



ENHANCING RESEARCH ETHICS REVIEW SYSTEMS IN EGYPT: THE FOCUS OF AN INTERNATIONAL TRAINING PROGRAM INFORMED BY AN ECOLOGICAL DEVELOPMENTAL APPROACH TO ENHANCING RESEARCH ETHICS CAPACITY

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Abstract

Recently, training programs in research ethics have been established to enhance individual and institutional capacity in research ethics in the developing world. However, commentators have expressed concern that the efforts of these training programs have placed “too great an emphasis on guidelines and research ethics review”, which will have limited effect on ensuring ethical conduct in research. What is needed instead is a culture of ethical conduct supported by national and institutional commitment to ethical practices that are reinforced by upstream enabling conditions (strong civil society, public accountability, and trust in basic transactional processes), which are in turn influenced by developmental conditions (basic freedoms of political freedoms, economic facilities, social opportunities, transparency guarantees, and protective security). Examining this more inclusive understanding of the determinants of ethical conduct enhances at once both an appreciation of the limitations of current efforts of training programs in research ethics and an understanding of what additional training elements are needed to enable trainees to facilitate national and institutional policy changes that enhance research practices. We apply this developmental model to a training program focused in Egypt to describe examples of such additional training activities.

Keywords

research ethics; Egypt; research ethics committees; developmental freedoms; organization systems theory

INTRODUCTION

In order to improve global health and health equity, significant changes need to be made to address the inequitable sharing of resources between the Global North and South. Representing the world’s wealthiest economies, the Global North has historically determined the course of research and innovation in international health. For example, the 2000 Global Forum on Health Research 10/90 Report revealed that 90% of global research expenditures target only 10% of the global burden of disease¹. To address this gap, the

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Global South has recently intensified its research activities; however, the capability for protecting human research subjects and the establishment of fully functioning ethics review systems have not increased proportionately in low and middle income countries (LMICs)², including those in the Middle East³.

To help develop individual and institutional capacity in research ethics, several training programs established during the past decade have provided training in research ethics to individuals from LMICs⁴. These programs primarily focus on enhancing the skills of individuals to be ethicists, educators, and researchers to help guide the conduct of research between global partners. For example, the Fogarty International Center of the National Institute of Health in the United States sponsors over twenty programs in international research ethics education⁵. Recently, several commentators have expressed concerns that the capacity building efforts of these training programs place too great an emphasis on promoting guidelines and enhancing research ethics review, which by itself will have limited downstream effects on ensuring ethical conduct in research⁶. What is needed instead is a culture of ethical conduct supported by national and institutional commitment to ethical practices that are reinforced by upstream enabling conditions (strong civil society, public accountability, and trust in basic transactional processes), which are in turn influenced by developmental conditions (basic freedoms of political freedoms, economic facilities, social opportunities, transparency guarantees, and protective security)⁷. Examining this more inclusive understanding of the determinants of ethical conduct enhances at once both an appreciation of the limitations of current efforts of training programs in research ethics and an understanding of what additional training elements are needed to enable trainees to facilitate national and institutional policy changes that enhance research practices. The task before us involves specifying how research ethics training programs can help trainees achieve these kinds of policy changes in their respective institutions and countries. As such, our aim in this paper is to develop recommendations that will enable an NIH-sponsored research ethics training program focused in Egypt impart to its trainees the necessary skills to achieve these goals.

ANALYTIC APPROACH

To develop recommendations regarding the future directions for trainee development, we need to delineate the existing gaps in research ethics that fosters impediments to ethical research conduct. This knowledge will help define what additional activities trainees need to undertake, which will then make clear the requisite skills they need to take on these activities. As such, the analytic approach of this case study consisted of the following steps: 1) review of a developmental model for research ethics systems; 2) examination of the current state of developmental and enabling conditions in Egypt; 3) evaluation of the status of the ethics review system that exists in Egypt within the framework of a developmental model; and, against this background; 4) examination of the current capacity building efforts of the Fogarty-sponsored Middle East Research Ethics Training Initiative (MERETI) to determine additional training activities that will help trainees target the foundational basis of ethical conduct in research.

DEVELOPMENTAL MODEL OF ETHICS REVIEW SYSTEMS

Both Lavery and Hyder emphasize that guidelines and research ethics review are alone insufficient to protect human subjects involved in research⁸. What is needed instead is a country's ability to establish a sustainable culture of ethical conduct in research that is "necessary for guidelines and research ethics review to function as intended"⁹. To unpack this concept, we use an ecological model adapted from the framework developed by Lavery and Hyder. This model includes the following domains listing in hierarchical order in terms of influence on ethical culture: developmental freedoms, enabling conditions, national strategy, institutional commitment, research ethics committee (REC) capacity, investigators' knowledge and attitudes regarding research ethics, and patients' knowledge of their rights as research participants. Items toward the lower end of the list, e.g., REC capacity and investigators' conduct, which are the usual focus of a research ethics training program, are dependent upon the stage of a country's development and enabling conditions that create a necessary "receptive environment" for a national strategy, which in turn, can influence an institution's commitment for ethical conduct in research.

The developmental conditions in this ecological framework are adapted from Amartya Sen's "basic freedoms" and serve as the foundational context surrounding the research ethics system¹⁰. These conditions include political freedoms, economic facilities, social opportunities, transparency guarantees, and protective security. Political freedoms encompass free participation in political processes, free elections, freedoms of expression and belief, free assembly, uncensored press, and opportunities for critique and dissent of authorities. Economic facilities enable opportunities for economic exchange of all kinds and the enabling powers of incomes and wealth in a society. Social opportunities refer to arrangements for education, health care and related opportunities, which influence individuals' abilities to live a better life and for effective participation in economic and political activities. Transparency guarantees represent mechanisms to minimize corruption and abuse of power. Finally, protective security refers to social and institutional arrangements that provide a social safety net to prevent the affected population from extreme poverty. All of these freedoms paint a picture of a country's current development structure and foster the enabling conditions that include a strong civil society, a climate of public accountability, and trust in basic transactional processes.

These enabling conditions allow a national strategy to develop and encourage an institutional commitment, both of which can enhance scrutiny, transparency, and accountability in research. A national strategy for research ethics includes legislation and guidelines for the ethical conduct of research, laws protecting research participants and their rights, regulatory bodies that provide oversight of research conduct including sanctions to achieve compliance with regulations, and a budget priority for capacity building in research and research ethics. Institutional commitment consists of the necessary set of structures and procedures that enable appropriate ethics review and emphasize ethical conduct within the institution. Examples includes a) policies that ensures the independence of research ethics committees and legitimizes the authority of the REC to approve, modify, and deny research; b) policies that monitor conflicts of interest; c) budget priority for ethics review; and d) monitoring of research attached with corrective actions. The effectiveness of both the

national strategy and an institution's commitment is ultimately manifested in the quality of the ethics review system and the attitudes and behaviors of investigators towards the research ethics system.

APPLICATION OF THE DEVELOPMENTAL MODEL AS APPLIED TO EGYPT TO UNCOVER GAPS IN RESEARCH ETHICS CAPACITY

1. Developmental Freedoms

In applying our ecological model to the current capacity of Egypt's research ethics system, Table 1 shows several indices that convey a comprehensive measure of Egypt's level of development. These indices relate to several of Sen's developmental freedoms that include political freedoms, economic facilities, and social opportunities. Regarding political freedoms, Egypt is characterized politically as "Partly Free" by Freedom House, an NGO that conducts an annual "Freedom in the World" survey¹¹. Despite the recent Arab Spring, recent events demonstrate that Egypt continues to be in a state of flux, as it faces continued concerns with political corruption, lack of transparency, restriction on speech and assembly, and continued censorship.

The Human Development Index (HDI) represents a composite index of three basic dimensions of human development: a long and healthy life (life expectancy); access to knowledge (mean years of schooling); and standard of living (Gross National Income (GNI) per capita)¹². The HDI represents a broader measurement of well-being than previous measures of national development, such as rate of economic growth and level of income. Egypt's HDI value for 2012 stands at 0.662, positioning the country at a rank of 112 out of 187 countries and is considered within the medium human development category. Egypt's HDI has risen by 2.1% annually during the past decade (from 0.407 to 0.662) and is slightly above the average of 0.64 for the other countries in the medium human development group and above the average of 0.652 for countries in the Arab Region¹³. Table 1 also displays each of the individual HDI indicators. Currently, the World Bank places Egypt among the middle-income economies¹⁴.

A drawback of the HDI is that it masks inequality in the distribution of human development across the population at the country level. Accordingly, the HDI can be viewed as an index of 'potential' human development and the actual state of development would need to be adjusted downward by the state of inequality. An important contribution to inequality is that related to gender. The Gender Inequality Index (GII) reflects women's inequalities in three dimensions: reproductive health, empowerment and the labor market. The GII is designed to reveal the extent to which human development is eroded by gender inequality and to provide empirical foundations for policy analysis and advocacy efforts¹⁵. Egypt fares on the lower end of the inequality index with a score of 0.590, which represents a loss of 11% due to inequality from the unadjusted HDI score of 0.662¹⁶. Women participation in the labor market is 23.7 percent compared to 74.3 for men (ratio = 0.319) and women hold only 2.2 percent of parliamentary seats. In general, these indices show discernible deficiencies in Egypt's state of human development.

2. Enabling Conditions

The states of development influence the extent of Egypt's enabling conditions, including a strong civil society, public accountability, and trust in basic transactional processes. Egyptian civil society has been growing steadily in recent years, but is experiencing dramatic new opportunities as well as challenges in the evolving context of the "Arab Spring". In addition to the external pressure of the still complex legal and regulatory environment in which civil society operate, organizations face internal challenges as well. For example, the sector is highly fragmented with weak structures, limited financial resources, weak management skills, an absence of transparency and accountability, a lack of internal democratic governance, and insufficient technical know-how and professional staff capacity¹⁷.

Egypt also maintains a low score in the Freedom of the Press index (158th), largely due to "legal voids, arbitrary appointments of state media chiefs, physical attacks, and trials and a lack of transparency"¹⁸. Finally, the Corruption Perception Index (CPI) provides a rough estimate of perceived corruption in the public sector and currently, Egypt holds a score of 32 on a scale of 0–100 (0 being the most corrupt), which ranks Egypt #118 out of 176 countries¹⁹.

3. National Capacity and Strategy

Presently, Egypt does not have national legislation that specifically addresses research ethics. The previous constitution included a provision regarding the obtainment of informed consent in research²⁰. A regulatory structure exists within the Central Directorate of Research and Development, but until now has not established a system for monitoring the practices of RECs. The conduct of research is routinely monitored through regular quarterly reports that are submitted to the National Research Ethics Committee of the Central Directorate, but this applies only to clinical trials sponsored by pharmaceutical companies and implemented in governmental health institutions. There is no formal link between this regulatory body and with research conducted at universities and research centers. As such, the National Research Ethics Committee does not monitor investigator- sponsored clinical trials and observational studies conducted in university hospitals.

Following the 25 January 2011 uprising that toppled the Mubarak regime in Egypt, there were appeals from academia to increase Egypt's limited science annual research budget. Over the following two years it rose from 0.25% to 0.4% of GDP, reaching a total of 1.3 billion Egyptian pounds (~US\$186 million). However, in 2013 the Ministry of Scientific Research returned 82% of the annual budget unspent, which will have the effect of reducing future annual budgets²¹.

4. Institutional Commitment

An institutional commitment to research ethics would be manifested by a set of structures and processes that enables appropriate ethics review and promotes ethical conduct²². A recent study involving Egyptian RECs showed that institutional commitment is lacking, as measured by the extent to which institutions have developed policies for conflicts of

interests, support investigator training in research ethics, and provides resources to support their RECs²³.

5. Functioning of RECs and Investigator's Conduct

The success of an institution's infrastructure in promoting a research ethics culture can be reflected by two outcomes: 1) the functioning of their RECs and 2) investigators' knowledge, attitudes, and practices regarding research ethics. Regarding RECs, Egypt currently has more than 40 RECs, many of which are registered with the U.S. Office of Human Research and Protections²⁴. A recent survey showed that approximately two-thirds have been in existence for two or more years and more than three quarters meet at least once a month²⁵. Studies exploring the capacity of these RECs have shown challenges to their effective functioning, which include the lack of national ethics guidelines, chairs and members of some RECs without training in research ethics, inadequate member diversity, and shortages of human and capital resources²⁶. Finally, a recent study using an REC self-assessment tool showed that as a group, Egyptian RECs require further enhancements to meet suggested international standards²⁷.

Regarding investigators' conduct, Egypt and other countries in the Middle East struggle with suboptimal investigator compliance with informed consent, submission of protocols to RECs, and practices regarding confidentiality²⁸. Several studies have explored the knowledge, attitudes, and prospective behaviors of investigators²⁹. These studies demonstrate that many investigators have not received any training in research ethics. Regarding attitudes, many Egyptian faculty believe that a review by an ethics committee would delay research, be more costly, and make research more difficult to perform³⁰, demonstrating an attitudinal barrier for research ethics system support. Another survey study showed suboptimal practices regarding informed consent³¹. Finally, these studies demonstrated that a significant minority of investigators believes that fabrication of data can sometimes be appropriate in a research setting. Reasons for this belief may stem from a culture that tolerates corruption and lacks accountability mechanisms, which would include comprehensive policies and oversight structures regarding authorship, peer review, and plagiarism.

Amidst the deficiencies of Egypt's ethics review system, there are data suggesting optimism. Studies reveal that an overwhelming majority of investigators believe that there should be formal training in research ethics for faculty, that RECs should be established, and that informed consent and confidentiality mechanisms should be mandatory to provide protections for research participants³². Furthermore, another study assessing perspectives of research participants showed that many were satisfied with the informed consent process³³. It is difficult to know, however, whether such satisfaction reflects reality or is due to research participants being unaware of their rights³⁴.

THE CURRENT FOCUS OF AN INTERNATIONAL TRAINING PROGRAM IN ENHANCING RESEARCH ETHICS CAPACITY

The MERETI Program, a Fogarty International Center/NIH sponsored training program, offers intensive, masters level training in research ethics with the aim of developing individual and institutional capacity in research ethics³⁵. This training program, based at the University of Maryland, offers a Master's of Science in Clinical Research and a certificate program in research ethics to individuals who are at the mid- to senior level of their careers. Trainees from both programs can pursue synergistic activities to enhance research ethics capacity at the institutional and national levels. These programs equip individuals with the critical skills necessary to assume important roles in their RECs, provide research ethics education, and pursue research in research ethics. Accordingly, trainees have pursued many activities that address several aspects of the previous described developmental model: a) national strategy and capacity: trainees have provided consultative advice in research ethics in the Ministry of Health; b) research ethics capacity: trainees have assumed leadership roles on several institutional RECs; have established RECs in other institutions; and have developed training programs for members of RECs; and c) researchers' conduct: trainees have developed curricular in research ethics at their institutions. While these trainees' activities serve as a measure of success of the training program, they do not address many of the other aspects of the described developmental model that are also needed to establish a robust ethics review system. Recently, a similar Fogarty training program focused on the countries in Central and Eastern Europe conducted a survey among its alumni regarding major impediments in their countries to protecting the rights and welfare of research participants³⁶. Responses were grouped in the following categories: a) developmental and enabling conditions: widespread corruption and lack of public transparency; b) national capacity and strategy: gaps in research ethics legislation and lack of regulatory enforcement; c) institutional commitment: lack of support for RECs; uncontrolled conflicts of interest; and lack of funding for research ethics training programs; d) REC capacity: lack of transparency in appointments and review, lack of procedural and regulatory clarity, and lack of training of REC members; and e) investigators' conduct: inadequate knowledge and training. These data provide additional impetus for training programs to expand its curriculum that will enable trainees to broaden their activities that will better ensure a culture of ethical conduct.

ADDITIONAL TRAINEE ACTIVITIES

At first glance, it might seem beyond the scope of training programs, and by extension the trainees themselves, to focus on developmental freedoms and the enabling conditions of their countries. Nonetheless, trainees can exert meaningful effects at the national and institutional levels to support an ethical culture by taking on activities aimed at policy and program changes and serving on regulatory agencies and on advocacy bodies dedicated to human subjects protection. Examples of specific activities are as follows:

1. Activities at the National Level

- Influence policy development and implementation by contributing to the national discourse on research ethics. As such, trainees need to acquire knowledge of their

country's mechanisms for policy change and understand the use of communication strategies to effectuate change.

- Service on relevant oversight and regulatory bodies devoted to protecting human research subjects.
- Adopt an advocacy role for research ethics by leveraging the current discourse on human rights occurring in the Arab Region. Trainees could make clear to the public how research ethics intersects with human rights. As such, the general population needs to realize their rights as research participants. Studies have showed that most members of the lay public are not knowledgeable about their human rights³⁷.
- Conduct of survey studies that elicit the attitudes and perspectives of key informants at the institutional and national levels to discover barriers and gaps in policies. An example would be the recently published interview study of REC chairs that revealed concerns regarding certain national policies that present barriers to the conduct of research³⁸.
- Establish a network of RECs, which by virtue of their numbers can motivate the national government to establish a legal and regulatory framework for research ethics. Such a network can also help raise awareness regarding research ethics among members of the public. Recently, several former MERETI trainees established a network of RECs in Egypt that has organized workshops in research ethics in many institutions throughout Egypt, established draft policies, (e.g., ethics of stem cell research), and have worked closely with the Egyptian MOH and the regional office of the WHO³⁹.

2. Activities at the Institutional Level

The protection of human subjects should be a priority for any institution performing research and such a focus requires the establishment of an ethical climate that influences conduct. As such, institutions need to borrow from organization systems theory, whereby individual behavior and performance are premised on a systems theory of causation⁴⁰. Defining a system as “an interdependent group of items, people, or processes with a common purpose,” systems thinking is concerned with the key interrelationships, structures, and processes that control and monitor behavior with an eye towards changing interactions or redesigning the system to produce different behaviors. A concept of how organizations shape individuals' behaviors makes clear that important determinants in achieving ethical conduct consist of the following: a) adoption of a set of underlying core values and b) establishment of the necessary infrastructure or system to ensure the implementation of the chosen values, i.e., the structures and processes that serve as important vehicles for ensuring that decisions, actions, and consequences reflect the underlying core values. Ensuring that values lead to appropriate decisions and behaviors represents organizational integrity. Systems thinking, therefore, represents the missing synergy between values and organizational performances, as values paints the picture of what the organization wants to create and the system itself ensures the outcome. To help achieve the integrity of their institution, trainees can take on the following activities:

Defining the organization's values—Trainees can help lead an organizational wide and participatory process of re-examining the organization's values. Strategic to such an effort is the support of leadership, as the search and reassessment of an organization's values must have clear commitment from the top leaders of the organization.

Development of an "ethics" infrastructure in the institution—To ensure that an institution's values lead to corresponding decisions and behaviors, trainees can play an instrumental role in shaping the necessary set of structures and processes. Elements of an ethics infrastructure that would enhance research ethics conduct would include the following:

- Comprehensive sets of policies and procedures that ensure the successful functioning of the REC. Examples would include policies that a) detail the appointment process of the REC chair and its members; b) mandate the educational requirements of the faculty and the members of the REC; and c) assures the independence of the RECs by establishing fair and appropriate representation on RECs, affirming the authority and legitimacy of the decisions of RECs, and prohibiting top officials from serving on the RECs.
- Establishment of conflict of interest policies for top officials, investigators, and members of RECs and confidentiality agreements with appropriate penalties for non-adherence. Such policies achieve trust in transactions.
- An appeals process to encourage principled dissent to practices or policies.
- Monitoring and overseeing the performance of the research staff (e.g., informed consent process) and the conduct of the research itself.
- Forums whereby members of the faculty and staff can discuss controversial ethical issues in the conduct of their research.
- A reward and compensation system to encourage attention to certain behaviors, e.g., financial compensation and promotional advancement for members of the REC.
- Meaningful institutional opportunities for gainful employment for people who pursue specialized training in research ethics.
- Accountability mechanisms to ensure that individuals are held accountable for their actions. Such measures can include imposing corrective actions, sanctions and penalties on researchers who are in violation of the rules; withdrawal of funding; and suspension of research.
- Establishment of a whistle blower hotline whereby research staff (e.g., research coordinators) and research participants can lodge complaints regarding researcher misconduct.

To help accomplish these processes and structures, trainees should place themselves on the relevant policy-oriented committees and raise awareness about research ethics among the faculty and staff. With regards to education, trainees should continue to develop curriculum in research ethics and ensure there is an adequate focus on responsible conduct of research.

Trainees may also desire to measure the ethical climate of their institutions by modifying established surveys⁴¹.

ADDITIONAL ACTIVITIES OF A RESEARCH ETHICS TRAINING PROGRAM

The above list of activities makes clear that training programs need to enable trainees to facilitate national and institutional changes that are directed towards enhancing the current research ethics review system. As such, training programs need to prepare their trainees to be “agents of change” when serving as ethicists, educators, and researchers⁴². This would necessitate the integration of a policy focus in the current curriculum, including practical training in how to use a variety of mechanisms to effect policy changes.

Curriculum content

Preparing trainees to effect policy changes can be complex and will require the following changes in curriculum content:

- Impart knowledge of existing in-country mechanisms for policy formulation by having the participation of previous policy makers to teach in the program.
- Develop new courses that review the different regulatory systems in other countries and determine which system would be adaptable to the current structure in Egypt.
- Enable trainees to influence policy development by equipping them with the skills necessary to formulate, implement, and evaluate policy.
- Incorporate additional courses in public speaking and critical thinking skills.

Recruitment strategies

While trainees can learn the specific skills necessary to be “agents of change” through master level courses, success would also depend to a certain extent on the knowledge and skills that trainees bring with them when they enter the program. Thus, it is important that a recruitment strategy be focused on selecting trainees with certain qualities and experiences. Accordingly, the following should be considered:

- Recruitment should target a wider range of actors that come from all sectors of the country, e.g., the Ministry of Health (MOH), public and private universities, and civil organizations. Trainees from the MOH can have a direct influence on national policy regarding research ethics, whereas trainees from NGOs that are involved with research involving women and street children can help direct policies regarding vulnerable populations.
- To ensure that trainees can help promote changes in their institutions, training programs should focus on key players in the organization. As such, recruitment strategies should target achieving a balance of senior and junior staff. It will be the seniors who will have the requisite authority and influence with the top officials with the shaping and promotion of the values of the organization; whereas the juniors will be the ones to sustain the culture once in place. Also, considering the existing hierarchical structures within institutions, junior staff can face significant hurdles in their efforts to instill new practices in their institutions (e.g., bioethics

curricular and re-structuring the operations of RECs) if members of the senior staff are not present to help them or even oppose their efforts.

- Training programs should also achieve broader diversity in its recruitment efforts so that all voices participate in the shaping of the organization's values. This type of diversity could bring more balance in gender, cultural, ethnic, and religious backgrounds, improving the capacity to think critically about the impacts of ethical conduct in society as a whole.
- Finally, whenever possible, recruitment should strive to select several trainees at any one institution rather individuals scattered over different institutions. With this approach, individual institutions can then become models of change for other institutions. This approach to behavioral and social changes conforms to the theory of "positive deviance", whereby a few individuals or institutions in a "community" embrace uncommon but successful behavior or strategies that enable them to find better solutions to a problem despite facing similar challenges as with their peers. These agents of change are referred to as positive "deviants"⁴³. With the existence of these models, one can then emphasize what is going right in an institution and amplify it instead of zeroing in on what is going wrong and fixing it.

CONCLUSION

The focus embraced by Hyder and Lavery takes into account the developmental and enabling factors that establish and sustain a research ethics culture. The significance of the model lies in its ability to make clear the barriers—as seen with Egypt—that fetter a country's capacity to expand its research ethics framework. By acknowledging such barriers, trainees of research ethics training programs can move toward developing long-term strategies for effective research ethics systems, both in policy and programming, and take the crucial steps necessary to improve health on a global scale.

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Table 1

Indices of Developmental Freedoms and Enabling Conditions

Freedom Rating ¹ (1,0 being free and 7,0 not free)	HDI ¹ (rank out of 187)	Life Expectancy Since Birth ¹ (years)	Gross National Income per capita ¹ (dollars)	Education index ¹ (mean years of schooling)	Gender inequality index ¹ (1 being high inequality)	Labor force participation ¹ (F:M)	Seats in parliament ¹ (F:M)	Freedom of Press Index ² (rank out of 179)	Corruption Perception Index ² (rank out of 176)
Partly Free (5.0)	113	73.5	\$5,269	6.4	0.599	0.297	0.038	158	118

¹ Developmental freedoms,² Enabling conditions