Published in final edited form as:

J Empir Res Hum Res Ethics. 2014 December ; 9(5): 46–55. doi:10.1177/1556264614552396.

The Impact of a Research Ethics Training Program: Romania as a Case Study

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Abstract

Case Western Reserve University's (CWRU) Training Program in International Research Ethics, funded by the Fogarty International Center, has been ongoing in Romania since 2000. The program consists of multiple components: a U.S.-based MA degree program for long-term trainees, Romania-based short courses, a U.S.-based opportunity for mid-and senior-level personnel to develop collaborative writing or research projects and present lectures, and a newsletter and various Internet-based activities. We evaluated the impact of the training program on bioethics in Romania through a survey of the training program's long-term trainees, a literature search for trainee publications, interviews with key informants, and identification of key events during the course of the program. Findings indicate that the program has had a considerable impact in the field of bioethics through trainee authorship of peer-reviewed publications, books, and chapters; trainee career trajectories that encompass activities related to research ethics; and the development of a Romania-based master's degree program in bioethics and a Center of Bioethics and Health Policy. We attribute these achievements to the establishment of strong relationships between CWRU in Cleveland and the University of Medicine and Pharmacy Gr. T. Popa in Iasi, Romania, prior to the initiation of the training program; collaboration with key Romania-based institutional partners that are equally invested in the program's success; reliance of the program on a solid theoretical framework; ongoing program responsiveness to trainee and country needs; and a sustained commitment of time, expertise, and funding by the funders, sponsors, and in-country collaborators.

Keywords

bioethics; Romania; research ethics; training program

It was not until the end of the Ceaușescu regime in 1989 that bioethics in Romania became once again a focus of inquiry and bioethical principles began anew to serve as a guide for the conduct of health care professionals. Numerous factors have played and continue to play a role in the re-emergence and establishment of bioethics as a legitimate and recognized discipline. We conducted this study to evaluate whether the initiation by Case Western

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Declaration of Conflicting Interests: The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Reserve University (CWRU) of a research ethics training program in Romania in 2000, with funding provided by the Fogarty International Center, is one such factor. We report here on the impact in Romania of this program and the implications of our findings for training programs based in post-Communist countries. This case study expands on the report by Strosberg, Gefenas, Loue, and Philpott (2013) on research ethics capacity building in post-Communist countries.

Background

During World War II, the ruling monarch of Romania, King Michael, had participated in the German invasion of the Soviet Union. Although he later tried to align the country with the Allied forces, the Soviet Union looked upon Romania as a vanquished nation. The Yalta Conference granted the Soviet Union a predominant interest in Romania and, in 1947, King Michael was forced by pro-Communist troops to abdicate. The country then became known as the Romanian People's Republic until 1965, when Ceaușescu became the General Secretary of the Communist Party in Romania. The early years of his regime were characterized by succeeding waves of imprisonments and executions as warring factions of the Communist Party attempted to gain control of the country.

Prior to Ceaușescu's rise to power, it appears that the members of the medical profession engaged in discussion, debate, and teaching related to ethical issues, particularly in the context of clinical care (Târcoveanu, Dorobăș, Vasilescu, & Astărăstăoe, 2012). Indeed, physicians initially opposed Ceaușescu's 1966 imposition of a ban against abortion (Iordache, 2014). However, physicians themselves were soon targeted through Ceaușescu's imposition of monthly birth quotas on physicians and other employees; the investigation by Ceaușescu's security forces, the Securitate, of alleged abortions; the posting of agents in all maternity wards and obstetrical-gynecological clinics; and the imprisonment of physicians who violated the abortion restrictions (David, 1990a, 1990b). Ceaușescu's policies created complex ethical issues for physicians who wished to provide appropriate care for their patients but feared the potential consequences of noncompliance with Ceaușescu's policies. In addition to Ceaușescu's increasingly restrictive limitations on the availability of birth control and abortion (Ceaușescu, 1966, 1985), he eventually halted the importation of contraceptives (David & Wright, 1971) and banned birth control altogether (Hord, David, Donnay, & Wolf, 1991).

In addition, Ceaușescu prohibited the study of disciplines deemed challenges to his authority and/or that would require international collaboration and interaction. Consequently, his regime effectively halted the study of and research relating to fields such as genetics and ethics. Materials and courses relating to bioethics were almost completely eradicated in Romanian medical schools.

Effective April 2000, Romania disbanded the system of nationalized health care established under the Ceaușescu regime (Cockerham, 1999), in favor of an employment-based insurance approach. This system is intended to cover the costs of medical care of not only employed persons but also the unemployed, children, and retirees through the payment of a tax by employers and those who are employed. However, the current poor economic situation is

such that there are high numbers of unemployed and underemployed, which has resulted in inadequate funding to cover the costs of all needed health care services (Holt, 2011; Rossi, 2014). The dismal economic situation has led to difficulties in accessing care, particularly for those groups in Romania that have historically been the targets of political, economic, and/or social marginalization and discrimination: the Roma (often referred to in the West as gypsies, although that term is considered pejorative), mentally ill persons, Jews, and sexual minorities.

The poor economy and the resulting lack of financial support for the health care infrastructure have raised significant ethical issues for Romania in both the research and the clinical contexts. For example, some physicians have been accused of taking bribes or demanding payment from patients in addition to the insurance payment as a precondition to providing services (Bilefsky, 2009). Questions have been raised regarding physicians' conflict of interest for their receipt of payments from the sponsoring pharmaceutical companies, while the care of hospitalized patients who are participating in research is borne entirely by the government (Holt, 2011). The voluntary nature of individuals' participation in research has also been subject to question in light of the difficulties associated with accessing and paying for needed care (cf. Anonymous, 2014).

The Re-Emergence of Bioethics

In 1995, Romania initiated efforts once again to train its health professionals in the area of clinical and research ethics through the development of ethics courses and an official suggestion from the government that medical schools establish research ethics committees (RECs), the equivalent of what in the United States would be institutional review boards (IRBs; Anonymous, 2006; Bogdan, 2009). Despite these efforts, the author found during her 4-month Fulbright Senior Scholar Award (1999) at the University of Medicine in Iasi and the Institute of Public Health in Iasi that none of the five public health faculty members she interacted with on a regular basis had ever heard of the Nuremberg Code or the Helsinki Declarations; the same was true of many of the younger medical school faculty with whom she discussed research ethics. Although a course on bioethics was listed among the available electives for medical school students, it had not been offered for some time, longer than anyone with whom she spoke seemed to be able to remember. This author's consultation in 1999 with medical school and public health faculty members at the university in Bucharest, reputed to be the most advanced Romanian medical and public health school, revealed that a course in bioethics was first developed in 1999 and included only 8 hr of instruction.

This author's discussions with numerous medical and public health colleagues and her direct observation throughout her several visits to universities and hospitals in Bucharest and Iasi in 1999-2001, totaling more than 7 months, further indicated that biomedical research was often initiated and conducted without independent scientific or ethical review or oversight of the protocol, and patients were often enrolled without understanding that they are being enrolled in research. Most institutions lacked any review mechanism comparable with an IRB; when such approval was required, a department chair routinely provided his or her signature. Review by the Ministry of Health or the local representative of the Ministry was often pro forma in nature.

During the early 2000s, Romania implemented numerous reforms in preparation for entry into the EU, which was achieved on January 1, 2007. A number of these measures had significant implications for research ethics. First, in 2000, Romania passed an anti-corruption law to address the widespread levels of corruption in Romanian institutions (Müller, 2002). In November 2000, Romania signed Protocol No. 10 to the European Convention on Human Rights, which prohibits discrimination on various grounds, including sex, religion, and ethnicity. Additional legal reforms were instituted during this period to ensure the rights of children, prisoners, asylum seekers, refugees, and ethnic and linguistic minorities (Müller, 2002); each of these groups is often considered to be vulnerable within the context of research (Council for International Organizations of Medical Sciences, 2003, 2009). In 2001, regional committees were established to develop ethical standards for the practice of medicine and the conduct of biomedical research for the regions of Iasi, Timisoara, and Cluj. Romania's national government mandated that all research be subject to review through independent committees, but this was not implemented uniformly at the local level. Depending on the region of Romania, locally sponsored research activities continued to be conducted without independent review.

The Romania–CWRU Connection

Prior to the initiation of the training program in research ethics, CWRU had had collaborative scientific research activities in Romania for approximately 15 years. Until 1997, this commitment was largely achieved through the development and maintenance of linkages between the Mandel School of Applied Social Sciences (MSASS), CWRU's school of social work, and various academic and nongovernmental organizations located throughout Romania. MSASS efforts emphasized the development of child welfare protections and the revitalization of Romanian civil society (Groza, 1999). CWRU's School of Medicine had collaborated with various institutions in Romania since 1997, often in conjunction with colleagues in MSASS.

In 1997, this author initiated a study of HIV-related knowledge and risk behaviors among pregnant women in Iasi, which revealed low levels of knowledge and high levels of risk due to the behavior of the participants' male partners (Loue, Groza, & ARAS Working Group, 1998). These findings provided the basis for a successful grant application to the United States Agency for International Development (USAID) to conduct a pilot community-based HIV prevention intervention through 24 pharmacies in Iasi. The author collaborated with other U.S. and Romanian investigators to examine the HIV risk among street youth in Bucharest (Groza et al., 1999) and later conducted a study of intimate partner violence in Bucharest and Iasi (Loue, 2001). Other studies were initiated by various CWRU investigators in collaboration with their Romanian colleagues, including an international study of medical mistakes, evaluation of the child welfare system, and assessments of child development in the context of institutionalization (Dickens & Groza, 2004; Gavrilovici & Groza, 2007; Groza, Conley, & Bercea, 2003; Ryan & Groza, 2004). These studies were conducted following approval by an IRB at the author's institution. It is of note that at the time that these studies were initiated, no provisions existed in Romania for the ethical review of the research, apart from approval by the relevant department, hospital, and/or university head. This would not be the case if the research were to be initiated today.

This author spearheaded Romania–CWRU collaborative activities in the area of bioethics. During the period of her 1999 Fulbright Senior Scholar Award, she was responsible for the development and implementation of a course on bio-ethics for faculty and postdoctoral trainees at the University of Medicine and the Institute of Public Health in Iasi. She developed a series of courses that was implemented at that time and has influenced the currently existing master's degree curriculum at the University of Medicine and Pharmacy Gr. T. Popa in Iasi.

Training Program Description

Until recently, Iasi had been the primary site of the CWRU Fogarty-Funded Training Program in International Research Ethics, begun in 2000. The training program has more recently expanded further into other areas of Romania through its partnership with the national physicians' association, Colegiul Medicilor, the equivalent of the American Medical Association. Iasi, situated in the northeast part of the country, is second in size only to Bucharest; the county of Iasi is one of the largest, poorest, and most crime-ridden counties in Romania. The county consists of both highly urbanized and extremely rural areas. The city of Iasi has schools of medicine, public health, law, and social work. We anchored our training program through institutional collaborations with the Colegiul Medicilor and the University of Medicine and Pharmacy Gr. T. Popa in Iasi. This strategy was designed to maximize sustainability through the development of the next generation of bioethics academicians who are then prepared to train subsequent generations.

Between 2000 and 2010, our training program consisted of four components: (a) a CWRU-based 1-year MA degree program in bioethics, enhanced and with a specific focus on research ethics for the trainees; (b) Romania-based short courses; (c) a 1-week CWRU-based opportunity for mid- and senior-level personnel to develop collaborative writing or research projects and present lectures relating to research ethics; and (d) a quarterly or semi-annual newsletter. We expanded the program in 2010 to include various Internet-based activities, such as a chat room, and the Electronic Ethics Training Repository for Information, Protocols, and Projects (EE-TRIPP). The EE-TRIPP is designed as a repository for program trainee and faculty submissions to ethics review committees, publications, and presentations. The repository serves as a resource for past, current, and future training program MA-level trainees.

In addition, we revised in 2010 the MA curriculum required of our Fogarty trainees to include several new courses and components. The two-semester, non-credit Advanced Research Ethics Seminar was designed to enhance trainee ability to critically analyze the relevant literature, prepare professional presentations and manuscripts, teach effectively, implement research, and negotiate and maintain collaborations. This seminar meets for 2 hr per month and is required of the Fogarty trainees in addition to the courses that are required of all students in the bioethics MA degree program.

We also instituted a requirement of a re-entry project to be carried out by each trainee upon his or her return home. Preparation of this re-entry project was begun through a newly instituted Bioethics Independent Study Course. The Fogarty trainees meet with the principal

investigator (PI) as a group to discuss the purpose of the independent study course and the parameters and possibilities for the re-entry project. The majority of subsequent meetings with the PI are arranged individually on a biweekly basis, so that each trainee can work intensively on his or her own project and receive individualized guidance. The trainees meet as a group once a month to discuss their progress on their reentry projects. A required course on IRB/REC administration was developed to familiarize trainees with approaches to interacting with investigators, record-keeping, identification and selection of appropriate community members for consultation, and approaches to electing and utilizing outside experts. Our experience based on both trainee performance in these courses and trainee feedback suggests that the addition of these curricular components has been not only helpful to the trainees, but has been welcomed and has not been placed an undue burden on them.

A Romania-based advisory committee to the program is responsible for advertising the availability of the program, for identifying potential qualified applicants, and for assisting with the selection of one to two trainees per year. The membership of the advisory committee has been rotated over the years to ensure diversity of perspective, with the exception of the continuing membership of the president of Colegiul Medicilor. Membership has variously included the chair of a hospital REC, the chair of a university REC, past Romanian trainees of our program, and medical school department chairs. Membership has also reflected demographic diversity: males, females, individuals of various ages, and individuals from a range of occupations, including surgery, psychology, pathology, biochemistry, law, public health, and social work.

Applicants from Romania to the Fogarty-funded MA bioethics training program are selected based on a review of their credentials, including university transcripts, reference letters from three individuals familiar with their work, a personal statement, and a satisfactory score on the TOEFL (Test of English as a Foreign Language) examination. A personal interview with the advisory committee was also required.

Each trainee accepted to the program was assigned both an academic advisor and a mentor at CWRU, who together were responsible for assisting the trainee with his or her transition to the academic and living environments (e.g., utilizing transportation resources, finding appropriate living arrangements balancing work– life commitments), providing guidance in formulating the re-entry project, and offering referrals to resources as appropriate. The CWRU program also provided university-based language, writing, and technological support to the trainees. In addition, each trainee was assigned a Romania-based mentor, who was responsible for assisting the trainee in formulating the reentry project, establishing linkages with key persons and offices in Romania that could lend support to the trainee's re-entry project and, upon the trainee's return to Romania, helping the trainee identify potential opportunities to utilize his or her new knowledge and experience.

Together, the various components of the program were intended to develop trainee knowledge and skills in various domains. These included the following: (a) identification of ethical issues arising in the context of proposed research and strategies for their resolution; (b) knowledge of international ethical guidelines for the conduct of research with human beings and legal requirements pertaining to the conduct of research; (c) critical analysis of

existing scientific and bioethics literature with respect to ethical issues; (d) preparation and delivery of lectures for teaching others and of presentations in professional forums; (e) preparation of publishable manuscripts relating to research ethics; and (f) enhancement of negotiation and communication skills to facilitate assumption of leadership positions in academia, industry, ethics review committees, and/or other venues.

We premised our training program and its components on andragogy (Knowles, 1970; Merriam, 2001), critical reflection (Freire, 1970, 1973), and Rogerian theory (Rogers, 1962, 1967). Andragogy theorizes that adult learning is best fostered when it (a) provides learners with a safe and comfortable learning environment; (b) involves the learners in the mutual planning of the methods to be used and the content of the curriculum; (c) involves the learners in the assessment of their own needs; (d) encourages learners to formulate their own learning objectives; (e) encourages learners to identify resources and how to best use those resources to achieve their goals; (f) supports learners in their efforts to achieve their learning objectives; and (g) involves learners in the evaluation of their own learning (Kaufman, 2003). Freire demonstrated that critical reflection by adult learners about the assumptions that underlie their “habitual ways of perceiving, thinking, feeling, and behaving” (Mezirow, 1981, p. 19) could bring about a transformation in perspective. Rogerian theory posits that learning is fostered when the instructor presents the learner with a real problem that has meaning and relevance to learner; trusts in the capacity of the student to develop his or her own potentiality; accepts and values the worth of each individual student; is empathic and understands how the process of education and learning appears to the learner; and provides the learner with necessary resources, including access to other individuals who may contribute to the learner's knowledge.

We designed the curriculum to facilitate transformational learning (Glass, 2001; Rogers, 1962, 1967) by integrating cyclical reflection and action into the training program. We were able to accomplish this through teaching techniques, group discussions, and written assignments that encourage the trainees to become more self-aware and to examine more fully their identity, attitudes, beliefs, practices, and relations with the external world (cf. Holmes, 2002). We speculated that our utilization of a student-centered teaching approach (Rogers, 1962, 1967) that emphasizes focused questioning and analysis (Freire & Faundez, 1992) would be most likely to transform our trainees into “reflective practitioners” (Holmes, 2002) in the field of research ethics.

During the course of our international research ethics training program to date (2000-2014), 13 trainees from Romania successfully completed the MA program. CWRU bioethics faculty have to date conducted a total of 16 in-country courses through our training program, in collaboration with our earliest Romanian trainees, who have served as faculty for a number of these short courses (Table 1). More than 1,700 students, faculty, clinicians, and ethics review committee members attended these courses that ranged from several hours to several days in length.

Method

We utilized several strategies to evaluate the impact of the training program on the development of research ethics in Romania and the careers of the individuals who had participated as trainees. These consisted of (a) a web-based survey of all of our Romanian trainees; (b) a review of trainees' curricula vitae (CVs) and various electronic databases to assess trainees' scholarly productivity and other activities in the field of research ethics; (c) individual interviews with key informants; and (d) the identification and review of key events that occurred during the course of the training program.

The survey consisted of 44 questions focused on trainees' educational background; participation in RECs or as an instructor of research ethics; authorship of peer-reviewed manuscripts, invited chapters, or books in the field of research ethics; and presentations related to research ethics at professional conferences. We supplemented the information provided through the surveys with additional information contained in trainees' updated CVs which they furnished to us, as well as information relating to trainees' professional presentations and published manuscripts obtained through a search of electronic databases most likely to house information relating to the trainees' educational backgrounds and current professional responsibilities. These databases included Google Scholar, PubMed, and PsychLIT.

Key informants were selected based on the extent to which their current professional role requires their familiarity with the current system of research ethics in Romania. A secondary factor in the recruitment of key informants was the extent to which they had knowledge of research ethics as it existed prior to the end of Ceaușescu's regime. This knowledge allowed them to compare the status of research ethics in Romania prior to and subsequent to the initiation of the research ethics training program. These eligibility criteria limited the number of potentially eligible key informants to 10 to 12; the number was further reduced due to individuals' unavailability during the time period of the evaluation in Spring 2014. Questions posed to the key informants are listed in Table 2. Each interview required approximately 40 to 60 min. Interviews were conducted in person by the PI in English or the PI and a translator in Romanian and were audio recorded, with additional notes taken by the PI. Key events were identified through discussion with Romanian collaborators, CWRU-based faculty participating in the training program, and the interviews with key informants. All survey and interview procedures were reviewed and approved by the CWRU IRB and any relevant Romanian REC.

Results

Trainee Scholarship and Contributions to Research Ethics

Nine of the 13 trainees (69.2%) who had completed the training at the time of the survey responded to the survey. Our review of trainee surveys and CVs and research databases revealed that over the course of the 14 years of our program, our 13 MA trainees had authored 94 peer-reviewed manuscripts, 64 book chapters, and 9 single or multiple author books and had edited or co-edited an additional 4 books. Ten of our 13 long-term trainees now have careers that focus in whole or in part on research ethics: faculty in a school of

medicine (5), research ethics staff in the pharmaceutical industry (1), private practice clinicians with involvement in professional organizations (2), and in other employment with research ethics-related activities outside of Romania (2). Three of the 13 trainees are now pursuing PhD programs in bioethics. The vast majority of our trainees are currently involved in activities related to research ethics as members or chairs of research ethics review committees (5), editors (4), or reviewers for peer-reviewed bio-ethics journals (3). Three trainees contributed chapters to the first volume of the first Romanian-language text on research ethics (Ast r staoe, Loue, & Ioan, 2009); 6 trainees contributed chapters to the second volume of this series (Ast r staoe & Loue, 2014).

Key Informant Interviews

We interviewed four key informants: the head of a hospital-based REC, the director of a regional oncology center, the president of a medical school, and the chair of a university-based REC. Each of these individuals was aware of the status of bioethics in Romania prior to the initiation of the Fogarty-funded CWRU training program and was employed in a capacity that required them to remain aware of the status of bioethics as a discipline and the existence and functioning of research ethics review committees.

The head of the university REC said that the Fogarty-sponsored training program had had “a huge impact.” In support of this statement, the individual pointed to the establishment of the Center for Bioethics and Health Policy that had resulted from collaboration with CWRU through the training program. The informant noted,

All people sitting on university ethics committees and at the national level are well-trained because of the Fogarty program and the training of others by the trainees ... People have benefited from the annual seminars ... Without the Fogarty, there wouldn't be anything.

The head of the oncology institute vocalized a similar opinion:

Most major hospitals now have at least one person trained in ethics. The core of this program was established with Fogarty graduates who are now used as trainers to train others. Everyone trained in research ethics in this country was trained through their hands. The program has had a major impact. Things are starting to work here. Everyone is doing ethics in their [medical] resident program. All hospitals now have ethics committees. The training program has changed the way things are run in the country.

A similar perspective was echoed by the university president. He noted that RECs now exist in universities that are located in major cities, in the Ministries of Education and of Health, in colleges of medicine, in the National Agency of Pharmacy, in pharmaceutical manufacturing companies, and in many major hospitals. He explained why these committees had come about:

The motivator? The [Fogarty] program trained people who could make the involvement with research ethics. The majority of the [research ethics] committee members are Fogarty [trainees]. The hardest thing is to set up committees logistically and to identify people who know what research ethics is. Almost 90%

of past and current members were trained via Fogarty. There is enough to have one person from Fogarty on a committee and they can educate the others.

Both the head of the hospital-based REC and the director of the oncology center explained that RECs are now required by both EU law and Romanian law. They both noted the conflict between the old and the new that confronted the Fogarty trainees as they worked to organize and lead the RECs. The head of the hospital REC stated,

The impact of the Fogarty is a new relationship with clinicians now, particularly those who are involved in clinical trials. It is not always a convenient relationship ...RECs are striving for transparency. Doctors don't always have the feeling that they are absolutely necessary. There is the confrontation of the old and the new.

The director of the oncology center explained, "Doctors are reluctant, it [RECs] is new. Researchers are embarrassed to have to submit their work."

Key Events and Accomplishments

Several key events were identified as having been turning points during the course of the training program. First, the training program in collaboration with Colegiul Medicilor convened a 2-day invitation-only conference in 2005 of all medical school faculty and administrators in Romania with responsibilities for the development and/or implementation of bioethics/research ethics courses. That meeting resulted in a consensus among the administrators that bioethics courses should be mandated for all medical school students in Romania. In 2005, the Romanian government approved Romania's first master's degree-level program in bioethics, which was developed by one of the Fogarty trainees and championed by the Colegiul Medicilor.

The training program collaborated with the Colegiul Medicilor to establish a Center of Bioethics and Health Policy, which now offers courses and serves as a resource for physicians and researchers throughout Romania. In conjunction with these activities, Colegiul Medicilor in 2003 established the first Romanian journal devoted entirely to bioethics, *Revista Română de Bioetică* (<http://www.bioetica.ro/>), which serves as a forum for discourse around issues critical to bioethics in Romania. In 2009, the president of the Colegiul Medicilor collaborated with this author and a past Fogarty trainee to edit the first Romanian-language text on research ethics (Ast r staoe et al., 2009), which includes chapters authored by three past Fogarty trainees. This text continues to serve as a resource for investigators and REC members and has, additionally, spurred the publication of other Romanian-language texts on bioethics generally and research ethics specifically, including a second volume (Ast r staoe & Loue, 2014).

Discussion

Our findings suggest that our training program has had a significant impact in Romania. Several aspects of the program appear to be central to this success.

First, this author made significant efforts prior to the program's development to engage in the teaching of bioethics and in research in Romania and, through these activities, to develop

relationships with Romanian colleagues. These relationships would later prove essential to the successful development and implementation of the training program.

Second, faculty members at MSASS at CWRU had a long-standing relationship with colleagues in Romania. These faculty members and their Romanian counterparts were never involved in bioethics education in Romania or in the United States and played no direct part in the establishment or continuation of the training program in research ethics. However, the very fact of a CWRU–Romania relationship may have engendered some level of trust to embark on a further relationship with CWRU. In addition, the experiences of the MSASS faculty provided context for the development of the training program.

Third, CWRU's partnership with the Colegiul Medicilor and the University of Medicine and Pharmacy in Iasi has likely been critical to our ability to administer the training program, to the ability of our MA trainees to identify potential employment and service opportunities in the field of bioethics upon their return to their country, and to the furtherance and validation of bioethics as a legitimate field of inquiry. As noted previously, Romania has had a history of widespread corruption, particularly in the public sector. Our ability to identify and collaborate continuously with institutions and colleagues was key. And, because the Colegiul Medicilor is the only professional association in the country with governmental authority to endorse activities for the continuing education for physicians and present certificates (the equivalent of continuing education credits in the United States), it is particularly significant that this organization co-sponsored and collaborated in training program activities.

Several factors likely contributed to the success of our program in transforming our trainees into reflective “practitioners of bioethics” that could have an impact upon their return to Romania. First, we premised our program on tested theories of adult learning that provided a framework for the development of the various program components and our approach to instruction. Second, we continuously revamped the program's components in response to the enunciated needs of both our trainees and our Romanian colleagues. Third, we provided strong mentorship that was designed to assist our trainees with their transition to the United States, their professional transformation, and their reintegration into Romania upon their return.

The comments of both the trainees and the key informants underscore the importance of the long-term commitment of the Fogarty International Center and CWRU to the development of a cadre of individuals trained in research ethics. Absent a sustained investment of time, effort, expertise, and funds, it is highly unlikely the training program would have had such an impact as that indicated through our evaluation.

We cannot know with certainty whether the training program would have had the same impact had Romania not been striving to attain membership in the EU. Although this author's focus on bioethics in Romania predated the commencement of Romania's reform efforts, the establishment of our training program and bioethics collaborations coincided in time with Romania's formal acknowledgment of human rights and adoption of anti-corruption measures as a precursor to EU membership. Two of our four key informants noted that RECs are now required in Romania as a function of both EU law and Romanian

law, but none of the four associated the growth of research ethics or RECs with Romania's preparation for or entry into the EU. And, although the questions posed to key informants did not include queries about the Fogarty-sponsored CWRU training program, all four respondents referred to the training program as a primary force in the establishment of RECs and research ethics education.

Our findings relating to the impact of our program are limited by the extent to which trainees' data were accurately recorded on searchable databases and CVs, the trainee rate of response to our survey, and the number and selection of our key informants. Nevertheless, the consistency of our findings from past trainees, key informants, and our search of the literature suggest that the Fogarty-funded training program has had a major impact on research ethics in Romania.

Best Practices

Our evaluation suggests that training programs directed to a middle-income post-Communist country are most likely to have a significant positive impact if (a) a working relationship exists prior to the initiation of the training program, (b) the training program is carried out through collaboration with one or more key institutional partners that are equally invested in the program's success, (c) the program itself rests on both educational and ethical theory and remains responsive to trainee and country needs, and (d) the funders, sponsors, and in-country collaborators are willing and able to devote adequate time, money, and expertise to the training program over a long period of time.

Research Agenda

Our findings suggest a variety of possible research questions:

Research Question 1: To what extent do the courses and educational programs in research ethics in Romania utilize the theoretical approaches to research ethics and to adult learning that are foundation to the CWRU MA training program?

Research Question 2: In what ways is the Romanian MA bioethics curriculum the same or different than that under which current faculty members were trained in the United States? What was the process by which this curriculum evolved?

Research Question 3: What factors at the individual, institutional, and environmental levels have facilitated or challenged the maintenance of the collaboration and sustained commitment to the training program?

Research Question 4: What is the comparative value of short-term training courses, long-term (>6 months) training, and professional development opportunities for mid- and senior-level professionals?

Educational Implications

The sustained investment by the Fogarty International Center and CWRU in Romania through both short-term and long-term training opportunities in research ethics geared to individuals at multiple levels of their career trajectories has yielded both a cadre of

individuals across professional disciplines that are well trained to assume leadership roles and a large number of individuals with sufficient knowledge to serve competently on research ethics review committees. The success of our training program underscores the need to (a) provide educational opportunities at multiple levels and of varying lengths and intensities and (b) sustain educational efforts through both repetition and continuity of commitment.

Acknowledgments

The author gratefully acknowledges the contribution of Martin Strosberg for providing results of the trainee survey conducted through a grant supplement funded by the Fogarty International Center, R25 TW007085.

Funding: The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: The training program noted was funded by the Fogarty International Center, R25TW001603 (Loue, S., Principal Investigator).

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Biography

Sana Loue is a professor of bioethics of Case Western Reserve University where she serves as vice dean for Faculty Development and Diversity. She has directed the Fogarty-funded training program for 14 years. Her research interests include HIV risk and prevention, severe mental illness, family violence, research ethics, and forensic epidemiology.

Table 1

Romania-Based Short Courses 2000-2005, 2007-Present.

Dates	Course title/content	Attendees	Number attending
October 2002	Bioethics in research with human subjects	Medical students (Iasi) Medical school faculty (Iasi)	100
April 2004	Conflict of interest and scientific misconduct Medical school faculty (Iasi)	Medical school faculty (Iasi)	187
	Medical mistakes	Medical students (Iasi) Medical school faculty (Iasi)	142
April 2005	Vulnerable populations in Romania and implications for research Medical students (Iasi)	Medical school faculty (Iasi)	80
	Bioethics curricula in Romanian medical schools; conflict of interest and scientific misconduct	Medical school deans (national representation) Medical school faculty (Iasi)	34
April 2008	Ethical conduct of research with human subjects (informed consent, confidentiality and privacy, vulnerable populations, ethical issues in genetic research)	Medical students (Iasi) Medical school faculty (Iasi) Industry researchers	80
April 2009	Ethical conduct of research	Medical students (national representation) Medical school faculty (national representation)	500
April 2010	Ethical issues in psychiatric research	Medical students	100
November 2010	Informed consent in research; international ethical guidelines for research; Romanian legislation relating to ethics and research; working with multiple boards (ECs, CABs, SABs, DSMBs); conflict of interest and scientific misconduct	Medical school faculty (Iasi) Medical students (national representation) IRB members (Iasi)	131
April 2011	Methodological and ethical issues in psychiatric research: Study design, recruitment and retention, statistical analysis, and associated ethical issues	Graduate and postdoctoral students, university faculty, members of ethics review committees	27
April 2012	Assessing and addressing vulnerability in research	Graduate and medical school students, postdoctoral fellows, faculty members, members of ethics review committees	61
September 14, 2012	(In)famous cases in research ethics Teaching ethics as both ordinary and extraordinary Religious ethics and the ethics of religion: Implications for research	Graduate and medical school students, postdoctoral fellows, faculty members, members of ethics review committees	200 each course
April 10, 2013	Ethical issues in social science research	Graduate and medical school students, postdoctoral fellows, faculty members, members of ethics review committees	47
January 28, 2014	Clinical trials and participant injuries: Ethics and epidemiology	Graduate and medical school students, postdoctoral fellows, faculty members, members of ethics review committees	50

Note. CAB = community advisory board; DSMB=data safety monitoring board; EC= ethics committee; IRB = institutional review board; SAB=scientific advisory board

Table 2**Key Informant Questions.**

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- Thinking back 10 or 11 years ago, what would you say was the state of the research ethics infrastructure in your country? What problems, if any, existed?
 - How has that situation changed, if it has, during the past 10 years? What factors do you think brought about those changes?
 - How widespread is the establishment of RECs in Romania? For example, do only some academic institutions have them? All institutions?
 - What factors motivate institutions in this country to develop RECs? Are there barriers to their development?
 - What is the process for obtaining ethical review of a clinical trial protocol by a competent (research) ethics committee in this country?
 - How many (research) ethics committees are there in this country?
 - What are RECs supposed to accomplish? What would constitute convincing evidence that they are accomplishing their goals?
 - What do you think the general public understands about research and RECs? Is there anything that has been covered by the media that might have affected public perceptions, such as an experiment or a report of a new drug or a scandal involving research?
 - If money were no object, how would you like to improve the system of research review here? What might prevent that from happening? What might facilitate its accomplishment?
 - Is there anything else that you think it would be good for me to know about?
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Note. RECs = research ethics committees.