Institutional Review Boards in the U.S.-México Border

Current Protocols and Practices

United States-México Border Health Commission

December 2010

The mission of the United States-México Border Health Commission
is to provide international leadership
to optimize health and quality of life along the
United States-México border.

Providing Leadership on Border Health Issues to—

Facilitate Identification, Study, and Research

Be a Catalyst to Raise Awareness

Promote Sustainable Partnerships for Action

Serve as an Information Portal

December 2010

Institutional Review Boards in the U.S.-México Border

Current Protocols and Practices

United States-México Border Health Commission

Institutional Review Boards

Table of Contents

Executive Summary	1
Introduction	3
Background	3
Methodology	6
Results	7
Observations and Recommendations	11
Conclusion	13
References	15
Annexes	16
Credits	16

Other related publications

Healthy Border 2010/2020 Strategic Framework

Health Research on the U.S.-México Border: Promoting a Binational Agenda

Health Disparities and the U.S.-México Border: Challenges and Opportunities

Frontera Saludable 2010 - Reporte de Medio Plazo - Frontera Norte de México

Healthy Border 2010 Midterm Review U.S. Border Area

Border Lives: Health Status in the Unites States-México Border Region

Researching Border Health: A Review of Initiatives to Develop a Border Health Research Agenda, 1995-2009

www.borderhealth.org

EXECUTIVE SUMMARY

This report presents the results of a study conducted to better understand the framework and operation of Institutional Review Boards (IRBs) in the United States and México, with particular attention to the states along the international border. The study is based on a self-administered survey and in-depth interviews with key informants conducted from December 2009 through February 2010. Participants in the survey included faculty, researchers, practitioners, and staff working in public and private health institutions with an active research program in any of the U.S.-México border states (Texas, New Mexico, Arizona, California, Baja California, Sonora, Chihuahua, Coahuila, Nuevo León and Tamaulipas). Most of the participants were selected among individuals who had conducted or were conducting research projects involving the study of binational or transborder populations.

The report also summarizes insights offered by U.S. and Mexican researchers regarding the way IRBs operate on both sides of the border and their recommendations to address existing gaps and limitations of human subjects protection in the region. Based on this information, a comprehensive list of concerns and recommendations is presented for the purpose of developing uniform guidelines for a joint IRB in the U.S.-México border region.

The study conducted for this report shows an asymmetry in the operation of IRBs in México and the United States. Based on the report survey, universities and research centers in México and the United States can be grouped in one of the following three categories: a) schools or research centers that have a permanent IRB with a well established review protocol; b) schools or research centers using or that have used ad hoc IRB protocols; and c) schools or research centers that do not have an IRB. In general, the first category was common among schools or research centers conducting studies in the biomedical fields while the last two categories dominate among schools or research centers conducting research in the social and behavioral sciences. Most universities, community colleges, and research centers in the United States have well established IRB protocols that apply to biomedical, social, and behavioral studies involving human subjects.

The survey and interviews for this report also indicate a consensus among participants about the need to develop common guidelines for IRB operation or the creation of joint or binational IRB protocols applicable on both sides of the border. One of the suggested actions includes promoting collaboration among academic institutions to discuss procedures and instruments to protect human subjects at the binational and transnational level. Other recommendations include the following: 1) creating a binational IRB task force with the endorsement and participation of México's National Council of Science and Technology (*Consejo Nacional de Ciencia y Tecnología*) and the U.S. National Institutes of Health (NIH); 2) developing a binational agenda for human subjects protection through consultation with researchers, practitioners, managers, policy-makers, and other public health advocates; 3) promoting the exchange of experiences between Mexican and U.S. researchers about IRB frameworks and their operation and establishing a curriculum to educate and train students and researchers about human subjects protection issues. It was suggested that these exchange and educational programs should be considered entry points for the development of broader programs to enforce and monitor protection of human subjects in binational and transnational projects.

INTRODUCTION

This report was produced on behalf of the U.S.-México Border Health Commission (BHC) to better understand the challenges and opportunities involved in developing binational protocols and procedures for the protection of human subjects in medical, social science, and behavioral research. To best meet this need, a study was designed and conducted to understand the frameworks and operation of Institutional Review Boards (IRBs) in the United States and México, with particular attention to the border states.

The study was based on a self-administered survey and in-depth interviews with key informants—faculty, researchers, practitioners, and staff working in public and private health institutions with an active research program in any of the U.S.-México border states (Texas, New Mexico, Arizona, California, Baja California, Sonora, Chihuahua, Coahuila, Nuevo León, and Tamaulipas). Most of the participants were selected among individuals who had conducted or were conducting research projects involving the study of binational or transborder populations.

The report summarizes the insights offered by U.S. and Mexican researchers regarding current IRB operations and addresses existing gaps and limitations of human subjects protection in the region. The report also includes a comprehensive list of observations, concerns, and recommendations presented for the purpose of developing uniform guidelines for a joint IRB in the U.S.-México border region.

BACKGROUND

The need for research guidelines dealing with human subjects emerged following the Nuremberg trials, when medical experimentation abuses perpetrated by World War II Nazi doctors came to public attention. These publicized abuses, in effect, led to the creation of the Nuremberg Code in 1945, which was the first legal attempt to address ethical issues of modern research. However, as biomedical research efforts expanded, the international need for a more specific code of ethics became evident and as a result, in 1964 the Declaration of Helsinki was approved (World Medical Association, 1964). To this day, the Declaration of Helsinki is an essential reference for sound research practices worldwide and has been the source for the development of international ethical and scientific regulations, including the International Ethical Guidelines for Biomedical Research Involving Human Subjects (Council for International Organizations of Medical Sciences), the Guidelines for Good Clinical Practice (International Conference on Harmonisation [ICH] and World Health Organization [WHO]), and the Operational Guidelines for Ethics Committees that Review Biomedical Research (WHO) among others (WHO, 2000).

Currently, a variety of terms are commonly used to refer to bodies and procedures when reviewing ethical aspects of research involving human subjects. For example, universities and medical facilities with an active research agenda will render terms such as "institutional review boards," "research ethics committees," "ethical review panels," "ethical review committees," or "human research ethics committees." According to the World Health Organization, a committee reviewing the ethical component of biomedical research is a

> *"… [g]roup of individuals who undertake the ethical review of research protocols involving humans, applying agreed ethical principles"* (WHO, 2009).

Research involving human subjects includes

> *"… [a]ny social science, biomedical, behavioral or epidemiological activity that entails systematic collection or analysis of data with the intent to generate new knowledge; in which human beings:*

1) *are exposed to manipulation, intervention, observation or other interaction with investigators, either directly or through alteration of their environment; or*
2) *become individually identifiable through investigators' collection, preparation or use of biological material or medical or other records"* (WHO, 2009).

The function of such a committee is to approve, monitor, and review research involving human participants with the aim of protecting the rights, safety, dignity, and welfare of the research subjects.

The U.S. Experience

Institutional Review Boards in the United States were first established in the early 1970s following efforts by the National Institutes of Health and the U.S. Public Health Service to set requirements protecting human subjects in all "extramural" research receiving federal funding. An event that catalyzed these efforts was the revelation of the Tuskegee Syphilis Study, in which 399 rural black men were left untreated for diagnosed syphilis even after effective antibiotics became available, which prompted Public Law 93-348 calling for the establishment of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (Department of Health, Education, and Welfare, 1979). In 1979 the Commission published general recommendations, known as the Belmont Report, that served as the basis for the formulation of federal regulations published in the Federal Register in 1979. The core philosophy of the Belmont Report centers around three principles: respect for persons, beneficence, and justice (Department of Health, Education, and Welfare, 1979).

U.S. federal laws governing the ethical aspects of health and medical research have continuously evolved as demonstrated from the revision of existing regulations from 1974 to 1991. Currently, the Office for Human Research Protection (OHRP) and the Food and Drug Administration (FDA) of the Department of Health and Human Services (HHS) are the two agencies responsible for overseeing aspects of independent IRB systems. The HHS Code of Federal Regulation Title 45 CFR Part 46 condenses the regulation for the protection of human subjects (see Annex I). In 1991, a uniform set of regulations for the protection of human subjects (subpart A of 45 CFR Part 46) was adopted by other U.S. federal departments and agencies (Williams, 2005). This uniform set of regulations is the Basic HHS Policy for Protection of Human Research Subjects, informally known as the "Common Rule," and is followed not only by HHS but also by other federal agencies such as the National Science Foundation, Departments of Energy, Veteran's Affairs, and others (HHS, 2009). The basic HHS Policy for Protection of Human Research Subjects (45 CFR Part 46) applies

> *"…to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by federal civilian employees or military personnel, except that each department or agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the federal government outside the United States"* (HHS, 2009).

Initially interpreted to mean any research directly funded by a federal agency, 45 CFR 46 did not immediately impact social and humanistic sciences when adopted in 1991. After the 1991 Common Rule, however, IRBs increasingly expanded their purview to include all research conducted in universities and colleges or in any federal agency, regardless of whether they were directly federally funded or not (Cohen, 2007).

Additionally, a number of private organizations have since voluntarily chosen to follow the Common Rule, though these are not subject to federal enforcement mechanisms if they fail to comply (Williams, 2005). The Common Rule sets out a series of guidelines which, as in practice today, affect nearly all research undertaken by students and faculty in U.S. colleges, universities, and federal agencies. The guidelines of 45 CRF 46 require that all research ensures full anonymity or confidentiality to human participants (referred to as "human subjects"). Furthermore, all research should ensure full informed consent of participants through the use of written consent forms. However, there are important exemptions to these requirements. Any research that involves "use of educational tests, … survey procedures, interview procedures or observation of public behavior" is fully exempt from IRB review according to the 45 CFR 46.101(b)(2), as long as data are gathered in a way that ensures the anonymity of all human participants. If participants could be identified in some way, or would be harmed – "at risk of criminal or civil liability … damage[e] to … financial standing, employability, or reputation" (HHS 2009: 45 CFR 46.101(b)(2)(i)), then the research is not exempt unless the participants potentially exposed to harm are "elected or appointed public officials or candidates for public office" (HHS 2009: 45 CFR 46.101.(b)(3)(i)).

The México Experience

In México, regulations to protect human subjects participating in scientific research is relatively new and its instrumentation is still a work in progress. Current practices for the protection of human subjects in hospitals and other medical facilities in México are based on a variety of laws and regulations. One such regulation is the General Law of Health (Ley General de Salud) which mandates the "creation of ethic committees in medical centers where research with human beings is conducted" as well as defines the functions of ethical committees in the Mexican heath system (see Annex II).

Title II, Chapter I of the Regulation of the General Law of Health in Health Research (Reglamento de la Ley General de Salud en Materia de Investigación para la Salud) provides specific guidelines about the ethical aspects of medical research involving human subjects (see Annex III). Article 13 of the code states that

> *"…in any investigation in which humans are subjects of study, the criterion of respect for dignity and protection of human rights and well-being must prevail."*

Article 14 clearly states that research involving human subjects can be conducted only

> *"… (a) if experimentation with lab animals or other scientific knowledge supports its relevance, (b) there is no other reasonable mean of obtaining similar knowledge, (c) expected benefits exceed predictable risks; (d) informed written consent is obtained from human subjects; (e) research is conducted by trained personnel with access to adequate human and material resources to provide good care of research subjects; and (f) have the approval of an ethics research committee."*

Article 16 establishes

> *"…[r]esearchers have the obligation to protect the privacy of the persons participating in the study and collect identifying data only when the research design requires so and it is authorized by the subject."*

Article 18 states

> *"[t]he principal investigator shall suspend research immediately in the event of foreseeable risk or damage to the health of the human subjects. Also, research will be suspended immediately at the request of the subject"* (Regulation of the General Law of Health in Health Research, 1984).

An important development in México's efforts to regulate medical research from an ethical perspective was the creation of the National Commission of Bioethics (Comisión Nacional de Bioética—[CNB]). Originally established in 1992 by a group of Mexican scientists interested in promoting a national debate about the ethical implications of new biomedical technologies, the CNB became a permanent body in 2000 by presidential executive order and in 2005 was transformed into an autonomous and decentralized body of the Mexican Ministry of Health. Today the National Commission of Bioethics is

> *"… [t]he official body responsible for defining national policies on bioethics, for establishing public health policies related to bioethics and to act as the national body to be consulted on specific issues on bioethics"* (CNB, 2009).

As it is stated in its bylaws, the mission of the CNB is to promote a bioethical culture in México. Some of the mandates of this institution include promoting the establishment of bioethics commissions in every state. At the onset of the CNB, only 9 out of 32 states had a bioethics commission. As recently as 2009, 20 states had a bioethics commission established.

In 2005 the CNB issued the National Guidelines for the Integration and Operation of Research Ethics Committees (*Guía Nacional para la Integración y el Funcionamiento de los Comités de Ética en Investigación*) (see Annex IV). These guidelines define the criteria for the integration and operation of ethical committees in México's health system including hospitals, schools, and research centers. One aim of these guidelines is to unify the operation of ethical committees in México under a common set of rules and protocols. As it is stated in the guidelines, the operational criteria of ethical committees in México should conform to accepted international practices and be consistent with existing national regulations. The Mexican regulations that were considered for these guidelines include México's Constitution, the Organic Law of the Public Federal Administration, the Internal Regulation of the Health Ministry, the General Law of Health, the Regulation of the General Law of Health related to Health Research, the Regulation of the Federal Commission to the Protection of the Sanitary Risk, the framework that regulates the compromise for the transparency in the relationship between physicians, health institutions, the pharmaceutical industry, and the Federal Law of Transparency and the Access to Governmental Public Information (CNB, 2005).

Although the terms of reference of the ethical committees described in the National Guidelines apply to any entity conducting research with human subjects in a biomedical context, the biomedical framework in which this guideline is elaborated is not appropriate to settings and disciplines conducting research involving human subjects in social and behavioral studies. Thus, at this point the application of IRBs in universities and research centers conducting social and behavioral studies is much more limited.

METHODOLOGY

The framework and operation of IRBs in the U.S.-México border was evaluated using a combination of methods that included a non-probabilistic online survey and a series of individual interviews with selected key informants.

The survey consisted of a convenience sample of individuals affiliated with universities, medical centers, public health departments, and non-governmental organizations who may have been involved in public health research in any of the U.S.-México border states. These individuals were invited to respond to a short questionnaire including questions about interaction with IRBs in their institutions, perceptions of the IRB process, and the need for common IRB protocols in the U.S.-México border context. Informants were identified using a directory of health agencies compiled by the U.S.-México Border Health Commission and recruitment was achieved using a formal invitation sent via e-mail. The survey and all recruitment material

were provided in both English and Spanish (see Annex V). The survey was posted online from December 10, 2009, to January 30, 2010, using the services of Qualtrics Inc., an internet-based survey system (http://www.qualtrics.com). Most of the selected participants received an initial invitation during the second week of December 2009 and a follow-up reminder the second week of January 2010.

Invitations to participate in the survey were sent to a total of 104 individuals during the first recruitment round. Of this original list, 7 names were eliminated because they were associated with undeliverable emails and 4 persons refused participation due to their lack of experience on the topic of human subjects protection. Most of the undeliverable e-mails (n=6) were individuals who received a questionnaire in Spanish. The final sample consisted of 93 individuals, 25 of which received the Spanish version of the questionnaire because they had an affiliation to a university or institution in México, and 68 individuals received the English version because they had an affiliation to a university or institution in the United States.

Fifty individuals responded to the online survey, a number that corresponds to a 54 percent response rate. Eleven participants responded to the survey in Spanish while 39 answered the English version. Among those who answered the Spanish questionnaire, 82 percent identified themselves as faculty and/or researchers and 18 percent as health care providers. Most of these participants were affiliated with institutions located in a Mexican border state (82%). Among participants on the U.S. side of the border, 74 percent identified themselves as faculty and/or researchers, 10 percent were graduate students, 5 percent were public health staff, 3 percent were health care providers, and 8 percent were directors or administrators. Most of these participants were part of an institution located in a U.S. border state (87%).

The key informant interviews were conducted with a group of 7 scholars who have been involved or are currently involved in binational or transnational research projects. Some of the informants also possessed experience participating as a member of an IRB in México. A semi-structured interview of approximately 45 minutes of duration was conducted between December and February (2009-2010) with each of these informants. Four interviews were conducted via telephone and the rest were conducted face-to-face. Three of the informants were working in a U.S. university at the moment of the interview while the rest were working as researchers in a Mexican university or in a health care institution. Most of the researchers (n=5) have approximately 20 years of experience conducting binational and/or transnational research in the U.S.-México border region (see Annex VI).

RESULTS

Online Survey

Most of the U.S. participants (97%) reported to have an IRB in their university, medical unit, or institution. Ninety-two percent of participants reported submitting a research protocol to an IRB, individually or as part of a research group. Around one half (54%) of U.S. participants (n=21) had participated in research projects involving human subjects in México although only 33 percent of these (n=7) had submitted an IRB application in this country. Among those who submitted an application, 4 out of 7 cases reported that their protocols were reviewed by more than one ethics committee, and 5 of 7 cases (71%) reported that they did not have access to information regarding IRB operation policies in México. An equal number of participants (n=5) who had experience with IRBs in México reported that their protocol was revised in a timely manner. Within this group, 86 percent (n=6) reported having had an academic partner in this country who facilitated the process of understanding and navigating IRB policies and procedures in México.

Most of the Mexican participants (82%) reported having an IRB in their university, medical unit, or institution. Seventy-eight percent reported submitting a research protocol to this committee. Among Mexican scholars, 36

percent (n=4) had participated in research projects involving human subjects in the United States and 75 percent (n=3) had submitted an IRB application in this country. Among those who submitted an IRB application, 2 out of 3 cases reported that their proposals were reviewed by more than one ethical committee and 1 out of 3 cases reported that they did not have access to information regarding IRB operation policies in the United States. In all the cases where a protocol was submitted to an IRB in the United States, the decision was announced in a timely manner. Mexican scholars who submitted an application to an IRB in the United States reported having had an academic partner in this country who facilitated the process of understanding IRB policies and procedures.

Interviews

Interviewed participants classified university and research center IRBs into three categories: a) schools or research centers that have a permanent IRB with a well established review protocol and mechanism, b) schools or research centers using ad hoc IRBs, and c) schools or research centers that do not have an IRB. In general, the first category is common among schools or centers conducting research in the biomedical area while the last two categories dominate schools or research centers conducting research in the social and behavioral sciences. In contrast to Mexican institutions, U.S. universities, community colleges, and research centers have a well established IRB protocol that applies to all research involving human subjects in the biomedical, social, and behavioral sciences.

The knowledge level of IRB operations was assessed among participants in the interviews. Among Mexican scholars, the knowledge level of current IRB practices in both México and the United States correlated with two factors: (a) participation as co-principal investigators in a binational project and (b) exposure to the IRB process while completing regular coursework in a U.S. university as a graduate student or in short-term training programs in the United States. On the other hand, the knowledge level of Mexican IRB operations among U.S. researchers correlated with having a specific project in México or having a Mexican colleague who introduced them to the Mexican IRB process.

Interviewed participants provided valuable information and insight about their experience with the IRB process both in México and in the United States. Their experiences are summarized below through the narrative of nine specific cases illustrating challenges and coping strategies adopted by scholars on both sides of the border.

Case Studies

Case 1: Alternatives to IRBs and limitations

During the interviews, a common barrier identified by U.S. scholars conducting research in México was their inability to find a university or research center with an established IRB. Even when these researchers came to México with a protocol previously approved by a U.S. university, they were required by their funding agency or university to obtain approval of the same protocol by a Mexican IRB. Under this circumstance, the inability to find established IRBs in México forces improvisation as illustrated by a U.S. researcher. Because the Mexican university where one participant was a visiting scholar did not have an IRB, this participant had to request from the home university authorization to use letters of support signed by the head and faculty of the host university in México as a substitute for a full IRB review. The submission of letters of support from Mexican universities or hospitals in lieu of an IRB approval is an extended practice among U.S. scholars conducting research in México. This practice became common because IRBs in U.S. universities recognize the existing national disparities in this area and accept such documentation as an acceptable substitute of an IRB review in México. Yet, access to this mechanism is limited by the existence of prior collaboration and networking. As explained during the interview, the participant did not face too many barriers obtaining support letters because this individual already had a strong connection with the Mexican academic community. These networks

enormously facilitated the research process since Mexican researchers were critical to connect the participant with the community, local authorities, and other key research stakeholders. In the opinion of this participant, acceptance of his/her research by the community and collecting data in México was completely dependent on the support that his/her project obtained from Mexican researchers. This participant is a U.S. scholar with almost 20 years of experience conducting research in northwest México.

Case 2: Long-term impact through IRB training

According to U.S. scholars, binational research can be a challenging process for participating institutions, especially in those disciplines where no tradition exists for human subjects protection provisions. Therefore, the process of establishing an IRB in a Mexican university with a social science program could take months and even years. According to two participants, this situation is a deterrent for binational projects as many scholars might not be willing to bear the burden of a time consuming, complex, and uncertain bureaucratic process. When describing the experience with a binational project in northern México, one participant stated that the university and its partner in México agreed on investing time and money in training human resources in research ethics. Both principal investigators wanted to be sure that their project would cover the requirement of the HHS regulation for the protection of human subjects (45 CFR part 46), so the team decided to send a Mexican scholar to a short training program in research ethics at a U.S. university. According to this scholar, training of local human resources is critical in the process of developing and establishing an IRB in Mexican universities. After the IRB was established, this Mexican university obtained an HHS-approval assurance, which was a requirement to release U.S. federal government resources for this particular project. This is a scholar with almost 20 years of experience conducting research in northern and central México.

Case 3: Ad Hoc IRBs

Since most Mexican universities and research centers do not have an IRB and frequently researchers in these institutions are required to demonstrate that their institutions have this type of committee, Mexican institutions often resort to creating ad hoc IRBs. Funding for binational projects provides the conditions that usually will derive in the establishment of an ad hoc ethical committee in Mexican institutions. While this practice often positively results in solving an existing need, it also bears some limitations. First, the possibility of utilizing an IRB process is unknown by most researchers as demonstrated by the fact that in some Mexican institutions, a group of researchers reported the existence of an IRB while other researchers in the same institution were not able to confirm the operation of such a committee. Second, ad hoc committees tend to be temporal and their operation is unlikely to transform existing human protection practices within the institution. Third, criteria for the integration of an IRB are unclear and their operation many times is based on convenience. The operation of an ad hoc IRB is promoted in most of the cases by researchers in the health-related area and its operation might be temporal.

Case 4: Balancing the IRB review process

A U.S. scholar noted that when a research protocol is reviewed by an IRB, it is important to differentiate the methodological aspects from the ethical dimensions of the research process. On the one hand, all the issues related to the scientific integrity of the study are placed on the relationship between research design and data quality. On the other hand, there are ethical issues of protecting human subjects that should be given equal weight and attention. According to this scholar, Mexican ethic research committees put more emphasis on the design aspect of research protocols and less on human subjects protection. This scholar further commented that it is important that each component of the research process be assessed independently and impartially, so reviews properly weigh the risks and benefits for participants. It is imperative that measures for protection of human subjects be clearly defined in the research design and be systematically evaluated by IRBs.

Case 5: IRBs and social/behavioral studies

Several researchers agreed on the necessity of developing and establishing IRBs in Mexican schools and research centers conducting social and behavioral studies. Studies conducted in social science institutions usually involve topics and situations in which the physical and emotional integrity of participants might be at risk, and these components need to be thoroughly evaluated before the start of the study. Some examples of such studies are projects addressing domestic violence, use of illegal drugs, and sexual behavior. Participants emphasized studies in these areas might be a source of stress among human subjects, and in extreme circumstances, they could even produce life-threatening situations for particularly vulnerable individuals. For instance, a woman disclosing physical domestic violence could be at risk of experiencing more violence if researchers are oblivious of the environment in which the interviews are conducted or are careless about the level of privacy required for this type of investigation. On the other hand, there are some topics that could impose an unacceptable level of risk to the integrity of interviewers, such as studies about the use of illegal substances or drug trafficking. In these cases, it is critical that an independent collegiate group, such as an ethical committee, review and assess the risk benefit of a particular study before the start of fieldwork.

Case 6: Culturally sensitive IRBs

There was consensus among participants regarding the use of written informed consent in studies in which some level of risk might exist for human subjects. These included any biomedical, social, and behavioral studies where biological samples and anthropometric measurements would be collected from human subjects or where the efficacy of any treatment would be tested. This also should apply to studies where vulnerable groups are the target population (children, pregnant women, prison inmates, people with mental disabilities, etc.). Any exception to this rule should be decided by an ethical committee and should not be left to the discretion of individual researchers. However, ethical committees should be cognizant of different institutional and cultural traditions in México and the United States. Under some circumstances, binational projects could be problematic because IRB procedures in U.S. universities can be prolonged and because some procedures to protect subjects might be difficult to implement in some Mexican contexts. For instance, anthropologists of both countries agreed that they had faced barriers to apply certain techniques and tools when the U.S. protocols required the collection of a written informed consent. Signing any type of document might be considered unacceptable in contexts where people do not trust formal institutions. This is something that goes beyond the level of rapport that an interviewer can have with a participant. Indeed it is something more related with the fact that some people believe that if they sign a document, this document might be used legally against them. It is also a factor related with participants' education levels because in some cases they are not able to read and write. Thus, this group of researchers suggested using a verbal informed consent procedure. This includes using adequate language and spending enough time with participants to inform them about the risks and benefits of the study.

Case 7: U.S. researchers working in México without an IRB

A Mexican scholar described the situation in which he/she was invited by the ethics committee of a local health department to review a research protocol of a U.S. team that was collecting data in a Mexican community in northern México. According to this scholar, some members of the community were uncomfortable with the topic and the questions that these U.S. researchers were asking. This prompted the creation of an ad hoc committee to evaluate the research protocol. After reviewing the protocol of this ongoing study, the committee decided not to approve it. Some of the reasons why this protocol was not accepted were the following: a) the U.S. team was collecting data about a sensitive topic (sexuality) among indigenous adolescents, and some members of the community did not feel comfortable with how adolescents had been approached, b) the study included a clinical component, where a physical exam required touching private areas of the adolescents' body, and c) the team offered program incentives to the participants which included gifts. Since this is not a common practice among Mexican researchers, this particular component

was identified as a form of bribery by some members of the community. The combination of these factors, along with the fact that the study was not considering the community's customs, provided the basis for the rejection of the protocol. This case illustrates the situation of a transnational study in which U.S. researchers were conducting research in México without connecting with any type of Mexican institution or Mexican researchers.

Case 8: Mexican researchers working in the U.S. without an IRB

A U.S. scholar described the situation of a team of Mexican researchers conducting research in the United States without establishing any type of formal connection with U.S. scholars or institutions. According to this scholar, a team of Mexican researchers and their students conducted a survey among individuals of Mexican origin in a U.S. border state. This circumstance raised concerns about whether this team had an approved IRB by a Mexican university and whether the IRB included a protocol of proper collection of biomedical samples from participants. It was apparent from this experience that there is a lack of information among Mexican researchers regarding IRBs and the risks of transnational research for human subjects. This situation illustrates the importance of having a collaborative partner across the border and highlights the need for a binational IRB framework.

Case 9: Social responsibility

The impact of research on the well-being of communities was also a point of discussion for some researchers. Scholars conducting research at the binational or transnational level have a social responsibility with both participants and communities. Some of these responsibilities include providing the community with feedback about major findings and recommending potential policy actions that might contribute to improve the well-being of the participants and their communities. Binational research should also provide opportunities for the development of local capacities. Thus, external sponsored projects offer an excellent opportunity to build capacities among students, community advocates, and other researchers in border communities. Given the economic asymmetry between México and the United States, any collaborative project should assure Mexican scholars full access to any data collected as part of the research activities. During the interviews, it was suggested the research findings resulting from projects conducted in México have a higher marginal value in México than in the United States. Thus, it is critical that any data or research result generated through collaborative projects be presented and discussed in Mexican forums as well.

OBSERVATIONS AND RECOMMENDATIONS

Research Ethics Issues in National and Binational Contexts

An important number of observations and recommendations were expressed by participants in the survey and the interviews. Approximately 54 percent of participants in both surveys provided some recommendations about how to improve the IRB review process in México and/or in the United States. Only 10 percent of the U.S. survey participants reported not having information about IRB operations in México. The following list provides a synthetic view of the main areas of concern and opportunity for IRB operations in the U.S.-México border according to the participants.

IRBs in México

1. Widely disseminate existing Mexican regulations to protect human subjects participating in medical research.

2. Develop IRB guidelines and procedures. These should include information about IRB membership, IRB

procedures, and training of members. It is critical to include a clear description of the review process defining the amount of time required by the IRB to evaluate research protocols.

3. Implement a web-based IRB submission facility. This includes making forms available electronically. Securing Spanish-English translations of IRB guidelines and tools is recommended.

4. Establish a transparent and harmonized review process so approval of research protocols can be accepted by any IRB in the border region. This will eliminate the need for a double IRB submission as is required in some instances in México.

5. Encourage the establishment of human subjects sections in Mexican universities and research centers without an IRB. It is also important to create and disseminate a directory of Mexican research institutions with IRBs in place.

6. Develop an ongoing web-based training program for researchers conducting studies involving human subjects. The program can be modeled after the Collaborative Institutional Training Initiative (CITI) or other similar programs.

7. Create a protocol to allow IRB clearances in México when projects have an approved IRB from a U.S. university.

8. Create a panel of specialists to design an IRB policy in México responsive to the necessities and culture of research in México.

IRBs in the United States

1. Streamline the IRB process and develop protocols that are better suited for social and behavioral sciences. Some current IRB practices appear to apply to clinical/product studies but do not seem to be applicable for field-based environmental epidemiology.

2. Design consent forms that do not just meet legal requirements and protect universities from liability but also include language that is understandable and sensitive to the concerns and customs of participants. Consent forms enforced by the IRB of some U.S. institutions are difficult to use in Mexican communities.

3. Renew letters provided by Mexican institutions to support projects of U.S. researchers every year regardless the researcher in charge.

4. Clearly define the amount of time required to evaluate binational research protocols since these types of projects tend to take more time to review compared to domestic projects.

5. Expand IRB personnel to provide timely review of protocols submitted for approval.

6. Provide basic information about IRB guidelines and tools in Spanish.

7. Provide counseling to external institutions about IRB operation and certification by HHS.

Guidelines for joint IRBs

1. Establish a clearinghouse that can be used by researchers on both sides of the border. This clearinghouse should provide uniform IRB guidelines for binational research projects.

2. Promote the establishment of a system that can be utilized for IRB submissions in the U.S.-México border.

3. Promote collaboration among academic institutions to discuss protection of human subjects at the binational level. The National Council of Science and Technology (CONACYT) of México and the National Institutes of Health (NIH) should develop and establish guidelines for joint IRBs. Canadian universities should also be included in this discussion.

4. Promote the exchange of experiences between Mexican and U.S. researchers about IRB frameworks and operations. This exchange should discuss aspects such as enforcement and monitoring of protection of human subjects in binational and transnational projects.

5. Learn from the experience of researchers conducting binational or transnational studies. Some researchers of both countries have developed strategies to work collaboratively complying with IRB requirements. For instance, researchers divide the research process between countries. Thus, while the field work and data collection is conducted in México under the supervision of Mexican researchers, the processing of data takes place in the United States. Under this model, U.S. researchers receive IRB approval from their institution to conduct secondary data analysis.

6. Promote the U.S.-México Border Health Commission as the logical platform to launch a binational discussion about IRB protocols in México and the United States and the need to mediate existing frameworks and practices.

Suggested Actions for the U.S.-México Border Health Commission

1. Distribute the IRB report to chief research officers at each of the institutions of higher education and health departments with emphasis on those located on the U.S.-México border.

2. Organize a media campaign to optimize distribution of the IRB report to faculty and clinicians who are engaged or may be considering engaging in binational research in México and the United States.

3. Disseminate the IRB report using all the U.S.-México Border Health Commission communication resources such as the E-Border Health bulletin and the website. When posted on the website, it would be critical to track the number of "hits" or access events to this document to estimate the level of report dissemination.

4. Secure English-Spanish translations of the IRB report to facilitate the discussion of this document among a broad group of Mexicans, including undergraduate and graduate students, health providers, and health staff.

5. Promote collaboration among academic institutions to discuss protection of human subjects at the binational and transnational level. México's CONACYT and the U.S. NIH should develop and establish guidelines for joint IRBs.

6. Promote the exchange of experiences between Mexican and U.S. researchers about IRB frameworks and operations. This exchange should cover aspects such as enforcement and monitoring of protection of human subjects in binational and transnational projects.

7. Promote the organization of conferences among universities and research centers located along the U.S.-México border to begin discussion of current U.S. and México IRB protocols and practices and the possibility to develop and establish guidelines for joint IRBs.

CONCLUSION

While IRBs are a vital instrument in conducting research across international borders and in protecting human subjects, applying IRB processes in other countries can sometimes become especially complicated,

involving other cultural and legal considerations not initially realized. Thus, to better address these issues and concerns with respect to the United States and México, this report demonstrates, beyond the recommendations delineated above, a need to develop common guidelines for IRB operation or the establishment of binational protocols applicable on both sides of the border.

References

Cámara de Diputados del Congreso de la Unión. (1983). *Reglamento de la ley general de salud en materia de investigacion para la salud*. México City: Diario Oficial de la Federación.

Cámara de Diputados del Congreso de la Unión. (1984). *Ley general de salud*. México City: Diario Oficial de la Federación.

Cohen, P. (2007, February 28). As ethics panels expand grip, no field is off limits. *The New York Times*. Retrieved from http://www.nytimes.com/2007/02/28/arts/28board.html.

Comisión Nacional de Bioetica. (2005). *Guía nacional para la integración y el funcionamiento de los comités de ética en investigación*. Guadalajara, Jalisco: Secretaría de Salud de México. Retrieved from http://www.cnb-mexico.salud.gob.mx/interior/temasgeneral/presentacionguias.html.

Comisión Nacional de Bioetica. (2009). *¿Qué es la comisión nacional de bioética?* Retrieved from http://www.cnb-mexico.salud.gob.mx/interior/queeslacomision.html#.

Department of Health and Human Services. (2009). *Code of federal regulations, title 45 public welfare part 46, protection of human subjects*. Retrieved from http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm.

Department of Health, Education, and Welfare. (1979). *The belmont report: Ethical principles and guidelines for the protection of human subjects of research*. Retrieved from http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm.

World Health Organization. (2000). *Operational guidelines for ethics committees that review biomedical research*. Geneva: World Health Organization. Retrieved from http://www.searo.who.int/LinkFiles/RPC_Operational_Guidlines_Ethics.pdf.

World Health Organization. (2009). *Research ethics committees: Basic concepts for capacity-building*. Geneva: WHO Document Production Services. Retrieved from http://www.who.int/eth/Ethics_basic_concepts_ENG.pdf.

World Medical Association. (1964). *Declaration of Helsinki*. Retrieved from http://ohsr.od.nih.gov/guidelines/helsinki.html.

Williams, E.D. (2005). *Federal protection for human research subjects: An analysis of the common rule and its interactions with FDA regulations and the HIPAA privacy rule. Congressional Research Service Report for Congress. Washington, D.C.: Library of Congress*. Retrieved from http://www.fas.org/sgp/crs/misc/RL32909.pdf.

Annexes

Annex I: Code of Federal Regulations (CFR) Title 45 Public Welfare, U.S. Department of Health and Human Services (HHS), Part 46 Protection of Human Rights
http://www.borderhealth.org/files/res_1733.pdf

Annex II: Ley General de Salud
http://www.borderhealth.org/files/res_1734.pdf

Annex III: Reglamento de la Ley General de Salud en Materia de Investigación para la Salud
http://www.borderhealth.org/files/res_1735.pdf

Annex IV: Guía Nacional para la Integración y el Funcionamiento de los Comités de Ética en Investigación
http://www.borderhealth.org/files/res_1736.pdf

Annex V: Institutional Review Boards in the U.S.-México Border: Current Protocols and Practices Report Study Questionnaires
http://www.borderhealth.org/files/res_1737.pdf

Annex VI: Interviewed Participants
http://www.borderhealth.org/files/res_1738.pdf

Credits

A special thanks to Maria Hilda García-Pérez, Ph.D., Assistant Professor, School of Transborder Studies, College of Liberal Arts and Sciences, Arizona State University, for her invaluable research, writing, and consultation provided to this project.

For additional information please visit our website at www.borderhealth.org.

Unites States-México
Border Health Commission
211 N. Florence, Suite 101
El Paso, TX 79901
Tel: (915) 532-1006
Fax: (915) 532-1697
Toll Free (866) 785-9867
www.borderhealth.org

Comisión de Salud Fronteriza
México-Estados Unidos
Avenida Durango No. 247, 4o piso
Col. Roma Norte, Delegación Cuauhtémoc
C.P. 06700 México, D.F.
Tel./Fax (01152-55) 3611-0765
www.saludfronteriza.org.mx