

IRB Standards and Comparative / Cross-Cultural Research

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Ethical Dilemma

Is it morally acceptable to impose IRB rules from one culture (i.e. the U. S.), to another, for purposes of performing comparative/cross-cultural social research?

Background

The IRB (Institutional Review Board) is an organization within each research institution that has been created to ensure that research involving human subjects complies with generally accepted regulations and guidelines. All research involving human subjects must undergo a review by the IRB of that particular institution. The IRBs that have been developed at most research institutions in the United States are a direct result of laws and regulations enacted from 1974 to 1991, which are designed to protect human subjects of biomedical and behavioral research. These legal guidelines, the origin of which can be traced to the Nuremberg Code, first developed to evaluate Nazi human experiments during the Nuremberg trials, and were heavily influenced by the Belmont Report (1978). The Belmont Report first defined the three basic requirements for the ethical conduct of human research that is ingrained in IRB and government research policies. Those three principles that are used to protect human research subjects are (U. S. D.H.H.S., 2001.)

- ***Respect for persons*** – underlying the need for informed and voluntary consent, the researcher must recognize the personal dignity and autonomy of individuals, protecting those with diminished autonomy.

- **Beneficence** – as the basis for protecting confidentiality and privacy of subjects and performing benefit-risk assessment, the researcher must protect subjects from harm by minimizing risks and maximizing benefits.
- **Justice** – underlying the need for fair subject selection, the researcher should distribute the benefits and risks of research in a just manner.

From these principles have come the IRB requirements of informed consent, risk / benefit assessment, and careful selection of research subjects. An IRB examines not only the objectives of human research projects, but it examines research procedures to ensure they have been designed with these three principles in mind. The IRB, its principles, procedures and guidelines, are a creation of the United States and a product of its version of Western Civilization thought. Do, or should, these guidelines still apply when a researcher is involved in comparative or cross-cultural research, especially in a culture that is not part of Western Civilization? This question covers not only the IRB rules under which research is approved or modified, but it also covers the potential of research to violate cultural norms due to the cultural ignorance of a particular IRB. The following simple hypothetical cases illustrate this point.

Sample Cases

Hypothetical Case A – Informed Consent

A researcher is conducting qualitative educational research in India, employing student interviews and questionnaires to gather data. These students are considered

minors in the U.S., as they are under 18 years of age. The sponsoring university IRB has required that consent forms be provided to all students, who are then required to obtain the signatures of their parents. This, of course, the researcher agreed to do. The researcher, expecting no problems, is surprised when the school principal states that no research will be conducted at the school. Parents had rejected the form, demanded the researcher leave the school, and the principal complied with their wishes.

What would cause such an adverse reaction? IRB rules demand consent forms be signed and kept by the researcher to ensure the researcher is adhering to the principal of “respect for persons.” This is something we take for granted. However, what these rules fail to account for is that “respect for persons” takes different forms in other cultures and can be accomplished outside of the means demanded in the U. S. While a consent form may be so pervasive as to be acceptable and understood in the U. S., it is an alien concept in some cultures and its very existence calls the researcher’s integrity and intent into question. An effective means to accomplish the same end would be to require the researcher to brief the teacher(s)/students on the research, without subjecting students and parents to written consent forms. This scenario also does not take into consideration the fact that many parents in India may not speak, read or write English; hence the consent forms would need to be translated into many different languages in order for true consent to be obtained by parents literate in multiple local languages, but not literate in the English language.

This scenario also does not take into consideration that, though some parents may be orally proficient in multiple languages, they may not have the ability to write, which would then subject parents to thumb-printing their signatures; another indignity, which they must endure.

Hypothetical Case B – Data Gathering

A researcher performing a comparative study of teenage social mores and habits between two cultures has chosen a girl's school in urban China to sample. One of the interview questions is "Are you still a virgin?" Though many of the girls answer the question, they seem rather upset during the remainder of the interview. Prior to the final interview, the school principal commands the researcher to leave and never return.

In this situation, the researcher has clearly overstepped cultural boundaries. The posed question is the ultimate insult to a young girl in such a culture. While a researcher can pose this question in an American school and receive a response, in another culture the same question would be unthinkable.

Hypothetical Case C – Treatment of Children

A university IRB approves a study of child treatment in sweatshops in Bangladesh. The study highlights the mistreatment of children in this culture, specifically showing more corporal punishment at home and in school, and showing a large degree of child labor in the lower socio-economic classes. This study becomes a referenced work in the U. S. press and by human rights organizations, becoming the basis for boycotts of

goods reputed to be products of child labor in Bangladesh. Exports from Bangladesh to Western nations decrease, putting more Bangladeshis out of work, especially children.

Is the study fair? Is the result justified? Who benefits from this study and who loses? Whose rights have been denied and whose rights have been respected? The answers are not apparent to those born in Western culture. We, in the West, are against child labor and the mistreatment of children, according to our standards of treatment. However, the context for child treatment is much different in the West than in many other cultures. In Western culture, there is a “safety net” via government funded programs for poor individuals and families that, when used, will ensure they have enough to eat and will ensure they have shelter. This structure does not exist in poorer countries, nor can it exist given the financial condition and demographics of many countries. A family that depended on the income of children for food or housing may not survive without that income. Removing that income is equivalent to removing their right to eat or right to live.

We should also recognize that our culture is not far removed from the child labor that we rail against. The U. S. public school system accommodated child labor (farm labor) via the summer vacation, which exists even today. Summer vacation in many cultures is unknown, but in the U. S. it was created to satisfy the need for farm children to help their families harvest crops that were planted in the spring.

Identifying the Alternatives

Is it morally acceptable to impose rules from one culture onto another culture for purposes of performing social research?

The most straightforward answers to this question are yes, no and something in between. However, the alternatives are more complex than yes, no and maybe.

- 1) No, do not employ IRB rules, but trust the researcher to do what is morally and ethically correct.**

In order for this to work, one would need a means to regularly certify the psychological constitution of each researcher as consistent with the principles of ethical research. This is not workable, as one cannot read the minds of researchers and anticipate what they may or may not do in a given situation. History has shown the problems associated with trusting researchers to do what is ethically correct. The moral and ethical compass of a researcher can and do differ from societal norms, causing harm to individuals when left free to do so. Thus, research involving human subjects must be subjected to an Ethics Review Board.

- 2) No, do not employ the IRB; instead, create a new set of research policies to employ within the target culture.**

Ideally, one would want to use the IRB Guidelines and the principles of the Belmont Report as a basis for developing guidelines for a particular target culture,

although the effort required to do so may be much more than the proposed research itself. If one were to propose a comparative research study between Romanian, Finnish and Korean elementary school pupils, to develop a set of human research policies specific to each culture would be a project of its own and would delay and detract from the original research. This alternative is not practical, though it would be ideal.

3) No, use whatever research rules (if any) are in effect in the target culture.

As international meetings in Helsinki are held to identify and refine standards for protecting human research subjects, one would expect a set of human research standards to be instituted in each country. However, that is not the case. In many countries, bioethics has not been addressed with respect to humans. In India, for example, bioethics has made more progress for animal subjects than for human subjects. While animal experiments are subject to review by a centralized Institutional Animal Ethics Committee and violators can be fined and jailed, those subjecting humans to experiments need only create an Institutional Ethics Committee to gain approval for research. Most research institutions at the time had no ethics committee to review human subject research. (Indian Express, 2000.)

By employing the approach of adhering to the research demands of the target country, one may be free to experiment at will, depending on the standards of a particular country. However, in countries having clearly defined standards of human subject research, a researcher could be exposed to legal or societal problems if those standards are

not adhered to. This alternative is unacceptable, as it would allow a researcher to completely ignore what one would consider minimally acceptable research standards in some countries, while adhering to required stringent standards in others. This creates the potential for abuse of human subjects.

4) Yes, continue to adhere to existing IRB rules when evaluating cross-cultural research.

This alternative has already been addressed in Cases A, B, and C, and shown not to work in those situations. However, another consideration that was not addressed by those cases, but is a cultural problem, can be characterized as the “power play.” The researcher, by being from the U. S. and representing money, education, power, status, and a pervasive culture, immediately assumes a power position. This position intimidates not only the powerless, but it also intimidates those having power equal to and even greater than the researcher. Though this can work to a researcher’s advantage, to expedite matters, for example, it can also negatively influence the results of the research. While people in US are taught to question authority, in many other cultures, people are taught to follow orders and respect authority. Therefore, a command-control situation with the researcher and subjects is created, removing any subject spontaneity. Subjects will try to please the researcher in any way they can. I have personally witnessed this on both ends; first, as an Indian national born and raised in India, observing interactions with British and American citizens, and later as an American citizen visiting India.

Further compounding this command-control relationship is an unconscious air of superiority (or arrogance) that Americans frequently assume when conducting them in a country “lesser” than the United States. No research is required to make these observations, as they are easily observed in print, video and on television. Simply following IRB guidelines does nothing to correct these cultural imbalances that negatively affect comparative and cross-cultural research.

5) Yes, adhere to IRB rules, but identify and try to accommodate those situations in which there may be cultural conflicts.

The objective under this alternative is to preserve the intent of IRB rules, while recognizing that cultural differences may cause some rules to be discarded, others to be modified and yet others to be strengthened. Human subject research guidelines from the target country would need to be evaluated to ensure that existing IRB rules conform to them and, if not, modify them to do so for the particular research project. One or more cultural experts would need to evaluate the proposed research and IRB rules and identify any potential adverse consequences of executing the particular research methods and IRB protocols. The IRB, in this situation, would need to be flexible enough to recognize that U. S.-based research guidelines may conflict with the local culture and require some modification.

Determining what is Morally At Stake

Based on the introduction, it is clear that the values set forth in the Belmont Report are at stake. Specifically, to what extent does each of the alternatives ensure or enforce the following:

- **Respect for the human subject**

What is meant by “respect” is to ensure that subjects are not placed in a position of physical or psychological harm without their prior knowledge and consent. The informed consent form is the tool of choice within the U. S. to ensure that this value is upheld. However, it is also used in U. S. society more to protect researchers and those issuing the consent forms from potential lawsuits than it is to protect the subjects. Does one really need an informed consent form, signed by parents in the presence of the researcher, after a lengthy explanation/translation of the form has been given, for a researcher to conduct brief interviews during school hours with students on study habits? Who, in fact, does the consent form protect? Who is most in harm’s way if these consent forms are not signed? The researcher.

It is a fact that U. S. society is the most litigious in the world, that researchers know and recognize their exposure and seek to limit it. However, this type of concern would be incomprehensible in some other societies, such as India, for example. As described in Hypothetical Case A, handing out a consent form for something considered so frivolous in such a society might cause more psychological harm to the subjects, to the

researcher and to the subject institution that is hosting the researcher. Following IRB guidelines to the letter to uphold this value in some cases will have the opposite effect.

- **Beneficence—Maximizing the benefit-risk ratio to human subjects**

The manifestation of this value is to design research to minimize potential physical or psychological harm to human subjects, while trying to improve the resulting benefits to society. As argued in the prior “respect for the human subject” value, research that adheres to U. S. societal standards may cause unintended harm to the subjects and subject institution through cultural misunderstandings. Hypothetical Case B also illustrates this point, since the researcher poses a question that would be perfectly admissible in U. S. -based research on teen mores, values and attitudes. In the U. S., a confidentiality agreement enables a teenager to discuss sensitive items with a researcher, whereas in other cultures these same items are forbidden. Ignoring or not identifying potential cultural differences, then adjusting research design to accommodate them has the potential to harm all involved.

- **Justice**

What “justice” means is to ensure that human subjects are fairly selected, not out of convenience or pliability, and that research results do not unfairly target one group, thus promoting discrimination, for example. It is important when comparing cultures to identify the potential outcomes and to identify how society or social research will benefit from these outcomes, specifically how the knowledge could or should be used. Choosing

a particular culture to compare should be considered analogous to targeting a particular ethnic or racial group and should be done with potential societal benefits in mind, while minimizing risks for the targeted culture or groups. Case C, concerning Bangladeshi child treatment, illustrates when this process either breaks down or is not followed to its conclusion prior to approving the research. In Cases A and B, out of cultural ignorance, research could not be concluded, depriving society of the benefits of that research.

Ranking the Alternatives

Employing the Virtue Theory of moral decision-making, each alternative is rated according to how it conforms to each of the three values that are important to this ethical dilemma. The lowest rating is 1 diamond, while the highest rating is 3 diamonds. One diamond indicates that the value cannot be enforced and it can also be contravened; two diamonds indicates that though the value is enforced, the extent to which the enforcement is effective is uncertain. Three diamonds indicates that the value is enforced and effective.

Alternative	VALUE		
	Respect	Benefit	Justice
#1 No IRB, trust the researcher	◆	◆	◆
#2 Create IRB-type policies for target culture	◆◆◆	◆◆◆	◆◆◆
#3 Use existing research rules in target culture	◆	◆	◆
#4 Use IRB as is	◆◆◆	◆◆	◆◆
#5 Use cultural experts to enhance IRB rules	◆◆◆	◆◆◆	◆◆◆

The low ratings on all values for Alternative #1 is due to giving the researcher responsibility for enforcing these values.

Alternatives #2 and #5 are given perfect ratings in all categories. These ratings assume that cultural experts have provided enough subject matter expertise to ensure these values will be upheld during approved research. The primary difference between #2 and #5 is the level of effort. In Alternative #2, an entire human subject research guidebook is created for each culture outside of the U. S.; this assumes use of cultural experts. In Alternative #5, cultural experts participate in IRB reviews on an as needed basis to evaluate IRB and research methods for consistency against those values.

Alternative #3 is rated no higher than trusting the researcher (Alternative #1), as some countries have no rules governing human research subjects, while others may have rules in some cases more stringent than the U. S.

Alternative #4, while strong, is less than perfect. Without cultural experts participating in some form on an IRB, and without the ability to modify mandated IRB procedures to fit other cultures, the Beneficence and Justice values might not be attained.

Therefore, the alternatives would rank as follows:

1. Alternative #5 – Use cultural experts to enhance IRB rules
2. Alternative #2 – Create IRB-type policies for target culture.
3. Alternative #4 – Use the IRB as is
4. Alternative #3 – Use existing research rules in target culture.
5. Alternative #1 – Trust the researcher

Alternative #2 is ranked lower than #5 due to the greater amount of effort and time required to create policies. Alternative #3 is ranked higher than #1 because, in addition to trusting the researcher, the researcher is required to follow rules within a country.

Choosing the Action

Based on the extent to which the values described in the Belmont Report are enforced, the preferred approach is to add cultural subject matter experts to an IRB and

ensure the IRB has the authority to modify procedures to attain the spirit of IRB guidelines. This approach is practical and is much less time-consuming than creating wide-ranging policy handbooks for each culture. It is also more effective than submitting cross-cultural and comparative research to sitting IRBs, assuming they have no such cultural experts.

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