For additional information, please visit the BHC website at www.borderhealth.org.
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EXECUTIVE SUMMARY


This year the forum addressed the following objectives:

- Identify opportunities and mechanisms to establish guidelines for a binational institutional review board (IRB) process.
- Identify processes for collaborative cross-border research that can be replicated.
- Provide an update on establishing a journal of border health.
- Promote resource sharing and collaborative partnerships.

The forum also included discussions on ethics in research, Healthy Border 2010/2020 initiative updates, and presentations on examples of binational research chosen through a call for presentations.

Throughout the forum issues surrounding binational research were discussed that identified challenges for the BHC as well as stakeholders, including research institutions in the U.S. and México, with the following recommendations made:

- Analyze existing U.S. and México laws and regulations as well as consider their respective ethical dispositions before establishing a binational ethics committee to clarify its roles and functions.
- Ensure research institutions promote research teams that are interdisciplinary, interinstitutional, and binational, including reevaluating their ethics guidelines so human subjects from any population, vulnerable and otherwise, are informed and protected should they choose to enroll in a study.
- The BHC reflect on the following questions regarding its own role in research:
  - Is the BHC supporting binational research in accordance to its functions and statutes?
  - What activities is it driving to strengthen the binational collaboration between researchers?
  - How can the BHC support binational research collaboration?
  - What are the benefits for researchers to collaborate with the BHC and vice versa?
- The BHC collaborate with philanthropic organizations throughout the border region as well as throughout both countries to leverage additional resources and ensure relevant information is made available to decision-makers and organizations that can provide resources.

The BHR Forum provides an opportunity for U.S. and Mexican academic and research institutions to collaborate and initiate cross-border research that governments can use to establish policy in both countries.
OVERVIEW

The U.S.-México Border Health Commission (BHC) convened the Fourth Annual U.S.-México Border Health Research (BHR) Forum, hosted by the California Outreach Office in collaboration with the Baja California Regional Office, on June 5, 2012, in San Diego, California, bringing together U.S. and México federal, state, academic, government, and non-governmental organizations to collaborate and provide an opportunity for academic and research institutions from both countries to initiate cross-border research that governments can use to establish policy.

This year’s forum focused on the following objectives:

- Identify opportunities and mechanisms to establish guidelines for a binational institutional review board (IRB) process.
- Identify processes for collaborative cross-border research that can be replicated.
- Provide an update on establishing a border health journal.
- Promote resource sharing and collaborative partnerships.

The forum also included discussions on ethics in research, Healthy Border 2010/2020 initiative updates, and presentations on examples of binational research chosen through a call for presentations.

Welcoming Remarks

Dr. J. Manuel de la Rosa, BHC Member-Texas, and Dr. Beatriz Díaz (in representation of Dr. Dora Elia Cortés), BHC Member-Chihuahua, chaired the BHR Forum. Dr. de la Rosa welcomed participants and provided a brief overview of the BHR Work Group and Expert Panel Meeting held the previous day, including recommendations on how the forum can proceed in developing a border research agenda.

Dr. Díaz thanked participants for their attendance and reiterated the importance of the forum for border residents. She described this meeting as a unique opportunity to establish and highlight the formal and informal communication and collaborations between academia, government, and non-governmental agencies who have collaborated in binational, multidisciplinary teams to create change along the U.S.-México border.

Mauricio Leiva, Chief, California Office of Binational Border Health, California Department of Public Health (CDPH), welcomed participants on behalf of Governor Jerry Brown and Dr. Ron Chapman, Director, CDPH, and the Office of Binational Border Health. He stressed that to achieve public health goals, especially in the U.S.-México border region, applied research should provide guidance to implement policies. He highlighted the border as an ideal place for research due to the large movement of people between the countries and the number of health disparities among Latinos. He underscored a challenge researchers face, which is providing public health practitioners guidance that can implement public health policies.

In closing, M. Leiva posed the following questions for participants to consider:

- What should we do to improve health access for border residents and mobile populations?
- What are appropriate interventions to reduce health disparities in border communities?
- How do we communicate effectively to improve health literacy?
- What are the cultural, economic, and technological barriers to improving health?
Dr. Lawrence Kline, BHC Member-California, provided opening remarks and discussed how relying on science as a guide will present the best opportunity to impact change in the border region. Of all the BHC activities, he identified the BHR Forum offers the most potential to make a difference for the future. He commended the BHR Work Group’s leadership in addressing the most challenging research areas and underlying challenges to be discussed throughout the forum, which included the following:

- Provide input to the Healthy Border 2010/2020 binational technical work group.
- Address binational IRBs.
- Address the ethical framework of binational research.
- Determine if a proposed border health journal is a feasible mechanism that can facilitate research and serve as a voice for the border region.

Dr. Kline encouraged participants to listen, participate, contribute, and take actions that have an ethical and scholarly focus as well as meaningful impact on those affected by public health policies.

Dr. Alfonso Valenzuela, BHC Member-Baja California, discussed how research is fundamental in public health and emphasized the importance of identifying border-specific problems to better collaborate on resolving these challenges. He stated that while not all issues may be resolved in the near future, it is fundamental that the BHC stay motivated to impact change. Dr. Valenzuela concluded by emphasizing the need for a clear methodology and the importance of objectively viewing research results.

**AGENDA DISCUSSION ITEMS**

**Ethical and Legal Conflicts for Establishing and Operating Binational Ethics Committees in Research: The Case of U.S.-México Border Health**

Nathalie Curuchet, Deputy Director of the Human Genome Department, Office Planning and Academic Development, National Commission of Bioethics in México, presented on ethical and legal issues that exist in binational research and focused on the following areas:

- Ethical issues in clinical research.
- Ethical committees and Mexican regulations and laws.
- Global paradigms in binational and multinational research.
- Challenges, considerations, and functions in establishing binational ethical committees.

N. Curuchet provided a brief overview of historical documents pertaining to ethics in research, including the Nuremberg Code and the Declaration of Helsinki. She also outlined common ethical dilemmas involving human subjects that should be considered in clinical research as follows:

- Research relevance—research should provide scientific or social value to the population being studied.
- Equal selection of subjects—a valid reason should be indentified for choosing a particular population.
- Risk-benefit analysis—participants should be informed of any risks and benefits they may experience; risks should not outweigh benefits.
- Independent evaluation—an external evaluator should be used to ensure researchers have followed protocols and ethical guidelines.
• Informed consent and confidentiality—participants should be properly informed of their rights and that all information and data collected is confidential.

M. Curuchet informed that in México, it is standard practice to include cultural, social, and economic perspectives of the population and the country with respect to clinical research involving human subjects. Because populations are not homogenous, their cultural and social norms, as well as their local economies, should be taken into account. For example, she identified that the culture in northern México is different than the southern part of the country, so researchers must consider how research outcomes apply to other populations even in the same country. If these three perspectives are not considered, adverse outcomes can occur. Furthermore, she stated that vulnerable populations, such as migrants or indigenous groups, should be protected and informed consent should be provided in a culturally appropriate manner, including accommodating different languages to ensure participants fully understand the research study as well as any risks and benefits.

N. Curuchet highlighted parts of the *International Ethical Guidelines for Biomedical Research Involving Human Subjects* published by the Council for International Organization of Medical Sciences (CIOMS). The most recent iteration of these guidelines focuses on low-resource populations and communities. According to the guidelines, before a study begins in a low-resource community, the investigator should make an effort to guarantee the research responds to the health needs and priorities of the population or community. Secondly, despite the potential research outcomes, an overall benefit to the population or community should be identified. These two guidelines are especially important when vulnerable populations from low resource communities are utilized, as the potential for exploitation is greater by investigators from high resource communities or countries.

N. Curuchet transitioned into describing the legal framework for health research in México. She identified that health research is regulated by the General Law of Health, which mandates the formation of ethics committees and defines their functions, and by the Regulation of the General Law of Health in Health Research, which provides specific guidelines about the ethical aspects of medical research involving human subjects. The Mexican Constitution also contains verbiage on the protection of health. Finally, guidelines are provided on the integration and operation of ethics committees established by the National Bioethics Committee. In 2011, the General Law of Health was amended that now makes it mandatory to establish hospital bioethics committees and research ethics committees in health institutions and related organizations that conduct research using human subjects.

Hospital bioethics committees make internal recommendations regarding clinical research whereas research ethics committees are able to dictate protocols for research that includes human subjects. These changes also now allow for the National Bioethics Commission to establish criteria for the integration of committees and define their functions and operations. Hospitals and any other institution conducting research with human subjects cannot be registered or licensed unless they have established an ethics committee. However, even with these changes, no sanctions exist to hold institutions and investigators accountable for research that involves human subjects.

In summary, the overall purpose of ethics committees is to advise those responsible for authorizing research in an institution, assist researchers to ensure research is conducted at the most optimal levels, and monitor the implementation of regulations and any other applicable provisions.

N. Curuchet emphasized that committees should be interdisciplinary, integrating health professionals from disciplines including nursing, psychology, law, social work, and other fields to effectively support research efforts and protect human subjects. They should also represent the values, culture, and social perspectives of the populations involved in research.
N. Curuchet also provided a more global perspective and identified new dynamics in clinical research. She identified that various international participants are involved in binational and multinational research through three principle elements: resources, human subjects, and location, which are important points to remember when discussing binational ethics committee roles and functions. As such, N. Curuchet posed two questions for participant consideration: 1) Should an independent binational ethics committee be created as an entity with legal and administrative authority according to the laws of both countries? and 2) Should ethics committees work jointly to facilitate agreements between institutions conducting binational research, such as an interagency agreement? While she noted these are not the easiest questions to answer, the greatest challenge is to balance the work that achieves the best desired results, which means identifying common goals.

N. Curuchet identified that a binational ethics committee could provide the following potential functions, emphasizing that it should not be a substitute for state and federal authority and should not create rules and regulations that violate its own legal powers:

- Provide advice and act as a consulting body.
- Establish ethical standards.
- Elaborate on guidelines.
- Promote training.
- Issue recommendations.
- Facilitate information exchanges between researchers.

In conclusion, N. Curuchet stated that while it is essential to try to standardize ethics committee operations working in a binational context, it is still critical to analyze existing U.S. and México laws and regulations, as well as consider their respective ethical dispositions before establishing a committee. She recommended a thorough study of each country’s laws and international ethical guidelines to aid in clarifying binational ethics committee roles and functions.

**Ethical Considerations in Establishing a Binational Institutional Review Board Process**

Dr. Cristina Rabadán-Diehl, Deputy Director, Office of Global Health, National Heart, Lung, and Blood Institute, National Institutes of Health (NIH), provided an overview of NIH’s mission and responsibilities. She stated its mission is to uncover new knowledge that leads to improved health for everyone, which is accomplished through the following:

- Conducting research in its own laboratories.
- Supporting non-federal scientist research in universities, medical schools, hospitals, and research institutions throughout the United States and overseas.
- Training research investigators.
- Fostering communication of medical information.

She continued with describing NIH’s structure and funding mechanisms and focused on the Fogarty International Center (FIC), whose primary aim is fostering research and training primarily in developing countries and the Office for Human Research Protections (OHRP).
The majority of NIH’s regulations are derived from OHRP which serves to accomplish the following:

- Provide leadership in protecting the rights and well-being of human subjects involved in U.S. Department of Health and Human Services (HHS) conducted or supported research.
- Provide clarification and guidance.
- Develop educational programs and materials.
- Maintain regulatory oversight.
- Provide advice on ethical and regulatory issues pertaining to biomedical and behavioral research.

Dr. Rabadán-Diehl also discussed NIH responsibilities and processes to ensure human protection while maintaining a focus on high quality research when a research application is received. NIH requires agencies to evaluate all applications and proposals involving human subjects with attention given to identifying the risks and benefits to human subjects, the adequacy of protection, and the importance of knowledge to be gained. In addition, she explained that not only do researchers need to be concerned with their own institutional IRBs but also whether the criteria addressing human subjects are met. Reviewers are required to assess human subject protections and look for actual or potential unacceptable risks, inadequate protections, or insufficient information, which is one of the most common problems.

Dr. Rabadán-Diehl outlined common concerns for human subjects identified in peer reviews, including physical and psychological effects, confidentiality issues, and financial risks that the researcher does not always adequately describe. Lastly, she discussed incidental findings, such as addressing an adverse or unexpected event.

Once an award is granted, NIH will continue to monitor every step of the research project. Regarding human research protections, NIH requires annual IRB approval as well as all of the required OHRP Unanticipated Problems and Adverse Events reports, if either of these occurs, during the research study.

Although the basic IRB requirements and informed consent are similar, HHS processes and regulations are perceived as synonymous with those of the U.S. Food and Drug Administration (FDA), but there are differences. As previously stated, HHS regulations are based on HHS conducting or supporting research, but FDA regulations are based on the use of certain products for research purposes like drugs, medical devices, or biologic specimens.

Following Dr. Rabadán-Diehl, Dr. Catalina Denman, Research Professor, Health and Society Faculty, Sonora College, presented on how to strengthen and consolidate ethical practice in research within a complex border region. She emphasized the importance of understanding social aspects of research because public health action involves a number of public, private, and social institutions in different countries that focus on the health of different people. She stated that social aspects of research include the following:

- Culture.
- Transborder themes.
- Social determinants of health.
- Health institutions and systems.
- Human rights.
- Justice and equality.
- Theories and knowledge.
Dr. Denman further described how power dynamics in relationships is central to ethics in research and identified the following examples: Doctor–Patient, Researcher–Institution, Government–Society, and Evaluator/Observer.

Dr. Denman also commented on the need for formalized ethical regulations as it applies to health research in México, illustrated by a survey she and her colleagues conducted with 50 Mexican social science institutes. The principal survey themes were as follows:

- Ethical committees.
- Informed consent procedures/processes.
- Participant and investigator rights.
- Regulations.
- Power dynamics in relationships.
- Ethical dilemmas and solutions.
- Student training.

Dr. Denman summarized the survey results as they applied to the aforementioned topics. Overall, the results showed that few institutions have ethical committees and that appropriate informed consent procedures are oftentimes not employed. In addition, of the 35 social science institutes that responded, only 2 have established ethical regulations, and those regulations pertain more to the protection of researchers and student researchers than to human subject participants.

Referencing the results and lessons learned from this example, Dr. Denman identified several challenges for the BHC with respect to addressing human subject protection in binational research that included the following:

- Creating awareness for responsible research.
- Recognizing and respecting differences between countries, states, populations, institutions, and disciplines.
- Creating a space for dialogue (real-time and virtual).
- Facilitating a process that respects the rights of human subjects.

Potential BHC actions Dr. Denman offered to address these challenges including the following:

- Motivating and normalizing research standards.
- Utilizing transborder spaces for exchanges and training.
- Documenting challenges and solutions.
- Documenting cases of negligence and corrective actions.
- Promoting reflections and identifying lessons learned based on experience.
- Listening to research subjects and investigators.

In conclusion, Dr. Denman recommended research institutions promote research teams that are interdisciplinary, interinstitutional, and binational. These institutions should also reevaluate their ethics guidelines so human subjects from any population, vulnerable and otherwise, are informed and protected should they choose to enroll in a study.
IRB Process Examples in Binational Research

Dr. Gudelia Rangel, Coordinator, Comprehensive Strategy for Migrant Health, México Ministry of Health and Researcher, College of the Northern Border (COLEF), provided two examples of Mexican and U.S. institutions working together on binational research projects. While she provided an overview of the actual projects and research, the overall purpose was to comment on the different types and methods of binational collaboration, discuss the experiences between institutions, and provide a reflection of the BHC’s role in binational research.

Dr. Rangel provided an overview of an NIH-funded project between COLEF, San Diego State University (SDSU), and the University of Wisconsin, where the principal objective was to estimate the prevalence of HIV infection and the associated risk factors present within the Mexican migrant and immigrant and populations in Tijuana, Baja California. The project called attention to the role of health services as well as social, economic, and cultural factors on the HIV status of migrant workers.

One of the obstacles the project faced was the lack of an ethics committee at COLEF. Previously, COLEF relied on the ethics committee at México’s National Institute of Public Health to review project proposals. For studies that collaborated with U.S. universities, the U.S. IRB usually provided a letter stating that in lieu of an ethics committee, an academic review committee at COLEF was sufficient to review and approve proposals. For this particular study, COLEF was required to establish an ethics committee since the project was receiving U.S. federal support.

Dr. Rangel outlined the Department of Population Studies’ strategy at COLEF to establish an ethics committee. She explained the established committee has binational representation and continues to be utilized by other university researchers and students. In addition, this project was recognized by the White House in 2009 for its methodology, which resulted in additional funding for four more years. It was subsequently recognized as a binational research model that could be duplicated across the border, highlighting it as a success and making it a model for other research institutions conducting binational research.

Dr. Rangel presented another binational project supported by the U.S. Agency for International Development (USAID) in collaboration with SDSU, Autonomous University of Baja California (UABC), University of California at San Diego (UCSD), COLEF, and other non-academic organizations including state health services, non-governmental organizations, and the BHC-Baja California Regional Office. The project’s primary objective was to create a binational infrastructure for developing human resources and program evaluation and facilitating binational health education opportunities and policy development in the area of HIV/AIDS. The two main project outcomes included establishing a master’s level course in San Diego, California, and a certificate program in Tijuana, Baja California. Due to the project’s success, USAID requested a proposal resubmission to expand the program that can also address drug addictions, which resulted in including more institutions to the network, and expanding the certificate program to include Juárez, Chihuahua. This project demonstrates that binational research is possible and can be successful if all organizations work together to identify common goals and identify solutions to any challenges.

Dr. Rangel also discussed the BHC’s responsibility to support border research that can improve health conditions of border populations through binational cooperation aimed at prevention and health promotion and offered two potential methods for consideration: 1) identifying the needs of public health in the border region and 2) supporting research that identifies and monitors health problems. She emphasized the need to

11These presentations were selected through a Call for Presentations on examples of binational, cross-border collaborative research models to highlight binational processes with an emphasis on communication between ethics committees, IRBs, and investigators in establishing agreements that can possibly be replicated across the U.S.-México border region.
facilitate binational research processes that can benefit researchers from the planning stage through execution and posed several questions to BHC members focused on reflecting and evaluating the BHC statutes regarding its role in research as follows:

1. Is the BHC supporting binational research in accordance with its functions and statutes?
2. What activities is it driving to strengthen binational research collaboration?
3. How can the BHC support binational research collaboration?
4. What are the benefits for researcher collaboration with the BHC and vice versa?

Dr. Rangel reiterated the BHR Work Group and Expert Panel’s purpose, which includes following-up with the BHR Forum, as well as the Expert Panel, agreements, and action items. As such, the BHR Work Group should be reflecting on who these results are communicated to and how these results are communicated. She also reiterated the need for more frequent BHR Work Group and Expert Panel meetings to better address complex issues.

Following Dr. Rangel’s presentation, Dr. Rabadán-Diehl provided an overview of NIH’s system for approving investigator-initiated research from other countries in which the researcher submits a grant proposal to NIH, which is followed by a scientific review panel of the proposal before it is passed to a program officer for additional review. Once reviewed, it is then passed to a National Advisory Council that advises NIH on whether or not to fund the project. If approved, the proposal is then submitted to the NIH Institute Director for final approval.

While NHLBI has been engaged in global health and supports international research, Dr. Rabadán-Diehl reported that the majority of its work is with domestic institutions that include foreign sub-components. Unlike other institutes within NIH, NHLBI first focuses on its domestic institutions, seeking opportunities to enhance knowledge gained from domestic research. As such, the application process is not exclusive to U.S. investigators. However, NIH allows foreign institutions to enter directly into the system, so the application process is not exclusive to U.S. investigators.

Proposals from foreign institutions, however, must meet additional stringent criteria. For example, during the review process, additional questions must be answered, such as why the research must be conducted in a foreign country and what is unique about the population being studied, the research itself, and the expertise used in the research that is different from the United States. In addition, the Advisory Council discusses the application and proposal at length.

The Advisory Council must vote whether or not to approve the proposal and is able to veto it even if the proposal has received positive feedback and scores from the Scientific Review Panel. The Advisory Council also has the ability to inform NIH what not to fund, but cannot inform what to fund, which applies to foreign applications as well. However, Dr. Rabadán-Diehl identified there are ways to circumvent this situation and still promote bilateral collaboration through bilateral agreements and multidisciplinary teams.

Dr. Rabadán-Diehl noted that NIH does not provide grants to individuals, but rather institutions. For example, the applicant is considered the university and not the professor, which can have implications concerning institutional and principal investigator responsibilities when complying with NIH and NHLBI regulations. This is particularly important if the grant includes a foreign component because it is the institution’s responsibility to enter into an agreement with the foreign institution, not the principal investigator, typically achieved through subcontract agreements. Ultimately, the U.S. institution is the responsible party because it is receiving the funding. This also means the U.S. institution and the principal investigator are responsible for what occurs throughout the research study, even if it is taking place in another country, and ensuring foreign institutions are in compliance with U.S. federal regulations.
In addition to complying with U.S. federal regulations, research needs to be compliant with the country’s regulations where the research is being conducted. Any foreign collaboration, whether direct or by foreign sub-components, requires U.S. State Department clearance. For example, if a U.S. investigator is collaborating with a Mexican investigator in México, all the project information will be entered into the Foreign Tracking System database. This information is wired to the U.S. Embassy in México and reviewed to ensure it does not conflict with any bilateral agreements or pose any danger or risk to local populations. The U.S. Embassy will then note that it has been reviewed and approved. However, the U.S. Embassy does not inform local governments of the NIH award as this is not part of their scope of responsibilities. As such, the local governments will not be informed of the NIH-awarded research proposal or that the research will be conducted in their jurisdiction by a U.S. institution. To address this issue, NHLBI requires IRB approval from the domestic institutions and from ethics committees in the foreign institution.

Dr. Rabadán-Diehl acknowledged that although this audience is focused on the U.S.-México border, she took the opportunity to highlight a NIH/NHLBI flagship program, the Collaborating Centers for Cardiovascular and Pulmonary Diseases in Developing Countries, which is an example of a multi-country study, and the intricacies and issues presented therein. She explained that this program started when she and other colleagues at NHLBI began examining the global burden of disease, including its causes and costs. They learned that 60 percent of the world’s mortality and morbidity are due to chronic non-communicable diseases, with the top four attributed to cardiovascular disease, pulmonary disease, cancer, and diabetes. Of the 60 percent, 80 percent mortality was found in low and middle income countries and where the majority of the world population is located with little or no capacity and infrastructure. As such, NHLBI concluded it was not only its responsibility to build research infrastructure, but it was also an opportunity to address these common problems around the world by engaging local researchers; establishing relationships with institutions in various countries to build local capacity; understanding barriers; developing research programs; and identifying sustainable research. The result was establishing the Collaborating Centers for Cardiovascular and Pulmonary Diseases in Developing Countries, which has become a partnership program. When NHLBI solicited partners in the developing countries, they requested institutions develop proposals that address their immediate needs in collaboration with a developed country partner institution. In addition, proposals needed to include a training program that reviews their own institution and identifies what is required to train future cardiovascular and pulmonary researchers in their country.

In 2009, NHLBI, together with the United Health Group, a leading health group that serves people worldwide, the program was launched with a network of eleven collaborating centers. The program operates as a network with funding from various sources and a variety of research conducted at each institution. By 2010, institutions began working across countries on joint projects posing a variety of challenges, especially related to IRB issues.

Dr. Rabadán-Diehl explained some of the human subject regulatory challenges this partnership currently faces (for example, not understanding U.S. federal regulations, particularly with respect to IRB approval terms that need to be included in IRB approval letters). In response, she identified possible solutions to these challenges as follows:

- Establish teams that include a regulatory affairs team, NHLBI, and a regulatory contact at each Center of Excellence (COE).
- Conduct quarterly regulatory webcasts that serve as an opportunity for partners to gain knowledge about federal regulations and to learn about activities in other partner countries and institutions.
- Provide sample letters to IRBs that include consistent language on required elements.
- Work with institutions individually to address specific circumstances.
Dr. Rabadán-Diehl concluded by providing additional resources through the NIH Office of Extramural Research and the FIC.

Dr. María Luisa Zúñiga, Associate Professor, Division of Global Public Health, Department of Medicine, Division of Child Development and Community Health, University of California-San Diego (UCSD) School of Medicine, presented on binational research collaborations between UCSD and other institutions in Tijuana, as well as some of the ethical implications in conducting community-based participatory research (CBPR) in a binational border context.

Dr. Zúñiga defined CBPR as, “One approach that engages diverse partners in strategies aimed at obtaining multiple perspectives in order to address community-identified concerns” (Minkler & Wallerstein, 2003). She explained in a binational context CBPR means allowing for the following:

- Meaningful engagement of U.S. and Mexican communities and partners.
- Equitable power structure and decision-making.
- Long-term commitment.
- Dynamic processes.
- Additional considerations to protect populations impacted by the border.

Dr. Zúñiga highlighted her work with the San Ysidro Health Center and the Binational Family Agency (Agencia Familiar Binacional, A.C.), their Mexican counterpart, as a prime example of cross-border collaboration. The San Ysidro Health Center, through its leadership and relationships within the community, has assisted UCSD with accessing San Diego and Tijuana populations to better understand their needs and identify ways that can improve their access to health. She explained the dynamic process of engaging communities in research and mentioned the importance of bioethics training as well as the need for trust between research partners and their study group. When working with individuals that represent communities on both sides of the border, part of the training process includes bioethics training standards and staff empowerment training that includes accurate, community-sensitive reporting to researchers while research is conducted. Part of this process includes fostering open lines of communication and trust as well as physically mapping the communication process, which teaches and empowers students and other research assistants to be responsible, ethical investigators.

Dr. Zúñiga identified that one of the most common challenges her colleagues have experienced is the inability of team members to cross the border for any reason. To address this issue, and similar challenges, she emphasized the importance of developing contingency plans that allow research to continue despite setbacks. In this case, contingency plans include alternate forms of communication such as teleconferences or videoconferences via Skype or other available technologies.

Dr. Zúñiga further discussed commitment to protecting participants, emphasizing IRB approval prior to initiating any research, including recruitment protocols, consent forms, and any survey measures. Secondly, field staff and investigators are responsible for ensuring they complete and are certified in ethics and human subject trainings. She and her colleagues have even developed curricula on these topics for their staff to empower them with information about conducting ethical research.

As the lead for the entire research study and the point of contact for engaging research committees, Dr. Zúñiga explained the principal investigator has additional responsibilities and obligations. In her experience, she has observed that it is of the utmost importance to understand what it means to seek research approval in another country. A U.S.-approved study does not imply automatic or quick approval in México; the research proposal still must undergo all appropriate channels and be approved in both countries before any research begins. These processes are critical to maintaining meaningful engagement of research participants and an
equitable power structure for all involved. Other technical issues she has observed include ensuring quality document translation and reviewing documents appropriately, which should be respected by counterparts.

Principal investigators also need to consider the potential for increasing vulnerabilities of the study population. This requires a heightened awareness of any sensitive issues the population may encounter throughout the study. Researchers, including principal investigators, should highlight additional steps or actions taken to ensure human subjects protection since IRBs and ethics committees may be unaware of vulnerabilities among the population. For example, if a survey instrument includes questions about citizenship status, it is the researcher’s responsibility to identify these topics as sensitive. As survey instruments are developed, the following questions should be posed:

- What may be the unintended consequences of inviting populations to participate?
- What are the potential impacts to the individual or population by collecting biomarkers and qualitative data?
- Who will have access to participant information and why?

Community perception of research involvement and participant expectations are also important to consider. Human subject participants may perceive they are entitled to additional benefits (also known as therapeutic misconception) for their participation, so expectations should be clarified during the consent phase. For example, if blood is drawn to measure glucose levels, the assumption may be that access to a physician is secured.

Dr. Zúñiga closed by stating that binational CBPR and bioethics are similar in that they allow for engaging multiple perspectives and border expertise in research, which ultimately improves the quality of research; improves sensitivity to the needs and realities of research participants; and promotes a more coordinated response to support responsible conduct of research.

**Binational Research Projects in the U.S.-México Border Region**

Dr. Luz Helena Sanin, Research Professor, Autonomous University of Chihuahua (UACH), stated this project, conducted by a group of researchers from UACH, is not a binational project but was conducted in a binational context.

Dr. Sanin identified that during the 2011 BHR Forum, the Expert Panel identified breastfeeding as a primary method to combat obesity and Type 2 diabetes. Based on this information, a Center of Excellence for Breastfeeding was proposed and funding was secured through the Mexican National Council of Science and Technology (Consejo Nacional de Ciencia y Tecnología [CONACYT]).

Dr. Sanin highlighted previous research demonstrating high obesity rates are associated with low breastfeeding rates among various populations including Hispanics in the U.S., indigenous groups, and border populations. She also highlighted results of the 2006 Mexican National Health Survey for the northern region of México, where the region reported the lowest threshold for breastfeeding and the highest for obesity. After briefly reviewing breastfeeding recommendations from the World Health Organization, Dr. Sanin discussed the breastfeeding advantages and long-term benefits for children and their mothers, which are based on natural intuition, anthropologic studies, observations, and interventions. Some breastfeeding advantages and benefits for the infant include optimal nutrition, increased immunity from infections, decreased risk of diabetes, obesity, cardiovascular disease and many other chronic diseases, and early mortality. Breastfeeding has also been associated with intellectual development and improved oral health. Some advantages and benefits to the mother include reduced risk of breast cancer, reduced risk of bleeding after pregnancy, improved bone density, psychological contact with the infant, and weight loss.
The overall objective of the study was to examine the prevalence of breastfeeding and its determinants in marginalized populations of breastfeeding women. Specific objectives included to understand the prevalence of exclusive and mixed breastfeeding practices until infants were six months of age and to identify the protective factors that contribute to breastfeeding for the first six months.

Dr. Sanin explained the selected group of women was targeted due to their location at a University Hospital and the direct access to this population by the researchers. The group of women participating in the study also closely fit the profile of women who migrate and are more likely to lack access to care. She also noted the women identified to participate in the study were low income and in many cases, they did not work and/or their spouse did not work. They also were unlikely to receive prenatal care.

The results, modeled by logistical regression, demonstrated changes in the percentage of women breastfeeding by month. Dr. Sanin stated the percentage of women breastfeeding at six months was still very high, 43 percent, compared to the National Health Study of México, 20 percent compliance at 6 months of mixed breastfeeding, and in the United States, 30 percent compliance at 6 months. Dr. Sanin stated several risk factors were identified and used to create the final research model as follows:

- Age (younger mothers are less likely to breastfeed).
- Single mothers.
- Education.
- Number of live births (previous experience breastfeeding).
- Gender of the child (female babies were less likely to be breastfed).
- Tobacco use.
- Breastfeeding aides.
- Place of origin-born in Chihuahua versus other states in México.

Dr. Sanin emphasized the need to continue educating women on the benefits of breastfeeding after they give birth. Researchers, service providers, and public health professionals also need to better understand the cultural aspects surrounding breastfeeding habits of women. As such, she proposed a Center of Excellence to continue researching, promoting, and evaluating breastfeeding. Issues to address include migration, cultural perspectives on breastfeeding, oral health, HIV, and women returning to work after giving birth. Research should also review resources available to women and infants. Breastfeeding promotion can be achieved in conjunction with existing WHO programs and local hospitals and clinics to include training, continuing education courses, and an information telephone line for pregnant women. Evaluation components may include interventions and training. Dr. Sanin proposed that next steps could include the following:

- Replicate the study in other cities along the border.
- Secure financing.
- Optimize all resources.
- Utilized existing laboratories.
- Create a real and virtual institute.

**U.S.-México Border Projects**

Andy Carey, Executive Director, U.S.-Mexico Border Philanthropy Partnership (BPP), shared the history of BPP as well as its binational membership and partners that include public and private foundations, corporations, governmental agencies, non-profit organizations, and academic institutions from both the
United States and México. He stated that BPP’s vision is to measurably improve the quality of life for residents in the border region by 2020 through collaborating and providing leadership on cross-border issues; mobilizing effective philanthropic resources to address border issues; and strengthening philanthropic capacity to further the sustainability of border communities.

A. Carey discussed the importance of building and strengthening community philanthropy in the border region and cited a relative lack of philanthropic infrastructure to support the emerging nonprofit sector as a major challenge, as well as the fact that few financial resources flow into the region from the public arena on both sides of the border.

To address these challenges, A. Carey explained significant resources have been invested through BPP’s donor collaborative. Over $20 million has been contributed to both U.S. and Mexican communities to support the strengthening of civil society organizations. BPP members’ assets have increased over 41 percent ($574 million to $812 million), and there are tangible results from cross-border collaboration at the regional level demonstrated by two projects where BPP serves as a partner: the Border Research Partnership and the U.S.-Mexico Data Collaborative Project.

The Border Research Partnership is a collaboration between the North American Center for Transborder Studies at Arizona State University, COLEF, and the Woodrow Wilson International Center for Scholars at the México Institute. It engages civil society organizations and conducts border region research that informs U.S. and México policymakers at the regional and national levels. Its agenda supports efforts to promote regional competitiveness, security, quality of life, and environmental sustainability.

A. Carey also explained that the Border Research Partnership advances research which can provide the necessary elements for transborder cooperation and communication. BPP recently launched the U.S.-México cross-border cooperation and innovation award that recognizes efforts between local and state collaborators to enhance quality of life for U.S. and México border residents. Additionally, the Border Research Partnership has developed the publication *State of the Border Report*, a comprehensive evidence-based assessment of the border scheduled to be published in October of 2012 in Spanish and English. This publication will focus on trade and economic development, security, environmental sustainability, and quality of life, to include examining processes for border planning, and binational and interagency coordination. This project also plays an active role convening and participating in meetings with U.S. and México border stakeholders and policymakers, including the Border Legislators Conference and Border Mayors Meeting, and plans to support the Border Governors initiatives.

One of the collaboration projects with BPP A. Carey identified included the U.S.-Mexico Data Collaborative Project, a collaboration project with the Foundation Center, the Philanthropy and Civil Society Project at the Autonomous Institute of Technology of México, and the non-governmental organization Alternatives and Capacities (*Alternativas y Capacidades*). This project measures the impact of grant money in México and categorizes philanthropic investment/giving by programmatic area to educate policymakers in México. Prior to this project, measuring impact was not possible in the northern Mexican border area and noted the impact and value of philanthropy has largely been ignored because it is not understood nor appreciated. One of the major challenges the philanthropic sector has faced is educating and informing government leaders about the support they provide.

One gap the project has filled is developing a central directory of philanthropic agencies in México. This directory will be used to identify who is giving what type of support to a particular region in México. This will further inform additional gaps and areas still in need.

A. Carey identified the project goals as follows:

- Promote the transparency and accountability of Mexican philanthropy as well as strengthen the Mexican philanthropic sector.
• Increase availability and accuracy of information regarding the philanthropic sector in México and the U.S.-México border region.

• Establish new and sustainable systems to collect data from grant makers and organizations in México and the U.S.-Mexico border region.

• Identify donation trends from donor institutions in order to improve the understanding of resource distribution in México and the border region to inform grant making and grant seeking policy formation.

• Create a successful partnership between expert organizations that can provide a broader impact and a model that can be replicated in other parts of Latin America.

A. Carey emphasized how this project can bring together foundations and organizations interested in working with the border community. This project also serves as an example of how agencies with different areas of interest, experiences, and expertise can work towards a common goal. Ultimately, this project will allow BPP to approach the Mexican government and inform them of the value and impact philanthropy has made, not only in the border region, but throughout the entire country.

A. Carey closed by encouraging the BHC to collaborate with BPP and other philanthropic organizations to ensure all relevant information is included and available for decision makers.

Dr. Eloy Cardenas, Autonomous University of Nuevo León, opened his presentation by stating that during the 2011 BHR Forum, he was appointed to investigate and identify the essential documents and requirements to submit or present a research proposal to the appropriate Mexican authorities.

Dr. Cardenas explained the Mexican equivalent to NIH is the Federal Commission for the Protection against Health Risks (Comisión Federal para la Protección contra Riesgos Sanitarios [COFEPRIS]), within México’s Secretariat of Health. He explained that in México anyone interested in conducting research, whether from México or another country, must follow Mexican law and clarified that the federal law is one component of regulations that needs to be followed, and the other components are the international agreements signed by the President of México and confirmed by the Senate. In 2010, the President insisted legislators align the Mexican Constitution to the United Nations Educational, Scientific, and Cultural Organization (UNESCO) Declaration of Human Rights. Dr. Cardenas pointed out that for the President of México to change the Mexican Constitution articles to align with the UNESCO Human Rights letter is a great accomplishment for human rights because UNESCO oversees all bioethics committees, including those that address medical, social, veterinary, botany, sports, and even international trade issues.

Referencing the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), Dr. Cardenas continued to discuss the international agreements that México has signed to ensure that Good Clinical Practices (GCP) are guaranteed. GCP provide a standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

Dr. Cardenas explained that México, as a co-signer of the GCP, has incomplete legislation but COFEPRIS evaluates legislation. As such, if two different pieces of legislation exist between México and a foreign country, México will adopt the one that provides the most human subjects protection. For example, colleagues in France have criticized North American translations of the term “subject” in reference to human subjects, stating it is derogatory. As a result, North American countries needed to clarify that this term was referencing people and not other subjects like animals or plants. They also referenced the GCP, noting they use the term “human subjects.” This example illustrates the importance of clear communication between researchers, especially those from different countries collaborating on the same study, including the need for
Dr. Cardenas discussed the role of ethics committees and referenced personal intervention experiences that have supported researchers. He also discussed the advantages to support an established ethics committee. One example he provided was a diabetes patient case requiring emergency surgery in which the hospital identified that the patient’s insurance covered the surgery costs. However, this was not the case, and the hospital ethics committee informed the family they needed to pay. The ethics committee role guarantees the rights, health, and dignity of human subjects in research. As such, he explained that part of the agreement with UNESCO includes requiring all ethics committee participants not only to take GCP training but also be able to provide GCP course training as well.

Dr. Cardenas reviewed the following steps a researcher should initiate to pursue a research study, as suggested by COFEPRIS:

1. Meet research protocol submission deadlines.
2. Submit an informed consent form, in accordance with laws.
3. Identify how research will be conducted.
4. Submit the financial agreements.

Dr. Cardenas discussed the pros and cons of payment and outlined that certain risks require payment as explained by NIH. He cited that payment, however, should not be coercive in comparison to the risk as human subjects’ health should not be jeopardized to earn money. He further stated that this is why ethical committees exist and the committee, not the individual, makes the decision as to the payment amount.

Once all paperwork is submitted, Dr. Cardenas explained it will undergo initial review. If the research project is accepted, then the process moves forward, but if it is not, recommendations are made to the researcher and the proposal can be resubmitted.

Dr. Cardenas also discussed the penalty process in México, explaining that if a research proposal is not approved, the hospital/research center is severely penalized, which is interpreted as non-compliant with the hospital’s ethics committee. In effect, recertification is denied. While he emphasized that a large number of researchers are attempting to comply with regulations, personnel shortages within COFEPRIS have resulted in research rejections due to the department’s inability to meet approval timelines. If a researcher submits a research protocol to COFEPRIS, and no response occurs within three months, the protocol is automatically denied. By comparison, in Europe, if a researcher does not receive a response, it signifies approval. Dr. Cardenas insisted this needs to be recognized by the research community.

Dr. Cardenas closed by emphasizing the ethics committees’ vital purpose in research and México’s continued efforts to work with UNESCO as much as possible to address research issues.

**Update on the Healthy Border 2010/2020 Initiative**

Dr. Marta Induni, Research Program Director, Survey Research Section, Cancer Surveillance and Research Branch, California Department of Public Health, and Dr. Eduardo González-Fagoaga, Coordinator, Border Migration Surveys, College of the Northern Border (COLEF), provided brief updates on the *Healthy Border (HB) 2010 Joint Closeout Report*. This report is currently in draft form and although the final report will be a joint U.S. and México report, the data and details are being developed separately by each country. Drs. Induni and González-Fagoaga are assisting the BHC and the HB 2010/2020 Binational Technical Work Group in gathering data and writing the report.
Dr. Marta Induni identified the *HB 2010 Joint Closeout Report* goals are as follows:

- Describe trends over the decade for all focus areas and objectives.
- Use data for the years 2000, 2005, and 2010, where available, as three points in time to depict progress.
- Use border county-level/border region data, where available, and state-level data where no other data is available.
- Use data similarly defined and collected in both countries when available.
- Document and cite all used data, including methodology.

Dr. Induni identified that the challenges in developing a joint report include finding data for the target years, 2000, 2005, and 2010; county/border region-level data; and data collected and defined similarly in both countries. She identified the proposed report format is meant to be reader-friendly, defining objectives, illustrating relevant data, providing short narratives, and citing sources.

Following Dr. Induni’s review of the HB 2010 focus areas and objectives for the U.S., Dr. González-Fagoaga provided a similar overview of the objectives and available data for México and stated data is still being gathered for some indicators. Since México collects and reports data across states in a more uniform manner compared to the United States, more comprehensive data and information is already available for some of their objectives.

The next steps include identifying county and regional-level data, submitting a first draft of the report, and determining a final report format. For objectives where data is still missing or county/regional level data is difficult to locate, state experts may be asked to assist in determining the best available data.

Since HB 2020 is still in the preliminary development stages, an update was not provided.

**Update on the Proposed Border Health Journal Feasibility Study**

Dr. Pedro Cantú, Chief Editor, *Journal of Public Health*, Autonomous University of Nuevo León, provided an update on the proposed *Border Health Journal* as a follow-up to the 2011 BHR Forum discussion and recommendations made. As a result of those discussions, Dr. Cantú conducted a feasibility study for the journal and presented the results of that study, including an electronic mock-up of the journal, to participants.

Dr. Cantú acknowledged the importance of a platform to present scientific findings on border health, emphasizing the consideration placed on the sustainability and permanence of establishing this type of a journal and providing basic information on the recognized definitions of a scientific journal as well as the different types of scientific journals, including academic and professional.

Dr. Cantú also explained the journal’s proposed purpose and format. The purpose would be to house research conducted on the border, focusing on research related to quality of life, health, and the social environment, and serve as a communication mechanism to those interested in border health, including service providers, decision-makers, and public health professionals in the scientific and academic communities throughout the U.S.-México border region, published in English and Spanish. These overarching themes could be used to ensure indexing, which is a major step to having a recognized and respected journal. He proposed an electronic format available through the Internet with open access, free of charge.

In addition, Dr. Cantú provided details on the human resources needed to publish the journal which would include an editor in chief, an assistant, two designers and information technology specialists, and two reviewers—one to review English and one to review Spanish submissions, as well as an editorial committee. Other resources include graphic design software, computers, and printers. As such, he stated the greatest
challenge is to find and secure financial resources and briefly spoke about maintaining the journal’s quality of work “research” and its importance to the relevance of the border community to support key border research.

During Dr. Cantú’s presentation, he suggested publishing the journal biannually at a minimum to sustain the number of research studies presented within the journal and also to comply with the quality assurance standards between both countries.

Dr. Cantú summarized the next steps to be taken for the 2013 BHR Forum including to secure the ISSN number, identify base data, and develop a four-year detailed plan for financial resources and sustainability. Dr. Cantú closed by encouraging the BHC to actively establish a plan that will solidify developing a border health journal.

Closing Remarks

In closing, Dr. de la Rosa identified the next steps are geared towards the BHC’s BHR Work Group. As such, the discussions and deliberations initiated by the BHR Expert Panel, as well as input from formal and informal discussions, will be used to begin developing an approach for the protection of human subjects, establishing the Healthy Border 2020 initiative, as well as reviewing the attempts and feasibility to establish a border health journal. These initiatives form an infrastructure for continued discussion.

RECOMMENDATIONS

Binational Ethics Committees

The overall objective in creating and establishing binational ethics committees should be to protect the dignity and rights of human subjects and support research that addresses the needs of the population. As such, its functions should include the following:

- Provide advice and act as a consulting body.
- Establish ethical standards.
- Elaborate on guidelines.
- Promote training.
- Issue recommendations.
- Facilitate information exchanges between researchers.

In addition, it is critical to analyze existing U.S. and México laws and regulations as well as consider their respective ethical dispositions before establishing a committee. Analyzing each country’s laws and international ethical guidelines can further clarify the roles and functions of a binational ethics committee.

Research institutions should promote research teams that are interdisciplinary, interinstitutional, and binational, including reevaluating their ethics guidelines so human subjects from any population, vulnerable and otherwise, are informed and protected should they choose to enroll in a study.
Binational Research Processes

A need exists to facilitate processes that benefit researchers, from the planning stage through executing the study. As such, the BHC should reflect on the following questions regarding its own role in research:

- Is the BHC supporting binational research in accordance to its functions and statutes?
- What activities is it driving to strengthen the binational collaboration between researchers?
- How can the BHC support binational research collaboration?
- What are the benefits for researchers to collaborate with the BHC and vice versa?

Community Engagement

It is imperative that all involved in research, from the principal investigator to students, receive bioethics training. This also translates into building trust between the research team and the study population. Community-based participatory research and ethics are similar in that they allow for engaging multiple perspectives and border expertise in research, which ultimately improves the quality of research; improves sensitivity to the needs and realities of research participants; and promotes a more coordinated response to support responsible conduct of research.

Proper training can help ensure appropriate protocols are followed, including properly engaging with study participants from the consent process through any follow-up processes.

Resources

The BHC should collaborate with philanthropic organizations throughout the border region as well as throughout both countries to leverage additional resources and ensure relevant information is made available to decision-makers and organizations that can provide resources.

Data Collection

The BHC should promote the U.S.-México border region as its own epidemiological unit to align data collection methodologies and definitions used.

The Healthy Border 2010 Joint Closeout Report should clearly indicate what each objective means and why it is important for the border region.

NEXT STEPS

The BHC will continue to lead discussions on cross-border research that can impact policy, bringing together federal, state, academic, government, and non-governmental organizations from the United States and México. As the BHC moves forward with addressing recommendations made during this forum, it will continue to answer the following questions that are central BHC research tenants:

- Who conducts research?
- How is research conducted?
- How is research published?
- How is research communicated and to whom?
- How is research used to establish policies?
In addition, the BHC will continue addressing some of the challenges identified, such as creating awareness for responsible research and recognizing and respecting differences between countries, states, populations, institutions, and disciplines, and move forward with the following actions:

- Motivating and normalizing research standards.
- Utilizing transborder spaces for exchanges and training.
- Documenting challenges and solutions.
- Documenting cases of negligence and corrective actions.
- Promoting reflections and identifying lessons learned based on experience.
- Listening to research subjects and investigators.

The BHR Work Group and Expert Panel plans to convene quarterly to address recommendations. In addition, the BHC plans to convene the Fifth Annual United States-México Border Health Research Forum in San Diego, California, in 2013.
APPENDICES

Appendix A: Agenda
Appendix B: Presentations
Appendix C: Question and Answer Session
Appendix D: Participants List
Appendix E: Acronyms List