HHS Public Access

Author manuscript

J Empir Res Hum Res Ethics. Author manuscript; available in PMC 2017 July 24.

Published in final edited form as:

J Empir Res Hum Res Ethics. 2014 April ; 9(2): 80–91. doi:10.1525/jer.2014.9.2.80.

Twelve Years of Fogarty-Funded Bioethics Training in Latin America and the Caribbean: Achievements and Challenges

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Abstract

The landscape in research ethics has changed significantly in Latin America and the Caribbean over the past two decades. Research ethics has gone from being a largely foreign concept and unfamiliar practice to an integral and growing feature of regional health research systems. Four

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[1]The Corruption Perceptions Index (CPI) developed by Transparency International ranks countries based on how corrupt their public sector is perceived to be on a scale from 0 (highly corrupt) to 100 (very clean). The 2012 index ranks countries as follows: Canada 84, United States 73, Brazil 43, Peru 38, Argentina 35, Mexico 34, Honduras 28, Venezuela 19. The only countries in Latin America with scores over 50 are Chile (72), Uruguay (72), and Costa Rica (54). Information available at www.transparency.org/cpi2012/results.

[2]The Brazilian government committed to effective and systemic implementation of mechanisms for research governance through Resolution 196/96, which provided the regulatory framework for research with human subjects and established the National Commission of Research Ethics (CONEP). A landmark regulation in LAC, Resolution 196/96 has been recently updated and replaced in June 2013 by Resolution 466 (available at http://conselho.saude.gov.br/resolucoes/2012/Reso466.pdf). The country's efforts to implement ethical standards in research have been successful (Hardy et al., 2010). See Lamas et al. (2010) for a comparative evaluation with research ethics regulation systems of other countries of Latin America and Europe. In 2012 "Plataforma Brasil" was launched, which is a national online system for ethics review, monitoring, and registration of research protocols, which committees are required to use. Brazil is the main source of research in the region, producing 70% of all randomized controlled trials in LAC published in 2010 (Reveiz et al., 2013). Arguably, the country's vast research production is both a cause and an effect of the research governance system.

[3]The information is available at www.healthresearchweb.org/en/americas.

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bioethics training programs have been funded by the Fogarty International Center (FIC) in this region in the past 12 years. Overall, they have contributed significantly to changing the face of research ethics through the creation of locally relevant training materials and courses (including distance learning), academic publications, workshops, and conferences in Spanish, and strengthening ethics review committees and national systems of governance. This paper outlines their achievements and challenges, and reflects on current regional needs and what the future may hold for research ethics and bioethics training in Latin America and the Caribbean.

Keywords

research ethics; ethics education; research ethics curriculum; research ethics committee; capacity building

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T**he landscape in research ethics has** changed significantly in Latin America and the Caribbean over the past two decades. However, significant advancement in the protection of research participants coexists with a negative public perception of research as inherently exploitative. The proliferation of ethics review committees and research ethics education activities has occurred amid limited and inconsistent governance of human subjects research. Despite the remarkable growth in research ethics education across the region, the participation of Latin America and the Caribbean in global discussions on research ethics is scarce overall. Four bioethics training programs funded by the Fogarty International Center (FIC) over the past 12 years have contributed significantly to the development of research ethics in the region. The complexity of the regional landscape warrants assessment of their achievements, along with reflection on the challenges and pending needs for research ethics education and the development of research ethics review systems in Latin America and the Caribbean.

The foundations for bioethics across the region were laid well before the initiation of the Fogarty International Center's International Research Ethics Education and Curriculum Development program in 2000. The Pan American Health Organization (PAHO)—the Regional Office for the Americas of the World Health Organization (WHO)—established its Regional Program on Bioethics in 1994, nine years before WHO created its Ethics Unit. A 1991 report described the significant deficiencies in research ethics oversight in Latin America: "Institutional Review Boards (IRBs), as we know them in the United States, either do not exist or do not function effectively. The only ethical control over research, health professionals said, is the good will of the physician investigator. Ethics committees are involved in therapeutic research review in a few places, but they are composed largely of a few handpicked physicians. The quality of their review depends more upon personal integrity than on the rigor of review standards or procedures. The Ministry of Health has authority to oversee research on human subjects, but this rarely occurs. Similarly, the internationally recognized principles and norms governing research on human subjects have little practical influence. (Drane & Fuenzalida, 1991, p. 327)"

PAHO's Regional Program on Bioethics sought to address these deficiencies through training and publications on research ethics, such as the landmark text *Investigación en sujetos humanos: Experiencia internacional* (Pellegrini Filho & Mackin, 1999). In 1999,

PAHO reported that weaknesses in ethics review persisted. Few of the national commissions for scientific and technological research in Latin America and the Caribbean had ethics review committees. Only a few countries (Brazil, Mexico, Costa Rica, Cuba, and Jamaica) had legislation or national regulation for research with human subjects or were working to define such standards (Argentina, Chile, and Venezuela) (PAHO, 1999). Further studies conducted by PAHO between 1999 and 2002 found that researchers neither understood nor valued ethical review of research protocols; ethical review processes were not formally established in many institutions; there was a widespread perception that research protocols developed abroad (which, then as now, constituted the majority of research conducted in Latin America) did not need local ethical review; and that there was little differentiation between ethical review of research and clinical ethics consultation services (Rodriguez, 2004).

An evaluation of PAHO's Regional Program on Bioethics conducted in 2000 recognized important progress, such as the establishment of the *Foro Latino Americano de Comités de Ética en Investigación en Salud* (FLACEIS, Latin American Forum of Health Research Ethics Committees) in 2000 in Mexico by WHO's Department on Tropical Disease Research (TDR). Still, it emphasized that research ethics education constituted a critical task that was still pending in the region (PAHO, 2000a, 2000b). Another study in Latin America further revealed that research ethics committees (RECs) themselves identified a lack of research ethics education among their members as their main weakness (Rivera & Ezcurra, 2001). Bioethics training programs funded by the Fogarty International Center (FIC) have sought to address this situation. In the past 12 years, four projects were funded in the region: (1) *A Training Program in Research Ethics in the Americas* (directed by Ruth Macklin and Florencia Luna at Albert Einstein College of Medicine and Facultad Latinoamericana de Ciencias Sociales—FLACSO, respectively); (2) *Ethics of Research in Latin American Countries—Advanced Program* (directed by Fernando Lolas at University of Chile); (3) *Creating Collaborative Research Ethics Education with Costa Rica* (directed by Elizabeth Heitman at Vanderbilt University Medical Center); and (4) *Pan American Bioethics Initiative, PABI* (directed by Kenneth Goodman and Paul Braunschweiger at the University of Miami).

These programs have used a broad range of educational approaches. Some have conducted long-term training, some have provided short-term training, and others have provided both. They have used multiple formats and combinations of distance education and inperson instruction. Some activities have been specific to a single country, and other projects have extended across the region. They have worked variously with individuals and institutions. One program has been run completely from Latin America, one program has operated simultaneously from Latin America and the United States, and two have been coordinated from the United States in cooperation with Latin American and Caribbean institutions. One program has provided training continuously since the first grant awards were made in 2000, another has experienced a short interruption, and they each started at different times. Overall these programs have contributed significantly to changing the face of research ethics in Latin America and the Caribbean. This paper outlines their achievements and challenges, and reflects on current regional needs for research ethics.

Context

While most Latin American and Caribbean countries have much in common—their origin as European colonies, decades of political strife and intolerance, and, with a few exceptions, the election of democratic governments that during the last few decades have replaced authoritarian regimes—the region's population is still divided by profound socio-economic inequalities, cultural differences, and political conflicts. Moreover, despite the region's sustained economic growth over the past decade, some countries battle inflation and economic instability, and many countries and sub-populations within countries remain very poor. Although there is a wide range of faith traditions in the region, political and governmental systems share a deep commitment to Roman Catholicism. The Catholic Church exerts a particularly strong influence on issues related to reproductive health and sexuality, often hampering research in this important area of public health. Across the region, limited formal review of research is further compromised by inadequate institutional accountability and lax enforcement of the law. According to Transparency International, a nongovernmental organization that issues an annual ranking of 176 countries/territories by their perceived levels of public-sector corruption, with the exception of Chile and Uruguay, Latin American and Caribbean countries have high levels of corruption.(1) Although these countries experience varying inequalities within their healthcare systems, a large percentage of the region's population receives some form of medical service through public health systems. Several cities in the region have large hospitals, comprehensive medical education systems, and training in various areas of biomedical research. However, many countries still lack a formal legal structure for the regulation and oversight of human subjects research. Existing regulations often apply exclusively to clinical trials with pharmaceutical products, and research with human subjects in some countries is governed only by nonbinding guidelines or by regulations that are too general to inform research in practice (OHRP, 2013). Governance of clinical research is often inadequate and systems for reporting research misconduct are rare. As in many low- and middle-income countries, a significant number of clinical trials conducted in the region are multicenter studies, using protocols written in highincome countries, sponsored by foreign funding agencies or multinational pharmaceutical corporations, and often carried out by investigators from foreign institutions (Minaya et al., 2012). Often, little information is returned to the local population from which participants are drawn, and participants may not understand that they are taking part in research. US institutions and funding organizations are frequently involved in these trials, and there are mixed views in the region about the US presence in research and its involvement in promoting research ethics.

Methods

We collated results from four sources of information. First, the paper includes data from yearly reports prepared by the training programs' directors, one of which has also been published as a special issue of *Acta Bioethica* (2012). Second, it draws on comprehensive reports produced by the programs at FLACSO and University of Chile that surveyed past trainees about their professional activities after completing training. These two programs also worked with past trainees to survey the current situation in research ethics in their respective countries or areas, and held meetings to discuss their findings and overall

assessment of accomplishments. A third source of information was a brief questionnaire on the specific topics covered in this paper answered by those responsible for each training program. The fourth source was an indepth, face-to-face discussion in May 2012 among the program directors, in which the topics addressed in the questionnaire were used as a basis for common reflection and consensus on the key achievements and challenges.

Description of Programs

FIC-funded training programs in Latin America and the Caribbean are aimed at meeting two different regional needs: (1) providing in-depth research ethics education to professionals who can assume the responsibility of educating others, and (2) providing instruction in practical research ethics to investigators and members of RECs (see Table 1).

Most FIC-funded training in the region is conducted in Spanish, although some programs have required fluency in English for longer-term components conducted in the United States (e.g., the master's program at Vanderbilt University). For many participants, the opportunity to improve their speaking and writing skills in English has been an appealing feature of the programs. Simultaneous or consecutive interpretation has usually been provided for lectures and courses taught in Latin America by English-speaking faculty, which has broadened the participation of US educators beyond the small number of bilingual ethics faculty.

A Training Program in Research Ethics in the Americas—A Training Program in Research Ethics in the Americas has provided long-term, in-depth education in research ethics at FLACSO in Buenos Aires, Argentina, since 2000. In 2007, a distance education component accessible throughout Latin America was introduced. The availability of online curricula made it possible to reduce the in-person period in Buenos Aires from seven months to four months, which facilitated enrollment among the many professionals who found it difficult to spend extended periods away from home and work. This approach also engaged trainees' colleagues, fostering dialogue and collaboration at their home institutions. Currently, the certificate program includes: (1) formal courses in which the trainees enroll during a three- or four-month stay at FLACSO; (2) a brief, three-session internal seminar to introduce the trainees to the principles of bioethics and major international documents in research ethics; (3) rotations among eight RECs at hospitals and research institutions in Buenos Aires; (4) an annual week-long seminar with renowned international guest faculty; (5) planning a practicum to implement some aspect of what the trainees have learned when they return to their home institutions; (6) mentoring sessions leading to a final research paper under faculty supervision; and (7) faculty tutoring of trainees during the Buenos Aires component. Once the trainees have returned home they undertake: (8) a 16-week distancelearning course, which also enrolls short-term trainees; (9) implementation of the practicum; and (10) completion of a final research paper. Subsequently, trainees may obtain a Diploma in Bioethics (an intermediate degree), which consists of four courses (one at FLACSO and three as distance learning). The program has just introduced a master's degree in bioethics at FLACSO, which is offered to new trainees to pursue online. Several former trainees have qualified for a Diploma and are poised to enter the master's program.

Ethics of Research in Latin American Countries— Advanced Program—The Ethics of Research in Latin American Countries—Advanced Program is a 12-month certificate program that began in 2001 with both online and face-to-face learning experiences, including a stay at the Centro Interdisciplinario de Estudios en Bioética (CIEB or Interdisciplinary Center for Studies on Bioethics) at the University of Chile in Santiago. During the first month, trainees work in their home institutions to complete assigned readings and online modules on research ethics in preparation for upcoming coursework. During the next three months they take courses in Santiago with local instructors and faculty from the University of Miami as well as ethicists from Argentina and Brazil; participate in various practical research ethics activities; and develop and present research or practical projects to be implemented in their home countries during the final eight months of the program. Typical faculty-mentored projects include creating research ethics curricula, establishing RECs, developing research ethics sites or programs, and participating in the development of research ethics guidelines, or normative or regulatory documents. Trainees each present a thesis on their research project to a faculty committee, which they are encouraged to publish.

Creating Collaborative Research Ethics Education with Costa Rica (CREE–Costa Rica)—CREE–Costa Rica was initiated in 2006 as a series of multilevel capacitybuilding activities in research ethics and research integrity designed to meet growing demand for research ethics education, particularly after new regulations mandated the creation of research ethics committees in the hospitals and major clinics of Costa Rica's national health service. At that time there was no formal, systematic instruction in biomedical or research ethics in the country. To help meet this need, leaders in research ethics at the National Children's Hospital in San José partnered with educators at Vanderbilt University Medical Center in Nashville, Tennessee, to develop both the necessary expertise in ethical design, conduct, and review of biomedical research and structures for ongoing ethics education and training. The specific aims of this program were to: (1) create a cadre of Costa Rican biomedical researchers with in-depth knowledge and practical skills in research design and the ethical conduct of clinical and epidemiologic research through a two-year master's degree program in clinical investigation at Vanderbilt; (2) create a cadre of Costa Rican REC directors with comprehensive practical knowledge of research ethics and skills in protocol review, administration of RECs, and instruction in research ethics through a five-week practicum course at Vanderbilt; (3) enhance the knowledge and practical skills of Costa Rican REC members and administrators and biomedical science educators through short symposia; and (4) create, evaluate, and distribute curricular materials in Spanish on research ethics and responsible conduct of research (RCR) tailored to the Costa Rican context.

The program evolved to provide a greater focus on research integrity and RCR, partly as a result of the January 2010 ruling of the Costa Rican constitutional court ("Sala IV") that the national human research regulations were inadequate and unconstitutional, which suspended virtually all clinical trials and the work of the country's RECs. An additional intensive short course on Ethical Study Design and Research Methods brought senior and mid-career researchers to Vanderbilt to learn research methods and educational strategies for enhancing

study design and statistical analysis in the Costa Rican system. *Pan American Bioethics Initiative (PABI).* The Pan American Bioethics Initiative (PABI) was inaugurated in 2008 by the University of Miami's Ethics Programs and the Collaborative Institutional Training Initiative (CITI), an online ethics education program (Litewka, Goodman, & Braunschweiger, 2008). PABI supported the development of country-specific educational materials and curricula on research ethics and RCR by PABI fellows in Argentina, Brazil, Colombia, Costa Rica, Honduras, Jamaica, Mexico, and Peru and their colleagues. PABI then made these materials available on the CITI Program platform to help overcome the region's long-standing reliance on foreign texts and curricula in research ethics education. Fellows were institutional officials and decision makers, including many responsible for developing and/or overseeing research ethics programs, who coordinated workshops and conferences in collaboration with the PAHO and various local institutions, led content-development meetings, and oversaw the ongoing task of developing curricula for the CITI website. The program sponsored opportunities for collaboration among its fellows and with the other FIC research ethics education programs in Latin America to create national and regional networks of scholars, researchers, REC members, regulatory authorities, and international bodies.

Achievements

The four Fogarty programs fostered active research ethics networks, organized conferences and workshops on research ethics, integrated research ethics in graduate medical and humanities curricula, established academic ethics centers and numerous RECs, and helped to improve normative and regulatory frameworks for research with human subjects. Since the inception of the Fogarty bioethics training programs in Latin America and the Caribbean, research ethics has gone from being a largely foreign concept and unfamiliar practice to an integral and growing feature of regional health research systems. The proliferation of RECs is one indicator of this progress: Even without an exhaustive accounting, PAHO has identified about 1,200 RECs in Latin America and the Caribbean since 2011.(3) Moreover, research ethics conferences abound and attract a significant number of participants, and bioethics networks are proliferating throughout the region.

Unquestionably, one of the most significant achievements of the FIC-sponsored regional research ethics education programs is their many graduates. To date there have been 93 long-term trainees (see Figure 1 and Table 2). FLACSO's Training Program in Research Ethics in the Americas and the Advanced Program on Ethics of Research in Latin American Countries (University of Chile) have focused on long-term training. Trainees' disciplinary backgrounds have been varied, including physicians, basic scientists, nurses, lawyers, social scientists, and philosophers. Training has provided a multiplying effect: past trainees developed research ethics training material, created new courses and bioethics programs in their institutions, collected information on research practices, published papers, and organized international conferences. The impact has not been only academic: trainees have established new RECs and strengthened existing ones, drafted or implemented ethical review guidelines, and proposed regulations on health research.

Today past trainees network with one another, and several participate in the *Foro Latino Americano de Comités de Ética en Investigación en Salud* (FLACEIS, the Latin American Forum of Health Research Ethics Committees). All of the programs have identified the establishment of networks of former and current trainees as particularly effective for promoting research ethics education, and crucial to other post-training achievements. Formal and informal networks, in which program leaders and instructors are also active, promote continued engagement, motivate participants and reinforce trainee commitment to continue educational activities, and facilitate the sharing of teaching materials and new publications.

The programs' shorter, more focused training activities have also equipped local leaders in research with practical skills and experience in research ethics review and administration, as well as insights on teaching ethical research methods. CREE–Costa Rica placed senior REC members and coordinators with mentors on Vanderbilt University's IRB and taught midcareer research faculty advanced practical skills in ethical research design and analysis as well as methods for teaching these skills to students and colleagues at home. Prepared with in-depth knowledge of international standards and insights into practical protection of human subjects in research, several trainees from CREE–Costa Rica, together with Costa Rican trainees from the PABI and FLACSO programs, supported the establishment of master's degree programs in bioethics and clinical research, and became the most articulate and effective advocates for the new national legislation.

PABI has convened more than 35 workshops and conferences in Argentina, Brazil, Colombia, Costa Rica, Honduras, Jamaica, Mexico, and Peru, leading to the creation of 26 online research ethics courses in Spanish, three in Portuguese, and one in English. PABI fellows and faculty from each country as well as other FIC trainees in the region, especially from the programs at the University of Chile and Vanderbilt University, determined local educational needs on research integrity and human subject protection, and analyzed the CITI Program's content to identify modules to be adapted or topics to be addressed through the creation of original material with local emphasis and content. More than 4,000 people in the Latin American and Caribbean region have received certificates for completing PABI's online courses, evidence of significant grass-roots capacity building in research ethics.

Challenges

Since their inception in 2000, FIC-funded programs have encountered various challenges to providing research ethics training in Latin America and the Caribbean. Some are strictly academic and some result from the environment in which training takes place. Because little formal ethics education was available in the region's health professional schools prior to 2000, few general trainees had prior experience in research ethics or bioethics. Similarly, practical and applied ethics were not covered in most of the region's philosophy or humanities programs, which typically focus on theoretical issues raised in continental philosophy (e.g., phenomenology, hermeneutics) or the history of philosophy. Individually, the Fogarty programs sought to overcome these hurdles by holding brief introductory sessions prior to or soon after the start of each training cycle or short-term activity. More importantly, despite their success in various professional areas, trainees overall had not been taught necessary analytical skills and were not accustomed to the critical thinking essential

to successful work in research ethics. However, the insights and abilities needed for critical thinking, which are indispensable to practical ethics, cannot be taught in a few hours or even a few days. This challenge is likely greater for programs conducting short-term training, because they have less time overall to overcome gaps in the trainees' background education. After completing a program, long-term trainees often felt isolated when they returned to their home countries, where there are typically few opportunities to further their ethics education and few colleagues with whom to discuss what they had learned. The expansion of distance-learning courses helped to address this challenge by enabling trainees to continue learning after their return and encouraging others to learn alongside them as teams. Similarly, the adoption of Internet-based networks, including listservs and resource exchanges, allows individual program participants to interact with others across the region.

At the intersection of academic and ideological challenges, FIC-funded ethics education programs in Latin America sometimes met with accusations of "moral imperialism" (Garrafa & Lorenzo, 2008). This charge was typically based in the political and ideological views of humanities and social science faculty from a small number of institutions who accused some FIC program directors, faculty, and trainees—and the NIH itself — of pushing a US-centered agenda and teaching concepts that serve only US interests. Their underlying contention that research with human subjects is inherently a violation of human rights hampered dialogue on meaningful protections, overall improvement in research ethics, and the establishment of international research collaborations against real threats to human health. The public mistrust fomented by such charges continues to affect important initiatives in research oversight, most notably delaying passage of Costa Rica's national legislation on human subjects research, without which no clinical investigation was possible, even in private institutions. That said, from a distance, despite their substantial differences in content and approach, it may be difficult for both clinical researchers and lay observers to distinguish Fogarty-sponsored activities from those of the international pharmaceutical firms that commonly include sessions on research in their marketing-oriented physician education programs. The influence of the pharmaceutical industry in the region's medical systems, its focus on economic profit, and its limited efforts to address the region's basic health needs lead many Latin Americans to view all clinical research as an exploitative commercial enterprise (Hearn, 2011).

Moreover, rivalries have plagued bioethics in Latin America for decades. Disputes over geographic "turf " and status have impeded the work of many would-be ethics educators, including former FIC trainees trying to establish themselves in the field. Institutional and academic affiliations in the region generally provide weaker support to professionals than faculty receive in North America or Europe. Protected research time is rare. Academics are compensated on the basis of credit hours taught, and they often teach at many different institutions in order to secure an adequate income. This practice leads to multiple time commitments and simultaneous affiliations with numerous institutions, each of which provides only limited support. Weaker institutional support renders trainees vulnerable in disputes about "turf " and status. Political and economic instability have also posed a number of challenges. For example, economic inflation in Argentina hampered the implementation of activities that had been planned and budgeted before inflation. Activities

in Honduras planned in conjunction with the Ministry of Health and Council for Science and Technology were temporarily interrupted after a 2010 coup ousted the country's president.

Furthermore, it is difficult to conduct programs that seek to promote the ethical conduct of human subjects research in countries that lack a formal legal structure for the regulation or oversight of such research, and where the responsibility of conducting research ethically falls exclusively on the individual investigator, as is the case of Honduras and Paraguay. Similarly, it is difficult to teach responsible conduct of research in a context where plagiarism and questionable practices such as honorary authorship are commonplace, and there are no systems for reporting research misconduct or protecting those who make allegations of misconduct (Heitman and Litewka, 2011).

Current Needs and Recommendations

In the last 12 years, regional FIC-funded research training programs have succeeded in developing a growing community of research ethics educators, helping to establish effective RECs, and promoting responsible research. Despite their multiplying effect, there is still a long way to go in Latin America and the Caribbean. The proliferation of RECs certainly reveals progress in terms of the protection of research participants, but, while crucial, ethics review is only one element of a research ethics system (Hyder et al., 2009). Some countries that lack a normative and regulatory framework for research with human subjects, or have a framework that is inadequate (PAHO, 2012; OHRP, 2013; Bartlett, 2009), are currently trying to address this situation: Ecuador is working on the development of a regulation for clinical trials; Bolivia, El Salvador, and Honduras are working on several aspects of the regulation of human subjects research. Other countries, such as Costa Rica and Chile, which made early progress in the development of human research standards, have experienced recent setbacks. Costa Rica was the first Latin American country to enact human subject research protections in 1973, but in 2010 the country's constitutional court (Sala IV) ruled its 2005 regulations unconstitutional on the grounds that medical research raised issues of human rights that needed to be addressed legislatively. The long-awaited law passed in late 2013 will create a new oversight structure, pending its review by Sala IV.

A regional trend toward an increasingly restrictive approach to research with human subjects, which prohibits or restricts research currently considered ethical on the basis of international guidelines such as the Declaration of Helsinki, is also evident. For example, Chile's 2012 Law No. 20584 regulating the Rights and Duties Incumbent upon Persons in Connection with Actions Linked to Their Health Care (www.leychile.cl/Navegar?idNorma=1039348) forbids research with adults who are not able to provide consent on their own. Peru's bill to regulate clinical trials, which was subject to public consultation in 2013, prohibits studies with placebo that are allowed by the Declaration of Helsinki. In the vast majority of countries in the region, there are no formal accreditation systems for ethics review committees, which suggests probable inconsistencies across RECs within countries and across the region (Lamas et al., 2010).

Some areas are clearly better off than others in terms of research ethics or general bioethics education. Argentina, Brazil, Chile, and Colombia are among the countries that have a cadre of experts in different areas of bioethics and a few well-established bioethics training

programs. Bolivia, Ecuador, Honduras, and Paraguay are among countries that lack sufficient experts to establish ethics education programs. Therefore, an initial recommendation is to work to augment research ethics education in the less-developed nations through educational partnerships across the region; both in-depth education and practical background training in research ethics are required.

Even in areas with the highest levels of education and training in these domains, academic theses and professional publications demonstrate that the vast preponderance of regional work in research ethics and bioethics is descriptive (*Acta Bioethica*, 2013, pp. 19–56). Normative work and empirical research on issues in research ethics are still very rare. A major challenge for training programs in the region is therefore to move beyond trainee projects focused on *descriptions* (of problems, of solutions provided to problems, of the literature, etc.) to the production of normative work that depends on *analysis* and strengthens analytic skills.

Educational programs should create and establish courses at all levels that develop critical thinking and analytic skills necessary to produce normative work. Ethics education should be strengthened through the incorporation of critical thinking exercises, case studies, and the practical application of new knowledge. The development of critical thinking skills and ethical analysis at earlier stages in professional education should be also promoted. In order to strengthen the analytical skills of individuals working in research ethics, as well as to foster the production of normative work, it is advisable to make normative work on bioethics more available in Spanish. At first, meeting this goal is likely to require translation of important international texts as well as the development of more publications of normative work on local issues with local perspectives.

It is imperative to continue providing research ethics education that is conceptually sound, conscientious, and geared toward application in regional contexts. Programs funded by FIC meet these criteria and constitute an alternative to what is offered elsewhere in the region, which includes curricula developed by pharmaceutical companies, theoretical and abstract ethics courses, and ideology- infused bioethics education that leads to the propagation of fundamentalist positions rather than reflection and analysis. Ethics education would benefit from measurable goals and objectives. In the absence of a universal metric for assessing the progress of learners in the field of ethics, trainees are currently evaluated by a variety of surrogate outcomes, including number of publications, implementation of ethics of research programs, collaboration on RECs, contributions on the Web, and contributions to regulations and policies. With respect to publications, and in light of the challenge to produce normative work, it is advisable to distinguish publications based on type, as well as venue and quality. To encourage Latin American ethicists to take part in the global discourse on research ethics and to raise the visibility of Latin American perspectives worldwide, trainees and established research ethicists should be encouraged to read and publish in international journals. Since, just as in biomedical science, the most respected ethics journals are published in English, rising Latin American ethics scholars will need strengthened skills in English writing. This goal notwithstanding, developing and publishing in high-quality national and regional journals is crucial to reach a wide range of Spanish-speaking researchers, administrators, and educators with normative material.

For training efforts to have the most impact, and in light of lessons learned in the region by all four FICfunded programs, trainees enjoying strong financial and administrative support are generally to be preferred over others. To promote networking among trainees and groups working on research ethics, it is also recommended that existing networks (e.g., FLACEIS) be strengthened and collaboration among FIC-funded programs and other research ethics training initiatives and bioethics groups (including national bioethics commissions) in the region be promoted.

Best Practices—FIC's overarching accomplishment in the region lies in having fostered the value that, in ethics education as in research, collaboration is more effective and much preferable to competition. Program faculty and trainees all benefit from their interaction as professional colleagues with the common goal of improving the ethical quality of research. The establishment of local, national, and regional networks of former and current trainees is particularly effective for promoting research ethics education through participants' continued engagement and the sharing of teaching materials, new publications, and opportunities for collaborative work. Trainees' contribution to research ethics education and oversight within their own systems and beyond is stronger and more accessible to researchers because of their collaboration. Because of the often hierarchical nature of academic, healthcare, and governmental institutions in Latin America and the Caribbean, it remains advisable to focus on trainees with administrative and financial support from their institutions, whose new knowledge and recommendations for institutional change are more likely to be heeded than are those of independent scholars.

Acknowledgments

The authors want to acknowledge the contribution of Joe Millum and Barbara Sina from the Fogarty International Center. The manuscript has greatly benefited from their various comments and suggestions, as well as those made by other directors of Fogarty's International Research Ethics Programs.

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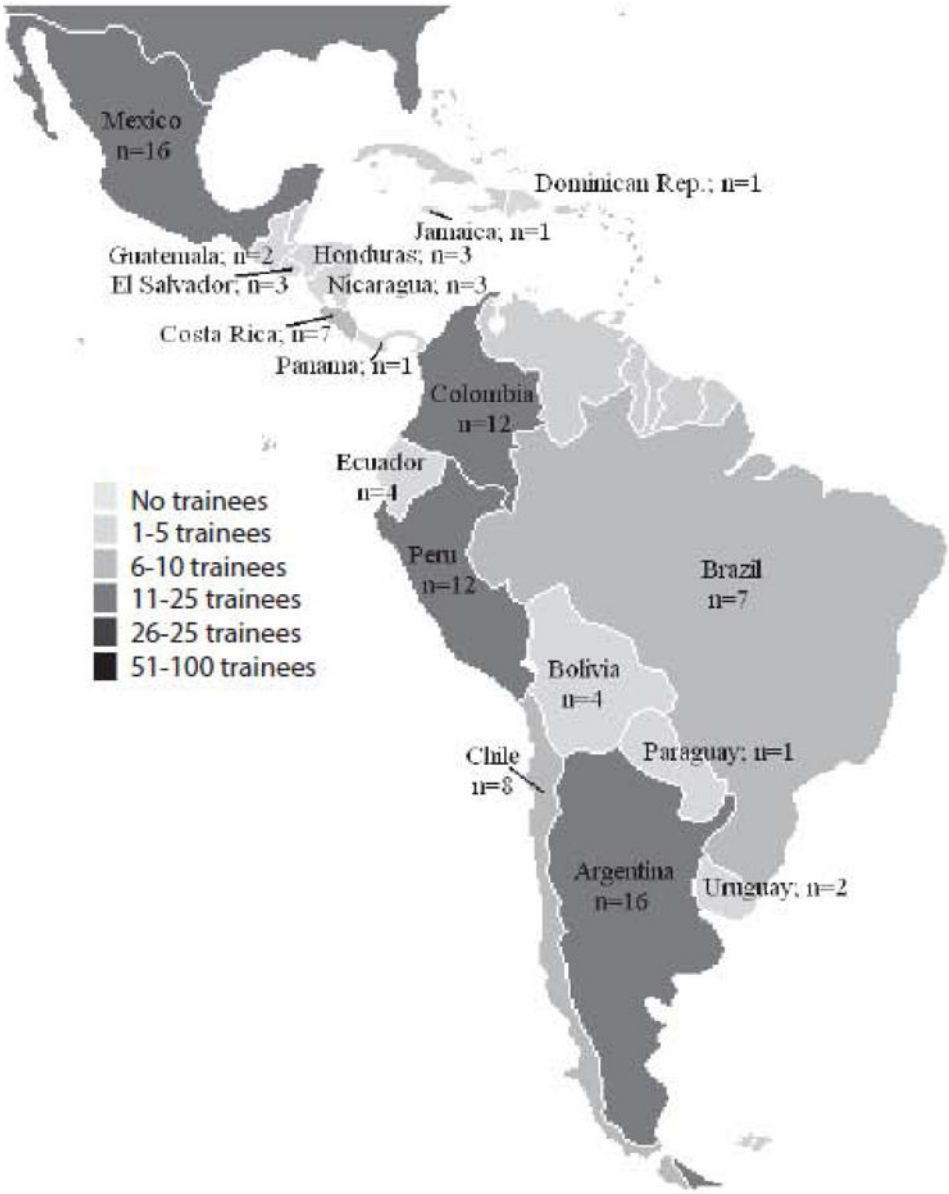

FIG. 1.
Latin America and the Caribbean long-term trainees by country.

TABLE 1

FIC Bioethics Programs Accepting Trainees from Latin America and the Caribbean.

Name of program	Years funded	Awardee institutions	Degree or nondegree	Length of training program	Locations of teaching	Nationalities of trainees
A Training Program in Research Ethics in the Americas	13: 2000–present	Latin American University of Social Sciences (FLACSO)–Argentina	Nondegree. Intermediate degree (“Diploma in Bioethics”) may be obtained if additional courses are taken	12 months	Buenos Aires, Argentina	Argentina, Mexico, Peru, Brazil, Colombia, Costa Rica, El Salvador, Bolivia, Guatemala, Nicaragua, Chile, Ecuador
Ethics of Research in Latin American Countries – Advanced Program	11: 2001–2012	University of Chile, Interdisciplinary Center for Studies on Bioethics	Nondegree	12 months	Santiago, Chile	Mexico, Chile, Colombia, Argentina, Peru, Nicaragua, Ecuador, Bolivia, Honduras, El Salvador, Brazil, Uruguay, Dominican Republic, Guatemala
Creating Collaborative Research Ethics Education with Costa Rica	6: 2006–2012	Vanderbilt University Medical Center	Degree (Master’s of Science of Clinical Investigation) and nondegree.	Degree: 2 years. Nondegree: 5 weeks (Practicum) and 2 weeks (Intensive Course)	San José, Costa Rica	Costa Rica
Pan American Bioethics Initiative, PABI	4: 2008–2012	University of Miami, Ethics Programs and Collaborative Institutional Training Initiative (CITI)	Nondegree	Fellows: varies (between 3 and 22 months).	Argentina, Brazil, Colombia, Costa Rica, Honduras, Jamaica, Mexico, Peru	Argentina, Brazil, Colombia, Costa Rica, Honduras, Jamaica, Mexico, Peru

J Empir Res Hum Res Ethics. Author manuscript; available in PMC 2017 July 24.

TABLE 2

Key Indicators on Bioethics Trainee's Home Countries.

						Health expenditure				Registered clinical trials	
Country	**Population**	**Area (Km^2)**	**GDP per capita**	**Human Development Index [UNDP]**	**% below poverty line [CIA]**	**%GDP [CIA]**	**Per capita [WHO]**	**Corruption Perceptions Index [Transparency International]**	**Gender Inequality Index [UNDP]**	**Clinicaltrials.gov searched July 2013**	**WHO's ICTRP searched August 2013**
Argentina	42,610,981	2,780,400	18,200	45	30	8.1		35	.380	1561	1914
Chile	17,216,945	756,102	18,400	40	15.1	8	1075	72	.360	837	1068
Colombia	45,745,783	1,141,748	10,700	91	34.1	17.6	432	36	.459	654	866
Mexico	116,220,947	1,964,375	15,300	61	51.3	6.3	620	34	.382	1891	2261
Brazil	201,009,622	8,514,877	12,000	85	21.4	9	1120	43	.447	3381	4362
Peru	29,849,303	1,285,216	10,700	77	31.3	5.1	289	38	.387	654	927
Nicaragua	5,788,531	130,373	3,300	129	42.5	9.1	125	29	.461	7	10
Ecuador	15,439,429	256,369	8,800	89	27.3	8.1	332	32	.442	79	119
Bolivia	10,461,053	1,098,581	5,000	108	49.6	4.8	118	34	.474	24	28
Honduras	8,448,465	112,492	4,600	120	60	6.8	193	28	.483	27	37
El Salvador	6,108,590	21,041	7,700	107	36.5	6.9	251	38	.441	25	41
Guatemala	14,373,472	108,889	5,200	133	54	6.9	214	33	.539	189	241
Dominican Republic	10,219,630	48,671	9,600	96	34.4	6.2	296	32	.508	86	107
Uruguay	3,324,460	181,034	15,800	51	18.6	8.4	1105	72	.367	42	56
Costa Rica	4,695,942	51,100	12,600	62	24.8	10.9	983	54	.346	114	185
Jamaica	2,909,714	10,991	9,100	85	16.5	4.8	270	38	.458	22	32