systems to prevent disease and promote health. However, ambiguities in national policy governing the review, approval, and monitoring of health research have created gaps in regulatory pathways, disrupting international research collaborations for country-relevant health research. As many developing nations seek to strengthen coordinating bodies to guide national health research systems, it is necessary to understand the policy landscape in which these coordinating institutions are being codified in national law.

A. Foreign-sponsored research in Sub-Saharan Africa

Developing nations have long served as sites for foreign-sponsored research. For the global research community, studies in developing nations are seen as less burdensome, with reduced costs, prevalent disease, and increased access to appropriate research subjects [1]. For the developing nation, increased health research is correlated with improved health outcomes, and there is widespread agreement that research capacity is essential to reducing global health inequities [2]. Given these prospective benefits to the researcher and the nation, Sub-Saharan

Africa has sought and seen an exponential increase in foreign-sponsored research in the past twenty years [3].

This foreign sponsorship is seen as necessary to develop research addressing the country-relevant health needs of Sub-Saharan Africa [4]. With Sub-Saharan nations contributing limited funding for health research (both absolutely and relative to overall health budgets), these nations continue to lack capacity for research to meet domestic public health priorities [5]. As evidence has pointed to a disequilibrium in global research expenditure—with only 10% of research dollars addressing the health needs of 90% of the world's people—the world's tradition of neglect for tropical disease has begun to change [6]. By highlighting this “10/90 gap,” global health governance has come to acknowledge the human rights and global justice implications of health research capacity. Responding to this through a budding series of short- and long-term international investments, African nations are developing the resources necessary for sustainable national health research systems [7].

These national health research systems—integrating research institutions for the improvement of public health [8]—are proving to be instrumental in structuring and maintaining the health benefits of foreign-sponsored research [9]. African states have looked to such systems to improve technical expertise, provide greater dissemination of research results, and create “centres of excellence” to compete independently for international research funding [10]. This capacity-building for clinical research, developed through international collaborations to address domestic priorities, has brought necessary financial, physical, and human resources to national researchers and health ministries, facilitating improvements in the public's health [11].

In spite of these advantages, further expansion of clinical research collaboration faces significant structural challenges in research governance, including opaque regulatory agencies,

complicated ethical review processes, and limited guidance for foreign researchers as they interact with domestic institutions. With many Sub-Saharan nations offering a wide range of uncoordinated regulatory institutions—differing sharply in member composition, scientific and ethics training, administrative infrastructure, funding schemes, review workload, and decision-making guidelines—foreign researchers have expressed frustrations with lengthy, inconsistent, unstructured, and at times corrupt approval processes [12]. Manifested most prominently in the protection of clinical research subjects, the existence of multiple independent research ethics committees in a single country has led to amorphous, shifting, and unpredictable ethical standards, with national approval often serving as a barrier to necessary research rather than a safeguard against harmful exploitation [13]. Foreign research sponsors have responded to these institutional hurdles by limiting their research investments in select countries [14].

To revitalize global development efforts to strengthen national capacity for the oversight of clinical research in Sub-Saharan Africa, the World Health Organization (WHO) began in the late 1990s to recommend that governments address the barriers faced by foreign-sponsored research, institutionalize research ethics committees to safeguard the rights of research subjects, and facilitate international partnerships reflective of country-relevant public health research priorities [15]. Through a succession of global health policy efforts, this strategy for health research (a strategy currently under revision) has come to emphasize the establishment of centralized coordination mechanisms for national health research systems [16].

B. Coordinating bodies for national health research systems

The creation of governance mechanisms to facilitate coordination among domestic review, approval, and monitoring institutions is viewed to be a necessary step to ensure the development of a sustainable national health research system. Through a single, unified national

health research coordinating body, such a consolidated bureaucracy can promote clinical research in the country, streamline protocol approval under national law, assure ethical compliance from foreign researchers, and facilitate international partnerships with domestic researchers.

A coordinating body for the national health research system provides nations with efficient avenues to host international clinical research projects and to translate research results into health policy, supporting the country-relevant benefits of foreign-sponsored research [17]. As a management structure to establish strategic planning, professionalized expertise, and capacity building for the regulation of research, such coordination mechanisms ensure staff training, improve oversight capacity, strengthen approval processes, encourage international collaborations, and disseminate research results [18]. Given authority to develop streamlined, predictable, and transparent processes, an independent coordinating mechanism is well positioned to provide comprehensive oversight in reviewing, approving, and monitoring research.

Additionally, coordinating bodies for the national health research system serve crucial functions in protecting individual rights – setting standards, granting authorizations, and evaluating operations for research ethics committees. Where the sharpest health inequalities often coexist in an environment conducive to violations of individual rights [19], there is a growing imperative to undertake clinical research with vulnerable populations [20]. While international research collaborations serve a crucial role in these disease prevention and health promotion efforts, the dangers posed by unethical research require that authorities not simply “rubber stamp” foreign research proposals to ensure international funding [21] but rather balance the risks and benefits of research, promote shared international responsibility, assure

confidentiality and access to care, and guarantee a right of informed consent [22]. By balancing the risks and benefits to the individual and community, coordinating bodies can structure research ethics committees to mitigate the risk of exploitation to vulnerable individuals (e.g., by harmonizing ethical standards and decision making processes across committees) while encouraging international research collaborations through predictable ethical standards.

Given the advantages of coordinating bodies in multi-stakeholder collaborations, the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) has required independent Country Coordinating Mechanisms (CCMs) to prepare program proposals and manage funded projects. Under the CCM model, Global Fund support is intended to reflect observed gaps in national strategic plans, create national ownership of projects, and set a participatory agenda best suited to the communities most heavily impacted [23]. To assure this coordinated governance among funding recipients, the Global Fund has established specific recommendations for CCM structures and functions, including representation from multiple stakeholders and enumerated procedures for meetings [24]. Where these institutions have been effective in overseeing projects sponsored by the Global Fund, nations would benefit if similar structures and functions were institutionalized in national health research policy. By creating legislation to codify such coordinating authorities—proscribing standards for the review, approval, and monitoring of research proposals—Sub-Saharan states can strengthen oversight of the health research system to promote country-relevant health research.

Legal institutionalization of coordinating bodies would improve collaboration between foreign and local researchers, harmonize processes for research oversight, and assure compliance with national and international ethical frameworks. Policy reform is seen to have normative power in framing the functions of health systems, altering institutions, constraining actions, and

facilitating accountability [25]. Where national health research policy is vulnerable to governmental priority-shifting, internal policy modifications, and institutional memory gaps, the promulgation of enabling legislation for independent coordination can avoid arbitrariness, increase efficiency, and promote stability in the approval process [26]. Such publicly-accessible laws can institutionalize transparent systems in national health research policy, allowing researchers to access what may appear to be an intricate regulatory framework for clinical trials [27]. Providing accountability in the national health research system, an enforceable national law that clarifies the structure and function of a health research coordinating body serves a larger movement toward global justice through health research.

II. Methods

By enabling coordinating bodies for health research systems through national law, Sub-Saharan African countries are pursuing the policy frameworks necessary to attract international research funding while addressing country-relevant health imperatives. Although many governments throughout Sub-Saharan Africa have authorized an evolving series of decentralized institutions to govern the national health research system, legislatures have recently begun to enact laws to consolidate these institutions through a singular health research coordinating mechanism. While others have discussed the need for this largely new and rapidly changing policy landscape, none has conceptualized these new institutions for research coordination or studied the comparative process, content, and effectiveness of these legislative efforts. To provide a conceptual base for understanding the current research coordination landscape, this exploratory research study conducted a comparative survey of national health research systems across Sub-Saharan Africa and a functional analysis of national health research coordinating bodies.

In this study of national health research systems, comparative policy analysis provides researchers with the opportunity to identify cross-national similarities in the policy development of national health research institutions and to understand salient distinctions across delineated functions of national health research systems [28]. The researchers identified information on each national health research system through a systematic search of publicly available internet resources (e.g., PubMed and Google Scholar), with all searches conducted independently by the researchers between November 2010 and March 2011. Identified on a country-by-country basis using keywords specific to “health research,” “research policy,” and “research system,” these searches resulted in a variety of documentary materials – including peer-reviewed articles, gray literature, and institutional websites. To confirm the validity and comprehensiveness of this publicly available documentation, the researchers complemented this systematic search with a series of semi-structured interviews with key stakeholders from national ministries, ethical review committees, and research institutions.

To compare these national health research systems across countries, it was necessary that facets of these systems be examined in accordance with a comparable set of policy functions [29]. Through thematic analysis of identified national health research policies [30], the researchers delineated seven key functions of national health research systems across Sub-Saharan Africa: 1) authorizing review committees, 2) monitoring and evaluating research programs, 3) coordinating and administering research funds, 4) serving as national forum on health research, 5) publishing information regarding health research, 6) connecting national and international health organizations, and 7) building capacity of the health research system. In accordance with this categorization, each identified national health research body was investigated—either through documentation or interview, researching the institution’s stated

mission, objectives, and activities—to identify how each institution functions as part of the larger national health research system.

Where national legislation had enabled a singular coordinating institution to oversee all these key functions, the researchers conducted a functional analysis to compare legal provisions across these health research coordinating bodies [31]. Examining national legislation that has codified either a general law to authorize a government ministry in coordinating research or a specific law to establish an independent health research coordinating body to oversee the review, approval, and monitoring of health research, this analysis looked to the institutional functions that have developed from these legal frameworks. Through this comparative analysis of national health research legislation and law reform efforts, researchers identified generalizable practices of health research systems, drew lessons for effective research system coordination, and identified facilitators of national policy reform.

III. Results

A. Survey – enabling legislative frameworks

While previous studies of African national health research systems found few regulatory bodies under respective ministries of health [32], this research finds that significantly more institutions exist, despite their lack of legal authorization, with these health research institutions identified by country in table 1 and categorized by the key functions common across health research systems:

[insert table 1 about here]

Of these myriad national health research institutions, developed overwhelmingly in countries home to foreign-sponsored clinical research, only four Sub-Saharan countries were found to have fully enabled health research coordinating bodies under national law. With this

movement toward coordination of national health systems rapidly evolving, table 2 outlines the scope and content of these published laws for national health research coordination.

[insert table 2 about here]

Although Sub-Saharan Africa possesses a wide diversity of institutions responsive to health research, these four specific laws are similar in scope and are designed as the by-laws or constitution of the health research coordinating body—including the institution’s structure and functions—following the design of analogous health system enabling legislation in countries as diverse as Australia, New Zealand, Peru, Venezuela, Brazil, and Russia.

B. Analysis – toward legal specificity

These laws that codify coordinating bodies for national health research systems in Sub-Saharan Africa have been designed in one of two forms: a general law that authorizes a government ministry to create coordinating institutions to promote research or a specific law that provides for the creation of an independent health research coordinating body.

General laws entail a single foundational legislative authorization, allowing for subsequent institutions to be created on an ad hoc or permanent basis depending on the needs of the authorized ministry. An example of a general law is Kenya’s 1977 Science and Technology Act, which created the National Council of Science and Technology as part of a larger ministry mandate to establish “machinery for making available to the Government advice upon all matters relating to the scientific and technological activities and research necessary for the proper development of the Republic and for the co-ordination of research.” Among divided parliaments, where legislation must reflect divided constituencies and entrenched interests, these general laws reflect constrained political feasibility in creating only a basic bureaucratic framework,

delegating expansive authority to the ministries to develop national health research policy without the need for subsequent legislation.

Specific laws, by contrast, authorize coordinating committees that are permanent and can be dissolved only by repealing or modifying the enabling legislation. For example, the 1990 Uganda National Council for Science and Technology Act incorporates the Council's by-laws, creating in legislation the (1) establishment, functions, and powers, (2) composition and meetings, and (3) specific committees of the Council. Similarly, Nigeria's 2008 National Health Bill institutionalizes the National Health Research Committee's (1) establishment, (2) composition, (3) tenure of members, (4) functions of sub-committees, and (5) relationship of the Committee with the Minister of Health. With greater legislative control, a specific law directly creates the institutions of national health research coordination, with the text of the enabling legislation explicitly codifying the objectives, membership, functions, internal structure, and processes of the health research coordinating body.

Although general laws have long provided national ministries with interpretive authority in the creation of policy—satisfying research needs as they arise, with legal flexibility crucial to changing imperatives—these laws have proven problematic where vague frameworks allow for arbitrariness, exploitation, and corruption through bureaucratic discretion. Obviating these opportunities for interpretive abuse, legislatures have codified specific laws to make any deviation from legislative intent clearly identifiable, with more transparent governance allowing governmental and nongovernmental observers to become aware of violations and inefficiencies. Thus, as specificity provides avenues for accountability—where external actors can more easily observe practices that would otherwise be inaccessible to them—specific laws have provided a more predictable framework for coordinating health research systems in Sub-Saharan African

countries. Where the priority for these countries is to facilitate domestic and international investment in country responsive research, a streamlined national process for the review, approval, and monitoring of research projects has ensured that such research system coordination is expansive, detailed, and leaves only limited room for interpretation. Reflecting these advantages, Kenya is taking steps to revise its 1977 Science and Technology Act to provide more specific legal authority to its National Council of Science and Technology. These reforms would bring Kenyan law in line with countries like South Africa, which explicitly grants its National Health Research Ethics Council the authority to regulate, approve, and monitor research ethics committees. Such a specific law—with distinct goals, regulatory limitations, and a clear mandate—would create a health research coordinating body capable of bringing together varied interests while satisfying national needs. Because this coordinating body would be difficult to modify or dissolve, the permanence, predictability, and transparency of such an institution would reassure the international and domestic researchers necessary to strengthen the national health research system.

III. Discussion: Key provisions of national health research coordination authority

Through comparative analysis of the enabling legislation for these national health research coordinating bodies and the multiple policies for other national health research institutions, the following sections delineate the practices that serve to mobilize resources, oversee protocols, disseminate results, and coordinate institutions. In order to frame national policies that will more effectively authorize coordinating bodies through national health research systems, the practices of these health research coordinating bodies will be addressed by examining their (a) governing organization, (b) functions, (c) size and makeup, (d) meeting logistics, and (e) criteria for review. This disaggregated analysis forms an empirical basis for the

identification of principles for model legislation that can assist countries in codifying appropriate national legislation to authorize research coordination efforts and can provide a conceptual base for future research to analyze the scope and content of law reforms.

A. Governing organization

National health research coordinating bodies can be supported organizationally by a combination of: government ministries (e.g., Ministry of Health); academic institutes (e.g., universities or private research centers); and private-public partnerships (e.g., the Global Fund). Although the coordinating bodies' structure and functions tend not to vary based on the governing organization, such supporting entities have an effect on an institution's membership and internal procedures [33]. Specifically, health research institutions sponsored by private-public partnerships tend to include members representing a wider array of government, civil society, and private institutions, whereas those sponsored by academic institutes or government ministries tend to be more limited in their membership. Further, the financing sponsor often determines the internal procedures of the research institution, including the degree of transparency in the consideration of research proposals.

Addressing the conflicting interests inherent in these governing organizations, many governments have sought to respond to concerns that external funding agents may create dependencies that influence the priorities of national health research institutions. In Cameroon, for example, the government has attempted to ensure legislatively that its Division of Health Operational Research can maintain independence in membership and procedures while remaining a government agency and retaining government funding. With Ghana creating an independent institutional structure through the Ghana Health Service, staff maintain a wider degree of managerial flexibility to carry out their responsibilities than would be possible if they

remained wholly within the civil service [34]. As an additional guarantee that sponsorship does not detract from independence, governments have often sought to incorporate in these institutions a strong international presence—in the form of an NGO or UN-based agency—to diversify funding sources and provide a balance to government power. Given the political implications of the governance structure, in particular the benefits that accrue to those assuming leadership over a health research coordinating body [35], collaborative relationships should be considered when developing policies that would centralize decision making – to assure ownership from the governing organization, allow independence through multiple sources of support, and to maintain “buy in” from existing actors in the health research system.

B. Functions

As states develop national health research policy to enable coordinating bodies, the functions of such coordinating bodies can draw on the delineated functions of national health research institutions, which vary by country and supporting entity but generally adhere to the key functions listed in Figure 1.

[insert Figure 1 about here]

Having surveyed these key functions through the national health research institutions detailed in Table 1, legislatures can select coordinating body functions that will lead to research responsive to the needs of the nation, focusing on the relevance of research to local populations and ensuring that foreign-sponsored research benefits domestic researchers and supports national health systems. In determining such functions under the Tanzanian health research system, the National Institute for Medical Research has established a national health forum that identifies country relevant research priorities and increases collaboration between previously independent research institutions, highlighting the main health and social problems in the country and

mobilizing coordinated research to address these problems [36]. Contrasted with the limited objectives of Uganda's National Council for Science and Technology, a coordinating body can serve simply as an informational clearinghouse – collecting and compiling information from research institutions and thereby allowing policymakers to examine approved protocols in setting national health research policy. Thus, when countries develop coordinating bodies that have clearly-defined objectives and comprehensive functions, the institution is better prepared to facilitate country relevant research, establishing specific practices to encourage the transparency, credibility, and efficiency necessary to realize the benefits of health research.

C. Size and makeup

To accomplish these functions, many international organizations seek to work with research institutions that possess a membership structure representing a diverse array of actors while still retaining a manageable number of individuals for effective leadership, decision-making efficiency and substantive expertise.

Balancing these membership imperatives, governments have developed varied frameworks to structure what type of leadership is necessary for effective governance of national health research institutions, including representation through:

- (a) An Executive Board;
- (b) A Secretariat; and
- (c) Committees (on such substantive topics as Monitoring & Evaluation of Projects, Internal Evaluation, Communication, Finance & Administration, Research Promotion, Information Technology, Public Relations, and Review & Selection).

With designated terms of reference for these leadership officers, internal procedures become necessary to create efficient communication among the full membership and to structure the

institution to be of a manageable size for centralization, management, and coordination at all levels – ranging in size from 10 members (e.g., Medical Research Council of Zimbabwe) to 30 members (e.g., National Council of Science and Technology in Kenya).

In assuring a distribution of interests within this limited group, health research coordinating bodies must look to institutionalized representation from a diversity of sectors, constituencies, and perspectives, creating a balanced partnership among all relevant sectors of society through guidelines that specify selection processes and rules for constituency representation. With diversity of institutional perspectives shown to improve functioning, limit corruption, and increase credibility, the involvement of affected individuals and communities provides the national health research system with experiences and expertise from those most directly involved in research while redefining the relationship between government and civil society [37]. Yet despite consensus on the benefits of diverse representation, few national health research institutions are composed of multi-sectoral representatives – including government ministries, civil society, international NGOs, and pharmaceutical companies. For example, institutions sponsored by educational institutes, such as the Noguchi Memorial Institute for Medical Research at the University of Ghana, include mostly professors and researchers, while government-sponsored coordinating bodies, such as the Health Research Unit at the Ministry of Health in Botswana, include mostly government officials [34]. This skewed membership (whether general or specific) has distorted national research priorities where interested parties dominate the institution and exercise predominant control over its agenda [12]. Looking to alleviate such disproportionate representation, Zambia has legislatively-mandated the distribution of the National Science and Technology Council's thirteen appointed members: two from a research institute; two from a university; one from a technical college; one engineer from

industry; one businessperson in the private sector; and one from each of the ministries responsible for science and technology, environment and natural resources, health, commerce and trade, agriculture and mines. To avoid representation distortions within national health research coordination bodies, it is necessary to institutionalize diversity, with an equitable number of distributed parties representing each affected sector and constituency [38].

D. Meeting logistics

To establish credibility for research coordination, functioning coordinating bodies would emphasize the need to meet regularly, in particular during the first years of operation. Although the number of meetings will vary depending on the coordinating body, legal minimums for other national health research institutions are often set at one meeting per month for the Executive Board, regular meetings for the standing and/or temporary committees, and daily operation of the Secretariat. In crafting such meeting requirements in policy, it is important to consider whether any of the meetings will be open to the public or will invite experts to address specific issues relevant the substantive issues of the meeting's agenda [39]. Evidence from research institutions has developed that open and public meetings are important in allowing for (1) wider dissemination of public information, (2) greater access from civil society actors who have no formal representation, (3) improved transparency, (4) enhanced oversight through external checks, and consequently, (5) increased legitimacy as a public institution [40]. Although diminished confidentiality and potential conflicts may discourage public access to the institution meetings, governments have developed meeting designs to alleviate these problems by opening only select meetings/issues to the public and allowing opposing interests to inform the institution on issues while not participating in internal decisions.

E. Criteria for review

Finally, in order to evaluate research proposals on scientific and ethical grounds, governments could establish coordinating bodies with a formal, codified set of criteria and scoring system to select the health research proposals that will be approved – either by the coordinating body itself or through authority delegated to autonomous research institutions [41]. In doing so, reviewing institutions are often authorized, either through law or regulation, to take into consideration the following as possible criteria for review:

- (1) Effect on national population and resources;
- (2) Feasibility with respect to implementation plan and management;
- (3) Potential for sustainability;
- (4) Relevance to the health needs of the local population
- (5) Ethical propriety, based on internal and national ethical criteria; and
- (6) Government relationship, if any, with applying entity.

However, the substantive criteria and application procedures for protocol evaluation must be standardized, particularly if such review is undertaken by multiple research institutions, with training and oversight to assure that scientific and ethical review is carried out consistently across the nation [42]. For example, South Africa's National Health Act created the National Health Research Ethics Council, which is charged with setting standards for all independent research ethics committees in the country as well as auditing new and existing committees for compliance with national regulations [43]. By structuring the decision-making of research institutions, formalizing authorities between the national coordinating body and research institution review, it is expected that approved research proposals would be more responsive to country relevant research priorities and protective of the individual rights of research subjects.

Conclusion

Enabling legislation has clarified the structure and function of coordinating bodies for the national health research system. By institutionalizing the scope, content, and process of research review, approval, and monitoring, Sub-Saharan African states can improve both the quality and quantity of international health research, strengthening research regulation as a means of promoting public health. To assure the country relevant benefits of such research—to national systems, clinical researchers, and individual subjects—national health research systems can develop harmonized, streamlined, and transparent research oversight processes – codified in national law and operationalized through a health research coordinating body.

Given a movement toward legislative institutionalization of the health research system across Sub-Saharan Africa, a model law of best practices would improve the authorities of national coordination bodies to assure public health benefits, supporting national legislators in establishing regulatory frameworks to coordinate the national health research system. To achieve imperatives for predictability and consistency in foreign-sponsored research, this research has outlined model legislative principles reflective of national efforts to develop health research coordinating bodies. While these model principles are neither sufficiently detailed nor appropriately relativistic for each nation in Sub-Saharan Africa, this model language—included in the following appendix—may form the basis of preliminary negotiations, bringing together national stakeholders to coordinate health research, catalyzing international discussions on health research systems, and facilitating policy research on the outcomes of these coordination efforts.

Acknowledgments

The authors are grateful to Josh Lewis and Glenn McLaurin for their helpful assistance in carrying out this research and to Stuart Rennie for his thoughtful comments on early drafts of this article.

References

1. Macklin R (2004) Double standards in medical research in developing countries. Cambridge: Cambridge University Press.
2. World Health Organization (2004) World report on knowledge for better health: strengthening health systems. Geneva: World Health Organization.
3. Whitworth JAG, Kokwaro G, Kinyanjui S, Snewin VA, Tanner M, Walport M, Sewankambo N (2008) Strengthening capacity for health research in Africa. *Lancet* 372: 1590-1593.
4. Commission on Health Research for Development (1990) Health research essential link to equity in development. Oxford: Oxford University Press.
5. Nchinda TC (2002) Research capacity strengthening in the South. *Social Science and Medicine* 54: 1699-1711.
6. Global Forum for Health Research (1999) The 10/90 Report on health research 2000. Geneva: GFHR.
7. Abrahams N, Adhikari R, Bhagwat IP, Christofides N, Djibuti M (2004) Changing the debate about health research for development. *Journal of Public Health Policy* 25: 259–287.
8. World Health Organization (2001) National health research systems: report of an international workshop. Geneva: World Health Organization.
9. Ijsselmuiden C, Matlin SA, Maïga AH, Hasler J, Pannenberg O, et al. on behalf of the Steering Committee of the 2008 Global Ministerial Forum on Research for Health (2008) From Mexico to Mali: a new course for global health. *Lancet* 371: 91-93.
10. Edejer TTT (1999) North-South research partnerships: the ethics of carrying out research in developing countries. *Brit Med Jour* 319: 438-441.

11. Lansang MA, Dennis R (2004) Building capacity in health research in the developing world. *Bulletin of the World Health Organization* 82 (1): 764-770.
12. Kass NE, Hyder AA, Ajuwon A, Appiah-Poku J, Barsdorf N, et al. (2007) The structure and function of research ethics committees in Africa: A case study. *PLoS Medicine* 4(1): e3.
13. Nyika A, Kilama W, Chilengi R, Tangwa G, Tindana P, et al. (2009) Composition, training needs and independence of ethics review committees across Africa: Are the gate-keepers rising to the emerging challenges? *Journal of Medical Ethics* 35: 189-193.
14. Coleman CH, Bouësseau MC (2008) How do we know that research ethics committees are really working? The neglected role of outcomes assessment in research ethics review. *BMC Medical Ethics* 9:6.
15. Pang T, Sadana R, Hanney S, Bhutta ZA, Hyder AA, et al. (2003) Knowledge for better health – a conceptual framework and foundation for health research systems. *Bull World Health Organization* 81: 815-20.
16. Røttingen JA, Buss PM, Davies S, Touré O (2009) Global-health research architecture: time for mergers? *Lancet* 373: 193-195.
17. Hadding SR, González Block MA (2006) Building health research systems to achieve better health. *Health Research Policy and Systems* 4:10.
18. D’Souza C, Sadana R (2006) Why do case studies on national health research systems matter? Identifying common challenges in low- and middle-income countries. *Social Science & Medicine* 62 (8): 2072-2078.
19. Beyrer C, Kass NE (2002) Human rights, politics, and reviews of research ethics. *Lancet* 360: 246–51.

20. Benatar SR (2002) Reflections and recommendations on research ethics in developing countries. *Social Science & Medicine* 54: 1131-1141.
21. Milford C, Wassenaar D, Slack C (2006) Resources and needs of research ethics committees in Africa: preparations for HIV vaccine trials. *IRB: Ethics and Human Research* 28: 1-9.
22. Emanuel EJ, Wendler D, Killen J, Grady C (2004) What makes clinical research in developing countries ethical? The benchmarks of ethical research. *Journal of Infectious Disease* 189: 930-937.
23. The Global Fund to Fight AIDS, Tuberculosis and Malaria (2008) Lessons learned in the field, health financing and governance: A report of the country coordinating mechanism model. Geneva: Global Fund. Available: http://www.theglobalfund.org/documents/publications/other/CCM/CCM_report.pdf. Accessed 4 March 2011.
24. The Global Fund to Fight AIDS, Tuberculosis and Malaria (2003) Guidelines on the purpose, structure and composition of country coordinating mechanisms. Geneva: Global Fund. Available: http://www.theglobalfund.org/documents/5_pp_guidelines_ccm_4_en.pdf. Accessed 4 March 2011.
25. Swanson RC, Bongiovanni A, Bradley E, Murugan V, Sundewall J, et al. (2010) Toward a consensus on guiding principles for health systems strengthening. *PLoS Medicine* 7(12): e10000385.
26. Gostin LO (2008) *Public health law: Power, duty, restraint*. Berkeley: University of California Press.
27. Maïga D, Akanmori BD, Chocarro L (2009) Regulatory oversight of clinical trials in Africa: Progress over the past 5 years. *Vaccine* 27: 7249-7252.

28. Marmor T, Freeman R, Okma K (2005) Comparative perspectives and policy learning in the world of health care. *J Comparative Policy Analysis* 7: 331-348.
29. Murray CJL, Frenk J (2000). A framework for assessing the performance of health systems. *Bull World Health Organ* 78(6): 717-731.
30. Leichter HM (1979). A comparative approach to policy analysis: Health care policy in four nations. Cambridge: Cambridge University Press. 327 p.
31. Michaels R (2006). The functional method of comparative law. In: Reimann M, Zimmermann R, editors. *The Oxford handbook of comparative law*. Oxford: Oxford University Press. pp. 339-382.
32. Kirigia JM, Wambebe C (2006) Status of national health research systems in ten countries of the WHO Africa Region. *BMC Health Services Research* 6: 135.
33. Alger J, Becerra-Posada F, Kennedy A, Martinelli E, Cuervo LG (2009) Sistemas nacionales de investigación para la salud en América Latina: una revisión de 14 países. *Rev Panam Salud Publica* 26: 447-457.
34. Tindana P, Boateng O (2008) The Ghana experience. *Journal of Academic Ethics* 6: 277-281.
35. Palmer A, Anya SE, Bloch P (2008) The political undertones of building national health research systems – reflections from The Gambia. *Health Research Policy and Systems* 7:13.
36. Kitua AY, Mashalla YJS, Shija JK (2000) Coordinating health research to promote actions: The Tanzanian experience. *BMJ* 321: 821-823.
37. Barry SP, Diarra-Nama AJ, Sambo LG, KirigiaJM, Bakeera S (2009) A review of national health policies in seven countries in the WHO African Region. *East African Medical Journal* 86: S3-S7.

38. Brugha R, Donoghue M, Starling M, Ndubani P, Ssengooba R, et al. (2004) The global fund: Managing great expectations. *Lancet* 364: 95-100.
39. Madan T (1987) Community involvement in health policy: socio-structural and dynamic aspects of health beliefs. *Social Science & Medicine* 25: 615-620.
40. Lurie P, Zieve, A (2006) Sometimes the silence can be like the thunder: Access to pharmaceutical data at the FDA. *Law and Contemp Probs* 68: 85-97.
41. Onyemelukwe C (2008) Research involving humans in African countries: A case for domestic legal frameworks. *African Journal of International and Comparative Law* 16: 152-177.
42. Bartlett EE (2008) International analysis of institutional review boards registered with the U.S. Office for Human Research Protections. *Journal of Empirical Research on Human Research Ethics* 3: 49-56.
43. Stroud A, Slack C, Mushariwa M (2005) HIV vaccine research – South Africa’s ethical-legal framework and its ability to promote the welfare of trial participants. *South African Medical Journal* 95: 598-601.

Appendix: Model law for national health research coordination- National Health Research Council Act

Chapter 1. DEFINITIONS, ESTABLISHMENT, HEADQUARTERS & OBJECTIVES

Article 1

This Act may be cited as the National Health Research Council Act.

Article 2

- (a) This Act establishes the National Health Research Council (Council)
- (b) The headquarters of the Council is in the capital [or alternative city] of [Country].
- (c) Upon request by the Executive Board, a ministerial order of the Supervising Minister shall establish representatives of the Council in other parts of the country.

Article 3

- (a) The functions of the Council shall include:
 - (1) reviewing and approving applications from institutions wishing to house review bodies
 - (2) monitoring and evaluating research programs
 - (3) coordinating and administering research funds
 - (4) serving as national forum on health research
 - (5) publishing information on health research

- (6) maintaining relationships with national and international health organizations

Chapter 2. MEMBERSHIP & ORGANS OF ADMINISTRATION

Article 4

(a) The Council shall be composed of the following organs:

- (1) Executive Board;
- (2) Secretariat; and
- (3) Committees.

Article 5 - The Executive Board

The Executive Board shall take all decisions relating to its functions detailed in the Act.

Article 6 - Functions

(a) The Board shall have the following functions:

- (1) to monitor the implementation of the Council's objectives;
- (2) to advise Government on policies and programs relating to health research capacity building;
- (3) to monitor and evaluate research programs based on the Council's goals and objectives;
- (4) to approve the appointment of the members of staff who are not appointed by any other organs;
- (5) to approve the appointment of technical experts and their remunerations;
- (6) to examine and approve annual plan of actions and budget for the Council;
- (7) to examine and approve annual activity and financial reports;

Article 7 - Membership

(a) The membership of the Board shall consist of no more than twenty-five (25) members and no less than fifteen (15) members, appointed by the Minister. Each member shall serve a term of office of three years, with a possibility of renewal.

(b) The membership shall be composed roughly of:

- (1) 30% government officials;
- (2) 25% civil society representatives;
- (3) 20% development partners;
- (4) 10% academic and research institutions;
- (5) 15% private sector.

(c) The membership shall include a Chairperson, a Vice-Chairperson, and an Executive Secretary.

(d) The Executive Board shall have the power to remove the Chairperson and Vice-Chairperson from office before expiry of their terms of service on the basis of incompetence.

(e) Upon request of one third (1/3) of its members, the Board may decide to remove the Chairperson or the Vice-Chairperson from office.

Article 8 - Meetings

(a) Meetings of the Board shall be held at least once every three months as well as whenever deemed necessary.

(b) The ordinary Board meeting shall be convened by a written notice ten (10) business days before the date of holding the meeting and shall be presided over by the Chairperson. Notice of the time, place, and the agenda of every meeting of the Board shall be served by the Executive Secretary on every member of the Board, either personally or by delivering to his or her principal place of residence or business.

- (c) In case of his or her absence, the Chairperson shall be replaced by the Vice-Chairperson.
- (d) In the event the Chairperson or the Vice-Chairperson do not convene the meeting as required under the law, it shall be convened and presided over by a member of the Board upon request by the Board's members.
- (e) There shall be an open national forum of all stakeholders to be held at least once a year to disseminate information on the activities of the Council.
- (f) Non-Council members from various constituencies may be admitted as observers at quarterly Council meetings.

Article 9- The Secretariat

The day-to-day administration of the Council shall be ensured by the Secretariat.

- (a) The Secretariat shall function:
 - (1) to assist the Board in monitoring and evaluating research proposals;
 - (2) to coordinate efforts and communication with donors, development partners, civil society institutions, business partners, health organizations and any other entity that is relevant to the Council's work;
 - (3) to prepare and organize health research events for the general public;
 - (4) to administer the process of evaluating research proposals.

Article 10

- (a) The Chief Executive Director shall have the following specific duties:
 - (1) to monitor the implementation of the Council's objectives;
 - (2) to monitor the day-to-day management of the Council's assets, finances and human resources;
 - (3) to implement decisions taken by the Board;

- (4) to serve as Executive Secretary to the Board, and as such, prepare the Board's meeting minutes;
- (5) to prepare the Council's strategic plan, annual action plan, and budget and to submit these to the Board for approval;
- (6) to prepare annual activity and financial reports for the Council;
- (7) to serve as a legal representative of the Council;
- (8) to represent the Council in national and international fora;
- (9) to carry out any other duties related to the mission objectives of the Council, as assigned to him or her by the Board of Directors.

Article 11 – Committees

The Council shall set up standing technical committees, organizational committees and/or temporary committees, as needed.

(a) Standing Committees

- (1) Steering
- (2) Research
- (3) Health Sciences

(a) Each Committee shall have no more than ten members.

(b) Each Committee shall have a Chair, who shall be the chief administrative officer of that Committee.

(c) Each Committee Chair shall be chosen by the Executive Board by a two-thirds vote.

Article 12 - Ethics Committee

(a) The Council shall create an Ethics Committee within the Health Sciences Committee that is responsible for reviewing and monitoring the ethical implementation of national public health research.

(b) Specifically, the Ethics Committee will:

- (1) Determine national health research priorities
- (2) Review applications from institutions wishing to house a Research Ethics Committee
- (3) Award research grants
- (4) Present relevant policy position papers to the Council
- (5) Document on-going and previously completed research
- (6) Report research results to policy makers

(c) In regards to (2), the committee shall establish clear and transparent instructions and requirements for institutions applying to house a Research Ethics Committee. These instructions along with an application form will be easily available. The deliberation on specific applications will be open to the public and the notes of said discussions a matter of public record.

Chapter 3. INTERNAL PROCEDURES

Article 13 - Criteria for Approval of Research Proposals

(a) The Executive Board shall decide what procedure is appropriate to approve research proposals.

(b) The criteria for approval of research proposals must be made public.

Chapter 4. FINAL PROVISIONS

Article 14

This Act may be modified only by Parliament.

Article 15

All previous legal provisions contrary to this law are hereby repealed.

Article 16

This law comes into force from the day of its publication in the official national *Gazette*.

Figure Legend

Table 1 – National Health Research Institutions

Table 2 – National Health Research Coordinating Bodies

Figure 1 – Functions of National Health Research Coordinating Bodies