Ethical Collaborative of Social Science and Behavioral Research and Institutional Review Boards (IRB): Binational Collaborations in México and the USA

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To investigate and explore research questions of shared interest to both the United States of America (U.S.) and México, researchers and scholars are increasingly reaching across the border to form scholarly collaborations to conduct rigorous studies. By forming partnerships across borders, researchers can facilitate stronger, more robust research protocols that can examine the study objectives in more breadth and depth, with a more nuanced perspective, while reducing assumptions and building on the expertise of all contributors. The merits and benefits of collaborative, multi-site, cross-border research include bringing cross-national—in addition to transdisciplinary—lenses to bare on the area of study, especially when the subjects of study move across borders or have a footprint in both countries. The U.S. and México share more than a border; they share a long and at times complicated history, as well as millions of Americans with roots in México, and millions of Mexicans with families in the U.S. In light of the continuous flow of people moving between these countries, research that impacts these communities is stronger if it is cross-national.

Like any research activity, these collaborations must rely on the ethical conduct of research. However, research protocols and requirements vary for scholars across countries, institutions, disciplines, and customs. Further, differences in national laws may result in

uncertainties related to applying and receiving Institutional Review Board (IRB) approval in each country. While navigating ethical research, rules, and IRBs can be challenging for researchers, such efforts are more than a legal and moral obligation for scholars. Researchers are duty-bound to ensure ethical standards, safeguards, and protection for all research participants. However, reaching across systems also increases the potential for misunderstandings, confusion, or errors that may compromise the ethical protection of participants.

This chapter examines these ethical issues of navigating the IRB procedures, while striving to maintain the highest ethical protection for participants engaging in cross-border social sciences and behavioral research between México and the U.S. Specifically, this chapter explores the following objectives: 1) clarifying requirements for international research between México and the U.S.; 2) navigating differences that may exist or emerge between the IRB processes in México and the U.S.; and 3) providing a guideline to assist researchers in receiving ethical protection of participants and IRB approval for their research protocols.

Institutional Review Boards (IRBs) have been established in most universities, large research centers, hospitals, and medical facilities, especially where research activities are expected. There are also private IRBs. Institutional Review Boards (IRBs) are also known by a list of other names including: independent ethics committee (IEC), human research ethics committees (HREC), research ethics committees (REC), Internal Review Boards (IRB), ethical review committees (ERC), ethical review panels (ERP), ethical review board (ERB), and research ethics board (REB). Generally, IRBs are a standing committee that seeks to review specific study research methods by applying research ethics standards and applicable laws to determine that the study protocols are ethical and safeguard the protection of participants in the research. IRBs may also conduct a risk-benefit analysis on the research protocols to evaluate

whether a study should be conducted or completed. The dominant goal of an IRB review is to protect the rights, privacy, and welfare of human participants and assure that the research protocols have been implemented and are guided by appropriate steps to protect and safeguard the research subjects. IRBs will typically provide some type of formal monitoring and review processes for medical or behavioral research that involves humans as research subjects.

The development of IRBs emerged out of the horrific crimes against humanity conducted in the name of experimental science on human participants 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 elaborate the code of ethics (World Medical Association, 1964). Revised over the decades, the Declaration 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. Additionally, the committee must take into consideration the laws and regulations of the country, any applicable international norms and standards existing where the research is to be conducted, and are not allowed to reduce or eliminate any of the protections and safeguards for research subjects (World Medical Association, 2013). Within the U.S., the Belmont Report (1979) further advanced the ethical protections for human subject participants and stated that a researcher's responsibility included their submission of their proposal research protocols to an IRB for review. The Belmont Report established three core principles of ethical investigation when conducting research on human

subjects: a) respect for persons, where individuals should be treated as autonomous agents; b) beneficence, where human subjects should not be harmed; and c) justice, where the benefits and risks of research must be distributed fairly (Caldamone & Cooper, 2017; Department of Health, Education, and Welfare, 1979; Kawar et al., 2016).

Emerging from the Nuremberg Code (1948), Declaration of Helsinki (1964), and the Belmont Report (1979), 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 provides assurances on de-identification, including protecting participant confidentiality, how and by whom the data is collected, and secure storage of the data (Caldamone & Cooper, 2017).

According to a United States-México Border Health Commission report (2010), the regulations in México to protect research participants in studies are relatively new and their instrumentation continues to be developed (Gómez et al., 2010; United States-México Border Health Commission, 2010). The current practices for the protection of human subjects in hospitals and medical facilities are grounded on several laws and regulations, including the General Law of Health (Ley General de Salud) and General Health Act (2011) regulations that require the development of ethics committees in medical centers and defines the functions of ethical committees in the Mexican heath system (Chavez et al., 2017; United States-México Border Health Commission, 2010). Also, the Mexican Institute of Social Security (IMSS) has a formal system of hundreds of local research ethics committees (LRECs), which have been established to review research proposals, typically in the medical and biomedical fields (IMSS, 1999; Valdez-Martinez et al., 2004; Valdez-Martínez et al., 2006). Also important 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, the existing guidelines in México apply primarily to research in the medical and biomedical context, and may often not be appropriate to settings and disciplines conducting research involving human subjects in social and behavioral studies (United States-México Border Health Commission, 2010). Consequently, seeking IRB review for social and behavioral studies in universities, research centers, and institutions is limited and challenging.

Further, 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 United States-México Border Health Commission report (2010) found that the vast majority (97%) of surveyed U.S. universities, medical units, or institutions along the US-México border had an IRB, whereas approximately 82% of surveyed Méxican universities and medical research institutes had and IRB (United States-México Border Health Commission, 2010). Often, institutions only had medical IRBs that will not review social science and behavioral research, resulting in these researchers not having access to established IRBs. Not surprisingly, researchers on both sides of the border have recognized the importance for Mexican universities and research centers to develop and establish permanent IRBs to review social and behavioral studies (United States-México Border Health Commission, 2010).

As is standard, a research protocol will be reviewed by the home institution of the lead researcher or Principal Investigator (PI), assuming the presence of such an IRB. In addition, the PI and their binational collaborators (Co-PIs and/or Co-Investigators) will similarly seek and IRB review from the second country. However, this process is based on several assumptions. According to Garcia (2009), this process of unilateral review of human subject protocols is

problematic as 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 (p. 353). It is not reasonable to assume that most IRB board members from one country are familiar with the people or cultures of another county (Garcia, 2009). Other assumptions include that an established IRB even exists in both countries and collaborating institutions, or that research, such as social science or behavioral research, requires IRB approval within the PIs home institution. Increasingly, large funders in the U.S. (e.g., the National Institutes of Health) are requiring researchers in multi-institutional, multi-site collaborations to have an IRB reliance agreement and decide on a Single IRB of Record (sIRB). In this model, one IRB—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 again creates tremendous challenges for cross-national research, with an IRB in one country potentially weighing in on research in another country.

There are three general levels for IRBs within universities and research institutions, including: 1) permanent IRB, 2) ad hoc IRB, and 3) no IRB available (United States-México Border Health Commission, 2010). In the first level, an institution has a standing, permanent IRB that can review the research protocols. The second level reflects universities or research centers that do not have a permanent IRB, but have established procedures, protocols, and/or experience to convene informed and knowledgeable researchers and scholars to form ad hoc committees as necessary to review a research protocol. In the third level there is no existing IRB or ad hoc committee to review research protocols. Based on the category of IRBs available in each university or research center, binational researchers are confronted by a number of IRB configurations and potential concerns.

In level one (Permanent IRBs), a full review by permanent IRBs in both the US and México does not mean the Board will review a social science or behavior research protocol, as it may be exclusively a medical or biomedical IRB only. Further, the existence of a permanent Board in both countries does not equate to having board members with expertise in social sciences and behavioral research. However, even this preferred standard of two preeminent IRBs is not without potential concerns, such as whether the board members have cultural or linguistic expertise pertaining to the other country. Also, the presence of a permanent IRB may be in only one of the research sites. For example, 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).

While a permanent IRB may not always be feasible, some universities or research centers may develop procedures for ad hoc IRBs to be formed as needed (Level 2). Although not as preferable as having a permanent IRB, ad hoc IRBs allow for research protocols to be formally reviewed by the institution. Potential pitfalls for ad hoc IRBs include selected board members who may be unfamiliar with the IRB review requirements and processes, or have less training or limited expertise to effectively review the ethics of a research protocol. In addition, such ad hoc committees tend to be temporal, and may not be able to monitor human protection practices once the research has begun (United States-México Border Health Commission, 2010). AD hoc committees may also lack formal accountability in the university or research center.

Level three (No IRB committee is available in the university, institution, or research center) is perhaps the most problematic. Research without an IRB review lacks ethical approval and as such, lacks safeguards for human participants, and should not be conducted. However, at

times in binational research, the study protocols receive an IRB review in one country, but cannot receive a review in the partnering country due to their lack of an IRB. Although not a rare binational situation, it nonetheless raises a number of potential ethical concerns, including lack of cultural sensitivity, potentially limiting the protection of subjects, confusion on translated text related to context and meaning, lack of support from one of the host sites, or inordinate control and decision-making in the hands of one or a few researchers from that site. Also, this unilateral review is challenging because the review from one county may not "ensure that all the risks in another county are identified and that corresponding safeguards are adequate enough to provide necessary protections" to the research participants (Garcia, 2009, p. 353).

Strategies/Recommendations

Binational research offers important opportunities for research, but binational ethical research remains paramount. Thus, it is the strongest recommendation that binational social science or behavioral research needs to be reviewed ethically in both México and the US. While it is not always possible to have two standing IRB committees review a binational research protocol, efforts to maximize the level of ethical review are recommended.

In an effort to promote and elevate the ethical reviews of social science and behavioral research the following strategies may assist binational researchers. An initial strategy is to consult with your home university's IRB. IRBs are a weighty source of support and aide. If your institution lacks an IRB, then consult with ad hoc IRB members if an ad hoc committee exists, with senior researchers who have conducted binational research, and/or with your Dean, Department Chair, or supervisor. IRB administrators, chairs, and senior researchers are often a wealth of information and have frequently assisted other researchers with their binational investigations. Consultation with other researchers who may have successfully—or

unsuccessfully—navigated the tricky waters of cross-national collaborations can save time, avoid the repetition of mistakes, and leverage important lessons that can launch the project toward success. Above all, it ensures 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.

Although a significant strategy and undertaking, supporting the developing and formation of a new IRB in the university or research center would be a substantial effort to foster and ensure ethical research. There are several online IRB supports in the U.S., with the U.S. Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP) being the decisive resource on forming an IRB. Specifically, the U.S. Department of Health and Human Services OHRP provides support, guidance, education, and compliance oversight for IRBs (U.S. DHHS, 2017). Beyond various governmental supports, there are also a number of academic resources that can assist institutions in forming, training, and administering their own IRB, including partnering with universities with an experienced IRB to facilitate the process (Dudley, 2009; Howard et al., 2010; Sugarman, 2000; U.S. DHHS, 2017). Additionally, the American Psychological Association has prepared a comprehensive guide on planning and developing an IRB (APA, 2009).

Another strategy when developing an IRB or strengthening an existing permanent IRB or ad hoc committee, is to continuously be aware of and support diversity on the board. For example, strive for the IRB to include a wide range of members from diverse backgrounds, culture, ethnicity, countries of origin, and religions, as well as research approaches, methodologies, and fields.

In social sciences and behavioral research there is often a clear resonance with social justice and social responsibility. Therefore, every effort is encouraged to ensure social justice and social responsibility through ethical research. Similarly, it is important that board members have ongoing training, which can include cultural awareness and sensitivity of the diverse populations that their institutional researchers will frequently engage with in their research projects.

Binational research may also seek to strengthen the relationship between universities or research centers across the México-U.S. border by considering developing memorandums of understanding (MOUs). Having a higher level institutional support may strengthen the research beyond the collaboration between researchers and open avenues to both develop binational and ensure higher 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 cross-national 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. Lastly, 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.

A frequently applied strategy in conducting research in another culture is to have sought out a cultural review of the research protocols. Although not required, MOUs may be supportive in establishing a requirement for having a cultural review to become a formalized component of the national research. During the drafting of the research protocols, but before completion, it is

recommended that the binational research team meet with key stakeholders, local experts, and members of the population under study to review protocols for appropriateness of the proposal, their customs, and cultures. Such a cultural review frequently improves and strengthens the integrity of the protocols (e.g., asking a question this way may have different meaning than researchers had intended or designed), support greater social inclusion and justice in the research collaboration while reducing unintended discrimination or bias, and increase the chances of a positive and successful project (e.g., increased cultural understanding of the populations, training of researcher assistants, improved recruitment efforts, even guiding interpretation of future findings or next steps in the research). A cultural review can also help ensure the ability to consent and integrate safeguards that are practical and feasible. For example, include stakeholders of the group under study (e.g., Native American in the U.S. or indigenous peoples in México) so they have opportunities to review the protocols and provide feedback. Indeed, indigenous researchers and representatives of indigenous communities have highlighted the importance of being consulted on any research done with their communities from the very earliest stages.

In the situation where one institution has a permanent IRB and can review the research protocols and the partnering binational university or institution does not, this can be challenging for any social science and behavioral researcher. Considering the importance of having an ethics review in both countries, it is recommended that the researchers do 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 or department's IRB that may be asked to review the study. Consider extending your binational research to include a facility that may have an IRB. In the case of the institution having a medical or biomedical IRB, can they be asked to review

protocols? It is recommended that binational research teams request a scientific review committee comprised of independent researchers who are not affiliated with the study, to come together and review the protocols. While this group is neither an IRB nor an ad hoc IRB, a scientific committee can review the ethics of the protocols using accepted guidelines and write a report that can be submitted to the one partnering institution that has an IRB to demonstrate the efforts pursued to obtain an ethics review in the absence of an available IRB. Conversely, if a group of scholars and/or researchers are not available, requesting a few independent and knowledgeable researchers to review the protocols and each submit a letter may serve as another alternative. Again, implementing a cultural review is also recommended.

It would also be important in the situation of not having a second permanent IRB, that the researchers request that their colleagues and research assistants complete the online training course from Collaborative Institutional Training Initiative (CITI) or an online equivalent training such as the National Institutes of Health (NIH) Office of Extramural Research NIH Web-based training course on 'Protecting Human Research Participants' (NIH OER, 2017: Link: https://phrp.nihtraining.com/users/login.php). These courses are offered in multiple languages, including English and Spanish, and a certificate will be issued to each individual that completes the human protection course. The certificates can then be included with the one IRB submission where the research protocols will be reviewed. It is also recommended that the researchers, when training any researcher or research assistant on administering the research, include significant training on research ethics and on the ethical conduct of research.

A final consideration is for the exploration of a joint IRB process with binational universities, institutions, and/or research centers. As stated above, the NIH has recently released a policy regarding the use of a single Institutional Review Board for multi-site research, which

may assist these collaborations (Gordon et al., 2017), especially when more than one institution is involved in México and the U.S.

Cross-national research will continue to gain critical importance as we witness the movements of millions of peoples on an extraordinary scale. Immigrants fleeing wars, 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. Moreover, it is imperative that such research be conducted according to the highest ethical standards. As outlined in this chapter, several strategies exist for navigating differences in IRBs and standards to ensure successful cross-national research.

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