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Ethical Considerations in Global Mental Health Research: Lessons Learned From Binational U.S.–Mexico Collaborations

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Abstract

Binational research is critical to better understand the health, mental health, and health outcomes of immigrant communities. Binational studies are often difficult to conduct, however, due to cost, challenges with participant recruitment and data collection, lack of appropriate cross-cultural instruments, and challenges ensuring ethical reviews and approval in both counties. This research note discusses ethical issues navigating institutional review board (IRB) procedures while striving to maintain the highest ethical protection for participants when engaging in binational behavioral sciences research between México and the United States. We discuss the need to clarify requirements for international research between México and the United States and navigating differences that may exist or emerge between IRBs in México and the United States. We provide some recommendations to assist researchers in ensuring IRB approval for their research protocols and ethical protection for their participants.

Keywords

binational research, IRB approvals, global research, global behavioral and social sciences research

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Mental health concerns do not recognize country borders. Immigrants and other displaced populations coming to the United States from Mexico and Central America are increasingly experiencing violence and trauma (Infante et al., 2012) and bringing with them their health and mental health issues in addition to their cultural and linguistic richness. They also retain connections with the country of origin. Millions of Americans and their families have roots in México and Central America, and millions of Mexicans and Central Americans have families in the United States. In light of the continuous, binational flows of people between our countries and regions, research that impacts these communities is stronger if it is binational.

To investigate research questions of shared interest to both the United States and México, researchers are increasingly reaching across borders and forming binational partnerships to conduct rigorous studies. These partnerships

can facilitate stronger, more robust research, with more breadth and depth of information and more nuanced perspectives and understanding. Binational research can also reduce assumptions and build on the cultural, contextual, and historical expertise of all contributors, in addition to their specific scientific expertise. It can help us better understand the health, mental health, and potential health outcomes of immigrant communities, by affording us the opportunity to follow populations across countries and contexts (Handley & Sudhinaraset, 2017). Binational studies, however, are often difficult to conduct due to their cost, challenges with participant recruitment and data collection, and lack of appropriate cross-cultural instruments, which requires lengthy adaptation and pretesting of survey instruments to fit cultural contexts (Gearing et al., 2021; Rubinstein-Ávila, 2009). Ethical considerations can also be a challenge in binational research, yet there are few sources to help navigate these ethical concerns.

Research requirements vary across countries, institutions, disciplines, and customs. Differences in national policies and laws may result in uncertainties related to applying and receiving institutional review board (IRB) approval in each country. Navigating ethics regulations and IRBs in binational research can be challenging, yet we are bound to ensure ethical standards, safeguards, and protection for all research participants. Reaching across systems also increases the potential for misunderstandings, confusion, or errors that may compromise the ethical protection of participants.

This research note discusses ethical issues navigating IRB procedures while striving to maintain the highest ethical protection for participants when engaging in binational social sciences and behavioral health research between México and the United States. Specifically, we discuss two key issues: clarifying requirements for international research between México and the United States, and navigating differences that may exist or emerge between IRBs in México and the United States. We also provide some recommendations to assist researchers in ensuring IRB approval for their research protocols and ethical protection for their participants.

Institutional Review Boards

In the United States, IRBs exist in most universities, large research centers, hospitals, and medical facilities, especially where research activities are expected. There are also private IRBs. IRBs may also be known as independent ethics committees, human research ethics committees, research ethics committees, internal review boards, ethical review committees, ethical review panels, ethical review boards, and research ethics board, among other names. Generally, an IRB is a standing committee that reviews specific study protocols and applies federally, nationally, and/or internationally approved research ethics standards and applicable laws to determine that the protocols comply with existing regulations and safeguard the protection of research participants. IRBs also conduct a risk–benefit analysis to evaluate whether a study should be conducted. The primary goal of an IRB is to protect the rights, privacy, and welfare of human participants and assure that the research protocols, as proposed, protect and safeguard the research subjects. IRBs typically provide some type of formal monitoring and review processes for

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medical or behavioral research that involves humans as research subjects.

IRBs emerged out of the horrific crimes against humanity conducted in the name of science by doctors in Nazi Germany during World War II. The Nuremberg Code, established in 1948, began the international standardization for legitimate human experiments, where consent replaced coercion, and participant rights and welfare were protected (Caldamone & Cooper, 2017; Litcherman, 2005). As research expanded, largely in the medical and biomedical fields, the Declaration of Helsinki emerged in 1964 to further delineate a code of ethics (World Medical Association, 1964). Revised over the decades, the Declaration of Helsinki established the requirement for research protocols to be submitted to the concerned research ethics committee for review and approval prior to the initiation of the study. The Declaration states that such committees must be qualified, transparent, and independent of the researcher, sponsor, or other undue influences. In addition, the committee must take into consideration the laws and regulations of the country and any applicable international norms and standards that exist where the research is to be conducted. Furthermore, the committee is not allowed to reduce or eliminate any of the protections and safeguards for research subjects (World Medical Association, 2013). In the United States, the Belmont Report (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1978; HHS Office for Human Research Protections, 1979) further advanced ethical protections for human subject participants and stated that a researcher's responsibility included submitting their proposed research protocols to an IRB for review. The Belmont Report established three core principles when conducting research on human subjects: respect for persons, where individuals should be treated as autonomous agents; beneficence, where human subjects should not be harmed; and justice, where the benefits and risks of research must be distributed fairly (Caldamone & Cooper, 2017; HHS Office for Human Research Protections, 1979; Kawar et al., 2016).

Emerging from the Nuremberg Code (1948), the Declaration of Helsinki (1964), and later the Belmont Report (1978), the National Research Act of 1974 led to the modern IRB system, which regulates research on human subjects. The National Research Act covers all research on subjects including medical and biomedical, as well as social sciences, behavioral research, and all areas of human research. The National Research Act also provides assurances on data deidentification, including protecting participant confidentiality, how and by whom the data are collected, and secure storage of the data (Caldamone & Cooper, 2017).

IRBs in Mexico

Regulations in México to protect research participants are relatively newer, compared with similar regulations in the United Statement, and their development continues (Gómez Velásquez & Gómez Espinosa, 2007; United States-México Border Health Commission, 2010). Current practices for the protection of human subjects in hospitals and medical facilities in Mexico are grounded on several laws and regulations, including the General Health Law and General Health Act (2011), which requires the development of ethics committees in medical centers and defines the functions of ethical committees in the Mexican health system (Chavez et al., 2017; United States-México Border Health Commission, 2010). The Mexican Institute of Social Security (IMSS) has a formal system of hundreds of local research ethics committees which have been established to review research proposals, typically in the medical and biomedical fields (IMSS, 1999; Valdez-Martínez et al., 2004, 2006).

Critical to the advancement of bioethics in México was the establishment in 1992 of the National Commission of Bioethics (Comisión Nacional de Bioética [CNB]), which became permanent in 2000 (CNB, 2009). However, existing guidelines in México apply primarily to research in medical and biomedical contexts and may often not be appropriate or even relate to social and behavioral researchers (United States-México Border Health Commission,

2010). Moreover, not all universities or research centers in México have established IRBs, and some may not require a review for social science research, regardless of the risks to human subjects (Garcia, 2009). The vast majority (97%) of U.S. universities, medical units, or institutions along the U.S.–México border have an IRB, compared with 82% of Mexican universities and medical research institutes (United States-México Border Health Commission, 2010). These medical IRBs will typically not review social science and behavioral research. Consequently, seeking IRB review for social and behavioral studies in universities, research centers, and institutions in México is limited and challenging. In a survey of binational researchers, 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 (United States-México Border Health Commission, 2010).

Seeking IRB Approval for Binational U.S.–Mexico Research

In binational U.S.–Mexico research, the typical approach is that the research protocol will be reviewed by the IRBs at the home institutions of the lead researchers in both countries, often with no communication, coordination, or reliance between the two (or more) IRBs. The approvals are thus separate and may seem more concerned with which researchers are allowed to collect data or interact with participants in which country, where the data are to be kept, who has access to the data, and so on, than with the actual protection of human participants. This approach is based on several problematic assumptions.

As posited by Garcia (2009), this unilateral review of human subject protocols is problematic because the IRB in one country is not necessarily in a position to adequately ensure that all of the possible risks in another country are identified and sufficient safeguards are provided, nor is it reasonable to assume that most IRB board members from one country will be familiar with the people or cultures of another county (Garcia, 2009). Also problematic are the assumptions that an established IRB even exists in both countries or collaborating institutions, or that the research, such as social science or behavioral research, will require IRB approval in both countries. While biomedical research is typically reviewed by IRBs in both countries/institutions following similar guidelines, social and behavioral science research protocols may not require review in the Mexican institution, or an IRB may not exist.

Increasingly, large funders in the United States (e.g., the National Institutes of Health [NIH]) are requiring researchers in multi-institutional, multi-site collaborations to have IRB reliance agreements and decide on a Single IRB of Record (sIRB). In this model, the sIRB is given the authority to review and monitor the research, while the IRBs of the other institutions defer to the decisions of the sIRB. This can create tremendous challenges for cross-national research, with an IRB in one country potentially weighing in on research in another country. In any case, reliance agreements between IRBs in different countries are in their nascent stage.

In several binational behavioral sciences research projects conducted by the authors of this article, the protocols were approved by the U.S. team's institution, a research-intensive university. The Mexican team was also at a research-intensive university with two IRBs, yet neither IRB reviewed social and behavioral sciences protocol. The studies were being funded through various small, U.S.-based, institutional and external seed grants, and the funders required the study protocols to receive IRB approval in both countries. Without approval in México, the study could not move forward. The solution recommended by the U.S. institution was to identify two social and behavioral sciences researchers at the Mexican institution who were not associated with the study in any way and had expertise in the area of study; have them review the research protocol; and ask them to write letters stating that the research protocol followed all human subjects' protections in Mexico and

carried minimal or no risk. Our study was then allowed to proceed.

This approach may work well when permanent or ad hoc IRBs are not available. It can ensure that the protocol is reviewed locally, with attention to culture, context, and ethical guidelines in the country. It is critical to ensure, however, that the individuals selected to review the protocols are familiar with IRB review requirements and processes and have the training and expertise to effectively review the protocol. An unresolved problem is that they may lack formal accountability in the university if a problem emerges with the research.

Strategies for Successful Binational Research Collaborations

Binational research is critical to understanding the health and mental health of populations in flow, but challenges remain ensuring the research is conducted in line with existing ethical standards. Our strongest recommendation, of course, is that binational social science or behavioral research must be reviewed and approved in both countries, preferably by IRBs. While it is not always possible to have a standing IRB committee in each country review the protocols, as was seen in the case we outlined above, efforts to ensure a thorough ethical review must be taken. To continue promoting the ethics reviews of binational social science and behavioral research, we offer the following strategies.

An initial strategy is always to consult with your home institution's IRB or ethics compliance office. IRBs and the offices that manage them are a weighty source of support and aide. If your institution lacks a permanent IRB, determine whether an ad hoc committee exists or whether there are senior researchers at your institution who have conducted binational research. Your Dean/Director, Department Chair, or Research Coordinator might be able to help find the right people. Consultation with researchers who may have successfully or unsuccessfully navigated the tricky waters of binational collaborations can save time, avoid mistakes, and leverage important lessons that can launch the project toward success. A number of successful research collaborations between the United States and Mexico have been undertaken, for example, under the auspices of the Research Program on Migration and Health, a program of the Health Initiative of the Americas at the University of California Berkeley (see https://hia.berkeley.edu/what-is-pimsa/ for a list of funded projects, results, and publications). Above all, these consultations will ensure that all options are considered in safeguarding the protection of human participants in research, especially in settings where those protections might not be guaranteed by law or established standards.

Another strategy, albeit a significant undertaking, is to support the development of a new IRB in the university or research center. This major undertaking would require a lot of collaboration but would be a substantial effort to foster and ensure ethical binational research. Several online IRB supports exist in the United States, with the U.S. Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP) being the authoritative resource on forming an IRB. OHRP provides support, guidance, education, and compliance oversight for IRBs in the United States (U.S. DHHS et al., 2017). Beyond governmental supports, a number of academic resources can also assist institutions in forming, training, and administering their own IRBs, including partnering with universities with an experienced IRB to facilitate the process (Dudley, 2009; Howard et al., 2010; Sugarman, 2000; U.S. DHHS, et al., 2017). In addition, the American Psychological Association (2016) has prepared a comprehensive guide on planning and developing an IRB.

It is important when developing an IRB or strengthening an existing permanent IRB or ad hoc committee to continuously be aware of and support diversity on the board. Strive for the IRB to include a wide range of members from diverse backgrounds, cultures, ethnicities, countries of origin, and religions, as well as research approaches, methodologies, and fields. In behavioral and social sciences

research, there is often a clear resonance with social justice and social responsibility. Encourage efforts to ensure social justice and social responsibility through ethical research, and ensure that board members have ongoing training, including cultural awareness and sensitivity of the diverse populations that institutional researchers will frequently engage with in their research projects.

Binational U.S.–Mexico researchers may also seek to strengthen the relationship between universities or research centers by developing memorandums of understanding (MOUs) between the universities. Having higher level institutional support may strengthen the research beyond the goals of specific projects: it can open avenues to develop binational standards of ethical conduct. Binational MOUs that encompass the overall institutions, rather than just the department or college, can provide access to important resources across the institutions. For instance, the researcher's department may not have anyone else who has engaged in binational research, but others in the university might have and can share their experience and resources. Moreover, the important task of providing oversight and continuous monitoring of the study once launched becomes a priority when the MOU is between the institutions. Finally, when challenges arise—and they always do—a conversation between two institutional research directors (e.g., Vice Chancellors for Research or Vice Chancellors for International Affairs) can get a situation unstuck much faster than a conversation between two researchers who may not be considering the bigger picture.

A frequently applied strategy in conducting research in another culture is to seek a cultural review of the research protocols. Although not required, MOUs may be supportive in establishing a requirement for having cultural reviews become a formalized component of binational research. During the drafting of the research protocols, but before completion, the binational research team should meet with key stakeholders, local experts, and members of the population under study to review protocols for appropriateness of the proposal, customs, and cultures. Such cultural reviews can have key benefits. They can improve and strengthen the integrity of the protocols (e.g., asking a question in a way that may have different meaning than researchers had intended or designed). They can support greater social inclusion and justice in the research collaboration while reducing unintended discrimination or bias. They can increase the chances of a positive and successful project through increased cultural understanding of the populations, training of research assistants, improved recruitment efforts, and guiding interpretation of future findings or next steps in the research. A cultural review can help ensure the ability to consent and integrate safeguards that are practical and feasible. By including stakeholders of the group under study in the review (e.g., Native American in the United States or Indigenous peoples in México), these groups can exercise their agency and autonomy, review the protocols, and provide feedback.

Another strategy might be to consider extending the team to include a researcher from an institution that does have an IRB in the local country. Researchers should not just accept the status quo and move forward with only the approval from one institution. The university or research center may have access to another institution's IRB or committee and can ask them to review the study.

A final consideration is for the exploration of a joint, binational IRB process that includes all universities, institutions, and/or research centers involved in the research. As stated above, the NIH has recently released a policy regarding the use of a single IRB for multisite research, which may assist these collaborations (Gordon et al., 2017), especially when more than one institution is involved in México and the United States.

Binational research will continue to gain critical importance as we witness the displacement of millions of peoples on an extraordinary scale. Immigrants fleeing wars or disasters, seeking better lives and opportunities, or wanting to be reunited with their families will continue to cross borders. Research that provides solid answers to help

improve their health, their quality of life, and their overall prospects must include research at the point of origin as well as at the point of destination. It is important that such research be conducted according to the highest ethical standards. As outlined in this article, strategies exist for navigating differences in IRBs, as do standards to ensure successful binational research collaborations.

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