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Ethical Review Issues in Collaborative Research between US and Low – Middle Income Country Partners: A Case Example

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Abstract

The current ethical structure for collaborative international health research stems largely from developed countries' standards of proper ethical practices. The result is that ethical committees in developing countries are required to adhere to standards that might impose practices that conflict with local culture and unintended interpretations of ethics, treatments, and research. This paper presents a case example of a joint international research project that successfully established inclusive ethical review processes as well as other groundwork and components necessary for the conduct of human behavior research and research capacity building in the host country.

Keywords

collaborative research; ethical review; case example; tobacco control

Background

Human subjects research issues in US / low – middle income countries

Controversies in the conduct of international research between developed countries and developing countries continue to cause challenges for systems of ethical review and protection of human subjects.[1] Past violations have raised concerns that studies considered unethical in developed countries are being carried out in developing countries in an exploitative manner.[2] Clinical studies in developing countries may involve populations with severe socioeconomic limitations, which make them vulnerable to abuse.[3] While a goal of applying the same ethical standards and procedures to all research regardless of location may seem admirable, socioeconomic realities, cultural factors, and research infrastructures in need of further development necessitate a broader examination of these standards.

Current literature identifies several key challenges in international research, including the lack of culturally appropriate ethical standards and practices, existing ethical review boards' focus on informed consent rather than the entire research protocol and ongoing oversight, and factors that contribute to culturally relevant conflicts of interests which interfere with an objective ethical review process. As global partnerships in research continue to develop, it will be critical to have systems for ethical review that bridge these gaps to human subjects protection across countries and cultures.

The current ethical structure for collaborative international health research stems largely from developed countries' standards of proper ethical practices (i.e., standards developed by the USA, European Union and Japan).[4] The result is that ethical committees in developing

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countries are required to adhere to standards that might impose practices that conflict with local culture and interpretations of ethics. These differences can be attributed to profound cross-cultural differences, inadequate health care conditions, high levels of social inequality, social structures that fail to respect human rights, and political influences.[5] For example, in Western culture, emphasis is placed upon individual liberty and autonomy, whereas in developing countries, the focus may be on the best interest of the community rather than the individual. Further, even basic issues of morality and differing philosophical views of what is 'good' or 'right' may differ across cultures and add a layer of complexity to determining what is ethically correct in research.[6] Hyder et al. point out that renewed stress within the US guidelines on appropriate cultural sensitivity in developing countries makes an impact on the opinions of host country health researchers, and that 'politics' (which is variably defined, but at any rate reflects interests that are beyond relevant ethical or scientific issues) can be viewed as playing an influential role in the functioning of both developing country and US ethical review processes.[7]

The purpose of the Institutional Review Board (IRB), which is typically called the Institutional Ethics Committee (IEC) at non-US sites, is to make certain that research protocols adequately address ethical issues.[8] While the role of an institutional review board, by regulation, has wide-ranging responsibilities for considering all ethical aspects of a research protocol, in practice, many IRBs and IECs tend to focus on informed consent documents.[9] Informed consent is generally held as essential in protecting the rights and welfare of study participants. However, the interpretation of the US federal regulations has resulted in extremely detailed and elaborate procedures for informed consent. From the point of view of researchers and subjects in developing countries, this approach may be culturally inappropriate and may differ from what research participants would see as important protections of their rights.[10] Therefore, even a concentrated focus on procedural aspects of informed consent does not guarantee proper ethical standards and practices in international research. The focus on a single aspect of a research project may lead to gaps in protections in other areas. For example, some ethical review committees in Latin America have particularly focused on the availability of treatment to research participants after the conclusion of the study, but fail to focus on protecting confidentiality of those participants.[11]

London states that review processes, therefore, need to develop new strategies for recognizing and strengthening the agency of individuals, groups, and communities whom institutional review has thus far only viewed as 'candidates for protection'.[12] In the realm of international research, however, factors such as money, power (political or economic), prestige, custom, indifference, health care needs, or lack of research expertise, may cause IECs to find themselves pressured automatically to approve research protocols that have already been approved in the funder's home country. For example, financial incentives (e.g., profits from pharmaceutical products or certain therapies; increase in salaries or promotions for researchers involved; potential profits from patents) may be sufficiently influential to shape entire research agendas in the developing and developed worlds.[13] In addition, in developing countries, treatment studies may be seen as the only means of accessing needed treatments, and the treatment offered through the study may be of a higher quality than what is available locally. Ethical review committees may therefore feel compelled to approve such studies that are perceived as an opportunity to provide medical care to impoverished or underserved populations.[14] This blurring of the distinction between medical care and research raises particular concerns about potential exploitation, and highlights the need for appropriate protections for human participants. Although in an ideal setting ethical review by IRBs and IECs should be independent of external influential factors, the reality may be quite different.

A related concern regarding exploitation is raised when the treatments being tested are beyond the means of the host country to utilize even if they are found to be effective.[15] Finally, there have been debates regarding the ethics of placebo-controlled trials in developing countries, particularly with HIV/AIDS research.[16] The Declaration of Helsinki requires that control groups receive the 'best' available treatment.[17] However, it is unclear whether 'best' refers to the medical care in the funding (i.e. developed) country or the 'local' standard of treatment in the host country, which may be of poorer quality than in the funding country or even non-existent.[18] The principle of 'equipoise' – not being certain about which treatment will confer the most benefits – requires that no research participant receive less than the best evidence-based treatment.[19] The Declaration of Helsinki states that research may be conducted only if the populations studied stand to benefit (Principle 19) and at the conclusion of the study, every participant should be given access to whichever treatment was most effective (Principle 30). These requirements are not universally accepted; for example, the US Food and Drug Administration (FDA) has not fully embraced the Declaration standards.[20]

Ethical Review in Latin America

Ethical review of clinical research in Latin America has not kept pace with the increases in clinical research activity in the region. Clinical research increased in the region from 300 new studies in 1995 to more than 1500 in 1999. If this trend continues, ongoing and new research could exceed the possibility of appropriate cultural acclimatization.

Limited resources for ethics committees in Latin American may cause noncompliance with regulations and guidelines set forth by the funding country.[21] For example, in the United States, ethical committees and IRBs are often distinct entities with clearly defined functions: ethics committees focus on overall ethical issues/practices affecting their respective organizations/institutions, while IRBs focus on specific research protocols. In Latin America, however, the duties of these entities often reside within a single committee,[22] thus increasing the demands on that group. As international research continues to increase in Latin America, the need to develop an ethical review process that is appropriate to the culture, socioeconomic environment and of equal ethical rigor as other ethical committees will become crucial.[23] Funding, training, capacity building, outreach and respect for cultural differences may be required in order for this effort to be successful.[24]

US Requirements for Ethical Review in Global Research

The research regulations of the US government only apply to projects that receive federal funding. When a non-US institution receives funds, either directly, or as part of a collaboration with a US grantee institution, the regulations of the granting agency must be complied with for all participating institutions both in the USA and abroad. The US Common Rule does make provision for agency heads to grant an 'equivalence' for foreign institutions that follow a different set of procedures and ethical policies.[25] In practice, however, foreign institutions usually opt for compliance with the Common Rule.

When grants are given to US institutions, they are responsible for ensuring that all participating institutions comply with the requirements for the protection of research subjects. This usually is accomplished by the US institution reviewing the project through its IRB and requiring all other institutions, both US and foreign, to show proof of IRB review at their institution.

When federal funding is involved, The Office of Human Research Protection (OHRP) is responsible for interacting with institutional review boards all over the world. Originally located, organizationally and physically, within the National Institutes of Health, this office

became an independent agency in the US Department of Health and Human Services in June 2000, in part to avoid conflicts of interest.

Federal Wide Assurance

In addition to institutional review boards, the OHRP requires a Federal Wide Assurance (FWA) and tracks these assurances as well all over the world. This FWA is a promise that the institution will abide by one of several ethical guidelines related to human subjects research, including the Belmont Report, the Declaration of Helsinki, or similar code. The FWA also requires compliance with the US Government regulations for human subject protection, which is known as 45CFR46 (CFR = Code of Federal Regulations). The FWA states that the signing official on behalf of the institution is aware of at these guidelines and promises that human subject research will, in fact, follow them to assure adequate protection for research subjects. The assurance is readily obtained in an online process but requires the IRB to be in place and registered first.[26]

Most US institutions that have a federalwide assurance (FWA) have elected to provide the same protections for all types of research, not just federally-funded research. Thus, most US institutions will require an IRB at collaborating institutions even if no federal funds are involved, so that the terms of their assurance remain valid.

HIPAA Compliance

The Health Insurance Portability and Accountability Act (HIPAA) regulations are promulgated by the DHHS and enforced by the Office of Civil Rights.[27] Like the Common Rule and 46CFR45, the HIPAA regulations are applicable only to US institutions (‘covered entities’). Unlike the Common Rule, however, there is no assurance mechanism and equivalent protections under HIPAA. This has lead to some confusion regarding international research and the confidentiality protections afforded by HIPAA.

The rule of thumb that is applied for international collaborations where data will be crossing boarders, is that once the information (‘PHI’) comes into possession of the covered entity – either by the US researcher receiving identified data sent to the USA from the forign site/ collaborator, or by the US researcher actually collecting the data in the foreign country – then it becomes governed by the HIPAA regulations.

HIPAA regulations can be difficult to apply in international studies and U.S. institutions and their IRBs have taken some different approaches. Researchers may seek approval of an altered or simpler form of the required HIPAA Authorization language. Sometimes, where cultural barriers are significant, a waiver of the requirement for HIPAA Authorization is considered appropriate. To grant any of these requests, the covered entity must determine that the request meets all of the waiver criteria in the HIPAA Privacy Rule.

Training Requirements

In 2000, the Secretary of DHHS instructed NIH to establish a requirement for training in human subject protections for all investigators receiving funding. NIH responded by instituting a system that requires institutions receiving NIH funds to certify that the ‘key personnel’ on the grant have completed some type of ethics/human subject protection training, which is considered adequate by the institution.[28] Thus, foreign collaborators who are considered key personnel must have received this training as well. Usually this is accomplished by the investigators at the foreign site either completing the US institution’s training program, or by completing an online program.

Dominican Republic Requirements for Ethical Review

The DR ethical review process currently provides IEC review for internal research projects, as well as for all joint international research projects. The DR government mandates that all joint international research projects must be reviewed and overseen specifically by the newly established Comisiòn Nacional de Bioètica en Salud ('CONABIOS' – the National Commission of Bioethics in Health). Many of the IECs in the D.R. are registered with OHRP and, although they may or may not have current FWAs, they provide review for all internal biomedical research projects. All of the FWAs must have IECs that are registered, but the reverse is not true – resulting in a variety of available IECs. Although CONABIOS is the review group for joint international research projects, CONABIOS is not established as a US registered IEC. Therefore, multiple review committees and processes exist to provide ethical review. Table 1 lists all DR IECs that are registered (Table 1 can be found on the OHRP website for both FWA and registered IEC/IRB in all countries that have them). Researchers seeking review for joint international projects in the DR must ensure compliance with an available IEC, and with the government-mandated CONABIOS.

The DR provided our project with one of several mechanisms for bioethical training for researchers through UASD (Universidad Autònoma De Santo Domingo). The UASD IEC provided our project a letter which met our University's IRB review requirements, and confirmed the names of those who successfully completed our 4 hour training.

Case Example

'Technology Assisted Dominican Republic Tobacco Control' is an NIH funded project to develop and test tobacco cessation interventions, and to build research capacity in the Dominican Republic (DR) using a community partnership model. The first 18 months of this five-year study were dedicated to building a sound administrative infrastructure to meet both US and DR IRB/IEC requirements to assure proper review and oversight of the research study.

US Institutional Review Board Procedures

The first step in the establishment of review processes appropriate to US funded government grants was to identify applicable regulations, and to involve the University of Rochester's (UR's) IRB early in the process to ensure compliance. The research protocol was presented to the IRB, which then directed the US project team to submit to an appropriate DR IEC and to demonstrate approval to our university's IRB prior to conducting research activities.

DR Institutional Ethics Committee Procedures

The initial task was to identify and establish official coordination with an IEC in the DR that was registered with OHRP, and to partner with an institution which either had an FWA or was eligible and willing to obtain an FWA. A sensitive challenge encountered during this phase involved responding appropriately to differing US and DR requirements. Specifically, the newly established government mandated Comisiòn Nacional de Bioètica en Salud ('CONABIOS': National Commission of Bioethics in Health, see above) was established as the review board for joint international biomedical research projects. As mentioned above, CONABIOS was not a US registered IEC, and did not meet US requirements for IRB review. Additionally, it was noted that the process of ethical review through this system was generally both lengthy and costly.

To address these challenges and meet OHRP regulations, the project team next identified IECs that were already established and registered, using the OHRP website (see Table 1). A number of IECs were identified that were registered with OHRP; direct contacts with these

committees, however, indicated that most had only dealt with local research projects, and did not readily prioritize working with other international research studies outside of their respective institutions. Ultimately, the IEC of the Universidad Autònoma de Santo Domingo (UASD) was identified as a viable committee. After introduction of the plan to UASD, both the sponsoring and host countries confirmed that this IEC would meet the needs for rigorous review and OHRP-based approvals. The IEC also provided the US team with a channel to receive culturally appropriate feedback on acceptable research procedures in the DR.

The DR mandate to use CONABIOS for review of international research protocols remained an important host-country requirement. Therefore, and with consultation across both project teams, it was determined that a dual review process (both CONABIOS and UASD), in addition to the University of Rochester's local IRB, satisfied all appropriate requirements. This ensured procedures for compliance and oversight from all collaborative partners, and demonstrated culturally-appropriate respect for and adoption of the ethical review infrastructures in both countries. From a project standpoint, it lengthened the period and cost of review and so timelines were adjusted so that all compliance needs would be satisfied.

Federal Wide Assurance (FWA)

A US requirement was to identify or create a US registered IEC in the DR for ethical review and oversight. After confirming UASD as the most appropriate DR IEC, the next step was to facilitate our collaborator's application for a Federal Wide Assurance (FWA). An application process was therefore initiated and the FWA was successfully obtained by Centro de Atención Primaria Juan XXIII with the close collaboration of the US and DR project teams. As part of the application process, UASD certified that they would work with the proposed project.

Challenges in Review

Establishment of ongoing IRB/IEC reviews for the current project presented successes and challenges for both the sponsoring and host countries. The review system that was established was successful in meeting requirements within both countries. However, differences in the ethical review processes presented challenges.

For example, the University of Rochester's IRB required different applications and used different approval procedures ('expedited' or 'full board') for protocols depending on the type of research being conducted (e.g. behavioral and social science research, clinical trials) and it reviewed these protocols as they were submitted with no delays due to deadlines for submission, etc. The DR committees conducted monthly full review meetings to assess and approve all submitted research protocols, with no specific application or process dependent on the type of research. This review process did not ensure that a submitted research protocol would be reviewed in the next scheduled monthly meeting, or that the timing of an expected approval could be predicted. Research protocols could thus be delayed for months before the DR ethical committees even began the review process. This situation was further complicated by the need for dual committee review in the DR. Various factors may have contributed to the delays, including the sheer number of research protocols to review and approve (combined with a shortage of qualified ethical committees in the country), limited time and resources of ethics committee members, and the lack of full understanding of the research methodology being proposed. Irrespective of reason, the process required considerable flexibility in project implementation schedules on the part of the research team.

Culturally appropriate procedures

The US team drew upon the experience of DR team members and of US co-investigators who had previously conducted research in the DR, to assist in developing procedures that

would be responsive to human protections requirements in both countries and would be culturally acceptable to research participants.

Informed Consent—An example of the development of culturally appropriate procedures related to the establishment of an informed consent procss. For US approval, the consent process needed to comply with informed consent and HIPAA regulations. This created several challenges. First, HIPAA regulations are US law and therefore cannot be enforced within the DR system. Second, the typical US consent form did not readily transfer to the DR environment. Many of the participants in the participating communities were of limited education literacy and would not be able to understand the written document fully. Further, and potentially even more importantly, the DR partners explained that the signing of a document has a very different meaning in the DR (as in many developing countries), from what it represents in the US. Providing a signature in these settings is viewed as something that carries serious implications of a contractual agreement with specific, enduring legal obligations, irrespective of clauses assuring participants of the voluntary nature of the project and the freedom to withdraw at any time, and it is generally viewed by community members with suspicion and as something to be avoided (also attributed to the 31 years of dictatorship suffered by these communities under the Trujillo Regime). The DR partners were clear that signing a consent form for the research project would be considered culturally unacceptable. Given the low-risk nature of the current project (research consisted of interviews and surveys with participants over time), an alternative was sought. The US project team explained these issues to the US IRB, and the resulting forms and procedures were designed within a culturally sensitive context specific to characteristics of the proposed target population.

The project team successfully obtained a waiver of documentation of written consent (i.e. ‘exempt status’) and subsequently established a two-step process to ensure informed consent. The first step was a verbal IRB/IEC-approved script that all data collectors would relay to potential research participants:

> ‘Right now we are interviewing various households in the community about general health information and attitudes and beliefs about tobacco from smokers and non-smokers. Your participation in this study is completely voluntary. You are free not to participate or to withdraw at any time, for whatever reason, without any risks. We would like you to complete the interview, but you may skip any questions that you do not feel comfortable answering. Your responses will be kept confidential. Are you willing to participate?’ (Script is from Surveillance, Community- and Smoker Cohort surveys, 2004).

The second step was the creation of business cards that summarized project objectives and provided both DR and US contact information, in the event that participants had additional or later questions or concerns regarding the research study or their rights as research participants.

Subject Reimbursement—A second example of a procedural adjustment to respect cultural differences occurred around reimbursing subjects for participating. In the USA, it is typical to offer some form of payment to research participants, and to inform them of this payment during the consent process. In the DR, however, this is considered coercive and therefore unethical. The project was responsive to this position, and complied with a DR IEC-acceptable solution, which was to provide participants with a small appreciation gift after they completed the interview, but not to inform them of this gift until the interview was complete.

Training in Bioethics

According to Kassel & Ross, tobacco research training is integral to all capacity-building efforts, particularly within developing countries, and the success of such training is contingent upon collaborative efforts that acknowledge and incorporate the differences in cultural contexts. [29] They state that the cultural context of the host country must inform and guide the content and the process of research and training initiatives. In the current study, US and DR teams jointly conducted bioethical training for all DR-based project staff that would meet both US and DR requirements, and would also help build ethically sound capacity for tobacco control research in the DR. This training included: 1) the Spanish version Belmont Report with exam;[30] 2) a bioethics course provided by the University or Rochester's IRB (completed by both the US and DR project investigator teams), and 3) in-country training.

The in-country course, approved by both DR and US ethics committees, included training in basic bioethical concepts, confidentiality, consent procedures and their meanings, as well as issues of data safety. Interactive role-plays and questions and answer sessions were included. All DR project staff were brought to a central location for a 2-day training session on project procedures. Bioethical training was conducted in a 4-hour block on the first day of training, and concepts were reinforced as the staff was trained in specific survey and data collection procedures throughout the remainder of training. The site PI from the D.R. research team chaired the 2-day training, and a bioethical expert from UASD provided the 4-hour bioethical training. DR and US team members provided subsequent training in study procedures. Bioethical training was approved by US and DR IRBs/IECs, and participants were provided with Certificates of Completion for Training in Bioethics.

Ongoing Assessment of Culturally-Specific Issues

In general, a lack of understanding of target communities and research participants in partner countries may impair the ability of a US-initiated research project and review boards to be responsive to culturally specific issues. To inform protocol development, the current project team initially drew on the experience and expertise of the DR-based co-investigators and US co-investigators who had conducted prior research in the DR. In addition, to further the team's sensitivity to cultural issues, the first component of the project that was implemented was a qualitative assessment of the participating communities.[31] Teams of US and DR investigators spent 2–3 days in each community, conducting in-depth interviews, participant observations, and focus groups with community members. The goal was to gain an understanding of the communities themselves, as well as to understand the attitudes, beliefs and practices of community members regarding tobacco use. These qualitative assessments were repeated in a later project year for follow-up. Lessons learned from these assessments not only informed the project about tobacco use but also sensitized the team members to community norms and practices which assisted in developing community partnerships and designing research protocols, for submission to IRBs/IECs, that would be culturally responsive and acceptable to the participants.

Discussion

The key lesson learned from the above Case Example was that the identification and establishment of a fully-approved IRB and IEC review process is both challenging and time-consuming, but can be successfully completed. Many unanticipated factors, although important and necessary learning experiences while initially building research capacity, created delays in the overall review and approval process of the current project. This further resulted in reassessing later project timelines for study objectives and goals. It is recommended that project timelines in international research account for such barriers by

lengthening the projected time needed for early project milestones, and by anticipating the need for flexibility.

In the effort to implement research projects and/or to build research capacity in the host country, it was learned that addressing these challenges in as collaborative and inclusive manner as possible between research teams is crucial in the creation of a sustainable infrastructure that meets international requirements and best assures a counterbalance to the past exploitative experiences in research within developing countries. Ongoing process reviews, creative problem solving, trainings, guidelines reviews and other processes are necessary for project progress and competent protection of human subjects.

Challenges in the ethical review of international research are influenced by cultural, social and economic factors. London provides two suggestions that can contribute to a new model for ethical review in developing countries that can favorably impact international research. The first suggestion to address the problem of cultural differences in interpreting ethical principles is to 'negotiate the ethics standard that recognizes the 'important truths' reflected in both approaches based on oral relativism and those based on moral fundamentalism' (p. 1082).[32] The second suggestion relates to the composition of the IRB/IEC in developing countries. Given the unique cultural and social aspects of international research, including a more diverse membership (members from the populations being researched; key officials from the religious, public health, education, medical, and other pertinent disciplines) within the ethical committees may ensure a more complete and inclusive ethical review process.

The current joint US–DR project experience has provided the US team with an opportunity to explore and create culture-specific methods to carry out recommendations supported by the international research ethics literature. Standards within this project are to discuss, research, and develop procedures that are culturally and ethically acceptable in both countries through regular meetings between US and DR core project teams. Another practice is to include members from the participating communities in the development of project interventions and protocols, and in interpretation of results. For example, the project engaged and trained local data collectors to conduct household surveys in participating communities. Preliminary results were shared with these data collectors by the US and DR core teams, and data collectors were asked for feedback on the consistency of these results with their own observations during the surveying phase. In addition, data collectors' suggestions on how to improve the surveying process were solicited.

A range of factors must be considered in the development and implementation of international research studies in developing countries. Economic, social and political stressors, along with a need to address under-treated health problems, may lead to pressures to implement studies that do not have adequate ethical protections. These stressors should not be accepted as 'standards' when trying to conduct research studies that would otherwise be considered unethical. A global concept of respect, beneficence and distributive justice, especially when working with 'vulnerable' populations, must be adopted. This, in turn, will create a 'bi-directional cultural influence between sponsoring and host countries'[33] and help create a new paradigm for ethical review in international research.

Ethical review in Latin America requires careful evaluation of the healthcare environment and the socioeconomic situation of the potential research participants. Issues such as the use of placebo, payment for participation or reimbursement of expenses, the feasibility of the consent process, and the expectation of the continuation of treatment after the study may require reconsideration within the framework of local values (both from the sponsoring and host countries).[34] This will in turn allow for core ethical requirements of research protocols

to be defined in a cross-cultural, as well as culture specific manner, to ensure ethically appropriate research practices within multi-site international research projects.

Cavazos describes the development of clinical research in Latin America as a technology transfer process – a process that undergoes cultural acclimatization in parallel with the modernization of the healthcare infrastructure.[35] As was learned in the above Case Example, the ethical review process, socioeconomic resources, and cultural characteristics are core components of this interactive practice. Identification and incorporation of these influences when developing research protocols is essential and challenging. Multi-site research studies (with project sites in both the developed and developing countries) should be involved in 'full partnerships' regarding the design and conduct of research.

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Biographies

Dr. Scott McIntosh, as Associate Professor at the University of Rochester, studies stop-smoking interventions and trains physicians and medical students. He is Site PI for a study of tobacco education in medical schools, and directs a community health improvement clerkship for 4th year medical students. He is co-chair of a series of international workshops on Web-Assisted Tobacco Intervention (WATI), and is a co-investigator on several projects, including obesity prevention and medical decision making.

Essie Sierra-Torres attended the University of Rochester and graduated with a BA in psychology and a minor in Spanish. She continued her education at SUNY Albany where she received her Masters in Public Health, with a concentration in behavioral and community health. Currently, she is pursuing her PhD with a concentration in Human Development in Educational Contexts at the Margaret Warner Graduate School of Education and Human Development, University of Rochester. Mrs. Sierra-Torres also works as a Project Manager for an NIH/Fogarty International Center funded project doing tobacco control research and capacity building in the Dominican Republic.

Dr. Ann Dozier, a doctorally qualified nurse and Associate Professor, leads program evaluations for NIH and CDC funded projects including the University of Rochester's Clinical and Translational Research Institute. She is the Principal Investigator for an NIH funded Community Based Participatory Research project to improve breastfeeding among low-income women. She also teaches Recruitment and Retention into Clinical Research and

conducts fieldwork in international health projects most recently in the Dominican Republic, Grenada and Tibet.

Dr. Sergio Diaz is a Professor and Program Coordinator for family medicine masters program at Pontificia Universidad Católica Madre y Maestra, Dominican Republic. He is also the Director of Centro de Atención Primaria Juan XXIII (public health clinic). In addition to his medical degree, he holds a Masters in public health and physiological sciences. Dr. Diaz is the DR based PI for an NIH/Fogarty International Center funded project doing tobacco control research and capacity building in the Dominican Republic.

Dr. Zahira Quinones is a Professor and Chair of the Health Sciences Faculty Research Unit at Pontificia Universidad Católica Madre y Maestra, Dominican Republic. She received her Masters in Public Health from the University of Rochester. She also works as a DR based Project Manager for an NIH/Fogarty International Center funded project doing tobacco control research and capacity building in the Dominican Republic.

Dr. Aron Primack is a Program Officer at the Fogarty International Center, NIH. His programs include one in International Research Training in Global Tobacco Cessation Research, one in Research Training in Global Trauma Research, and the International Clinical Research Scholars and Fellows Program. Dr. Primack is a medical oncologist who has been the medical director of progam integrity at the Health CareFinances Administration of the US Government, the Area Medical Officer for the US Peace Corps in West Africa as well as the director of the International Health Program at the Uniformed Services University of the Health Sciences.

Dr. Gary Chadwick is an Associate Provost at the University of Rochester and Professor of Clinical Community and Preventive Medicine and Medical Humanities in the School of Medicine and Dentistry. He is the Director of the Office for Human Subject Protection, which is responsible for the operation and support of the University's Institutional Review Board (IRB) system. He is the coauthor of the widely used training book, *Protecting Study Volunteers in Research*. He serves on several national and international committees as a human subject expert.

Dr. Deborah J. Ossip-Klein is Chief, Division of Social and Behavioral Medicine, and Director, Smoking Research Program at the University of Rochester Medical Center and the James P. Wilmot Cancer Center. Her research focuses on community-based tobacco control interventions that reach underserved populations and provide access to smokers over large geographic areas. She has conducted a series of trials on quitlines, mailed interventions, and web-based approaches. Projects have included targeting mid-life/older smokers and underserved groups through quitlines, primary care interventions for adolescent smokers, tobacco use in nursing homes, nicotine replacement medication use through quitlines, and the current trial of tobacco control research and capacity building in the Dominican Republic. Dr. Ossip-Klein has served on local, state, national, and international working and advisory groups and in NIH and state study sections.

Table 1

Institutional Ethics Committees in the Dominican Republic*

Organization	City
Fundacion Dominicana de Infectología, Inc.	Santo Domingo
Hosp Infantil Dr. Robert Reid Cabral	Santo Domingo
Instituto Dermatologico y Cirugia de Piel	Santo Domingo
Instituto Oncologico Regional del Cibao	Santiago
Profamilia	Santo Domingo
Secretaria de Estado de Salud Publica y Asistencia Social	Santa Domingo
Universidad Autònoma De Santo Domingo	Santo Domingo

*Available registered IEC's at the time of project development.