

**Human Subject Research and Developing Countries:
Beneficence and Protection of Human Rights**

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Human subject research, with increasing frequency, is conducted outside of the United States, with a growing number of clinical trials located in developing nations. Although the globalization of medical research has the potential to generate greater opportunities for combating disease and improving local health care within developing countries, this trend also generates unique ethical questions, challenges, and responsibilities. The involvement of developing countries in the research enterprise has served to focus attention on the adequacy of the structure and system of ethical review aimed at the protection of human subjects.

Children, the mentally disabled, prisoners and the socio-economically disadvantaged are among the groups traditionally recognized as particularly susceptible to coercion and manipulation in the medical research setting.¹ Populations in developing countries, however, also require special protections as a result of pervasive poverty, illiteracy, lack of education, and lack of available medical care.² Individuals may have little understanding about the nature of testing and the research process, including the concept of placebo controls.³ Where access to medical care is not readily available, individuals may be desperate for any form of medical attention. Participation in clinical trials may be perceived as a source of health care or as a means to access care.⁴ The inherent imbalance of power between the individual participant and the researcher or research institution that exists, regardless of where a trial takes place, is considerably greater in developing countries. Potential participants are more susceptible to coercion and more likely to volunteer as participants in research studies. Among other challenges, the heightened susceptibility to coercion has a direct impact on the ability to give adequate informed consent.

All of this raises unique challenges for institutional review boards (IRBs) in the United States that may have initial or ongoing oversight responsibilities for clinical trials conducted in

developing countries to ensure adequate protections are in place to safeguard the rights of research participants. To this end, IRBs must be cognizant of the characteristics unique to the host population and culture, and must be able to work collaboratively with local review bodies or institutions. Inclusion of and consultation with members of the host population when determining complex issues related to informed consent, recruitment and confidentiality can permit the adoption of steps that contribute to the protection of vulnerable participants.

This paper reviews the sources of historical guidance embodied in regulation and ethical codes, and examines relevant guidelines adopted more recently by academic institutions in the U.S. that sponsor or conduct research in developing countries. It reports on the results of a survey commissioned by the former National Bioethics Advisory Commission in the U.S. that probed the experiences and views of researchers in developing countries with respect to externally-sponsored clinical trials, and reports on international ethical guidelines formulated to address problematic ethical issues. Finally, the paper raises the apparently irreconcilable difficulty inherent in ethical mandates requiring that host populations have access to the experimental therapy following the conclusion of the study, assuming safety and effectiveness have been established, with the economic disincentives that exist for pharmaceutical manufacturers first, to conduct research on conditions unique to the host country, and second, to provide a needed therapy to countries lacking the economic resources required to purchase new drugs.

The Reach of U.S. Regulation

In the United States, human subject research supported by federal funding, conducted by a government agency, or intended for submission to the Food and Drug Administration, is required to adhere to federal regulations generally known as the “Common Rule.”⁵ The

“Common Rule” requires that all research protocols be reviewed and approved by an IRB to ensure the inclusion of adequate safeguards for human subjects. Research that falls outside of the categories listed above may also fall within the reach of federal regulation. All research that is “subject to regulation,” must be reviewed and approved by an IRB operating in accordance with 45 C.F.R. §46.^{6,7}

The “Common Rule” applies not only to human subject research conducted in the United States, but also to human subject research conducted in foreign countries.⁸ However, in the event the host country’s regulations are equivalent to or more protective than US regulations, the foreign standards will govern.⁹ The FDA has been involved in efforts through the International Conference on Harmonization (a tripartite effort by the U.S., the European Community, and Japan) to formulate general principles for the conduct, performance, and control of clinical trials, in an attempt to reduce differences among regulatory agencies.¹⁰

In September 2001, the Department of Health and Human Services, Office of Inspector General, issued a report titled “The Globalization of Clinical Trials: A Growing Challenge in Protecting Human Subjects.”¹¹ The report addressed issues related to the increasing number of non-U.S.-based clinical trials involving pharmaceuticals. It also recognized the importance of the trials, many sponsored by U.S. pharmaceutical firms, as an important source of data in New Drug Applications submitted for FDA approval.¹² Sponsors who wish to submit data from a foreign clinical trial must be responsive to FDA’s requirements for investigator qualifications, good clinical practices, and FDA inspections.¹³ FDA oversight extends to clinical trials conducted overseas through its statutory role as “gate-keeper” of new drugs marketed in the US. The agency’s regulations encompass not only clinical standards, but also require that foreign clinical research be conducted in accordance with the ethical principles set out in the Declaration

of Helsinki or the laws and regulations of the country in which the research is being conducted, whichever represents the greater protection of the individual.¹⁴ For each foreign clinical study submitted under this section, the sponsor must explain how the research conformed to the ethical principles contained in the "Declaration of Helsinki" or to the foreign country's standards. If the foreign country's standards were used, the sponsor is required to explain in detail how those standards differ from the "Declaration of Helsinki" and how they offer greater protection.¹⁵

A number of academic institutions in the U.S. involved in clinical research have imposed additional requirements for research conducted through their institutions. The standards may correspond to the values of the specific institution, the location of the research trials, and the type of research conducted. For example, Yale University and the University of Chicago require that research conducted outside of the United States conform to the standards of domestic human subject research and that all research conducted through their institution be subject to federal regulations, regardless of funding.¹⁶ Yale requires that international human subject research comply with all relevant laws of the host country, and be subject to review by both the IRB in the U.S. and the local IRB, whenever possible.¹⁷ The IRB must be knowledgeable about and sensitive to, local community composition, and standards of conduct.¹⁸ In the event no local IRB exists, researchers must identify a local institution to serve in a comparable capacity (ie: a tribal council, school board, town committee, hospital board, etc.)¹⁹ A relevant excerpt from the University of Chicago IRB & Investigator Manual may be seen in Appendix A to this manuscript.

Host Country IRB Review

Although IRBs in the U.S. and in other “developed countries” may be better suited, because of experience, resources and infrastructure, to raise questions related to research design and bio-risk,²⁰ host IRBs or their equivalent are, in most instances, more attuned to ensure that decisions about recruitment and confidentiality are culturally sensitive, and that informed consent is meaningful within the cultural context of the host population.²¹ Essential to achieving this end is early involvement of and consultation with local or host IRBs. Collaboration between IRBs in the U.S. and the host country will increase the likelihood of empowerment and greater protection of populations deemed to be “vulnerable”, and will help to ensure that research protocols satisfy and respond to both “western” ethical standards and local cultural and ethical sensitivities.²²

Although policies instituted by academic institutions may require review by a host country IRB or comparable body, there are many international research trials involving human subjects that do not undergo any type of host country review. A recent study commissioned by the former National Bioethics Advisory Commission (now the President’s Council on Bioethics) in the United States involved a survey of researchers in developing countries on issues related to review of research protocols by U.S. and host country IRBs.²³ The survey included 169 questions directed to the concerns and opinions of the researchers with regard to the ethical review process and performance of local and United States IRBs. Of the 670 researchers surveyed, 203 returned complete responses. The majority were physicians employed at foreign universities. Forty-four percent of survey respondents reported that their studies underwent no review (technical, scientific, or ethical) by the Ministry of Health in the host country.²⁴ Twenty five percent of the respondents reported that their studies had no ethics review by either an IRB,

ethics board, or Ministry of Health.²⁵ Of the researchers whose studies were collaborative and funded by U.S. sources, 69% responded that a host country ethics review was required by U.S. institutions for collaborative research, but generally was not done.²⁶

Research institutions, such as Yale University, mandate that all international research conducted through the institution comply with both U.S. and host country regulations. These institutions also mandate meaningful host country ethical review.²⁷ However, as the National Bioethics Advisory Commission Study revealed, compliance with this requirement is less than optimal, even for studies funded by U.S. institutions.

The Commission's Study found that developing country IRBs were most concerned about the cultural appropriateness of the studies, the need for local language consent forms, the relevance of the research question to the host country population, and the availability of the intervention (ie: drug or device) to the host country following completion of the study.²⁸ The study respondents deemed the issue of cultural sensitivity a weakness within U.S. ethical guidelines.²⁹

Local IRBs are likely to be more sensitive to and aware of relevant cultural constructions of autonomy, which can influence effective and meaningful informed consent. Informed consent, the general principles of which originated in the Nuremberg Code, is often characterized as an "act of communication" between the researcher and the potential research subject.^{30,31} The process of informed consent is the primary mechanism through which to respond to the fears, preferences, values and expectations of the participant and to incorporate these issues into the decision to both enroll and continue in a research trial.³² Of significant importance is the realization that U.S. or "western" assumptions about autonomy, individuality, and the meaning attached to these words and concepts, may differ significantly in the region in

which the study is being conducted.³³ Local culture may be unique in its understanding of social relationships and the social positioning of individuals within families, institutions and communities.³⁴ For example, in some local communities the religious, tribal or community leaders play a significant role in the decisions of individual members of the society.³⁵ Local IRB members, with knowledge and understanding of unique social concepts, are able to take into account the decisional capacity of the individual and to tailor the informed consent process as needed.³⁶

International Ethical Guidelines

The Nuremberg Code, the Declaration of Helsinki, and the guidelines developed jointly by the Council for International Organizations of Medical Sciences at the World Health Organization (CIOMS Guidelines) delineate principles of conduct that reflect respect for persons, beneficence, and justice.³⁷ The CIOMS Guidelines on international research are comprehensive, and make a number of recommendations for IRBs to consider when reviewing cross-cultural research protocols.³⁸ However, to date, there is no mechanism in place to enforce the Guidelines.³⁹

The CIOMS Guidelines address many cross-cultural conflicts, and serve as a useful tool for IRBs charged with the responsibility of ensuring that international research protocols provide adequate safeguards for participant rights. Strengthening the capacity of local IRBs to conduct independent ethical review is an important goal of the Guidelines.

The Guidelines respond to concerns that ethical review boards in developing countries may fall short of promoting rigorous standards for human subject research given that they are poorly funded, lack oversight experience and properly trained staff.⁴⁰ CIOMS Guideline Twenty articulates an additional responsibility of research sponsors and investigators, that being to

strengthen the developing country's capacity to conduct ethical and scientific review as well as its capacity to conduct biomedical research.⁴¹ This "capacity building" includes the establishment and strengthening of local IRBs and ethics review committees, training research and health care staff, and educating the community from which research subjects are drawn.⁴² One stipulation under the CIOMS Guidelines is that, prior to conducting research in a host country with little or no capacity for independent ethical review, investigators should include in the research protocol a plan that specifies the contribution they will make to increase the host country's capacity.⁴³

In many developing countries where medical research is underway, there are insufficient procedures, knowledge and understanding regarding proper ethical review and oversight.⁴⁴ The Strategic Initiative for Developing Capacity in Ethical Review ("SIDCER") was developed by the World Health Organization (WHO) to foster competent, independent in-country decision-making and to "monitor the quality and effectiveness of ethical review worldwide with mutual understanding and respect for cultural, regional and national differences."⁴⁵ SIDCER is a network of "regional fora," composed of health researchers and invited partner organizations. The SIDCER network is working to improve the substance of debate on health research ethics, and to mobilize resources that will ensure the sustainability of regional review networks.⁴⁶

The "regional forum" approach is intended to bring together individuals who have up-to-date international and "western" expertise in human subject protections and the most "concerned and capable" individuals in the developing world.⁴⁷ The aim is to provide not only the opportunity for individuals in developing countries to learn about current and cutting-edge human subject protections, but also to contribute ideas about respect for and accommodation of complex cultural, regional, and national differences.⁴⁸ The exchange of ideas, values and

information is intended to promote mutual understanding on issues affecting the dignity of research subject and their communities.⁴⁹

Beneficence

IRBs have the increasingly complex task of ensuring independent and competent review of studies conducted overseas. However, the requirement that all studies be beneficent may reduce the risk that vulnerable populations might be coerced into bearing risks for which they will derive no benefit. Again, collaborative review is essential. Including local IRBs in protocol review can ensure that trials conducted in developing countries are limited to those that are beneficial to the host country's population. Of continuing and key significance is that individuals in developing countries are vulnerable to coercion in the medical setting, due to lack of education, lack of available medical care, and pervasive poverty, all of which create a heightened potential for exploitation and oppression.

The Belmont Report, published in 1978, outlines three universal ethical principles applicable to human subject research: (1) respect for persons, (2) beneficence and (3) justice.⁵⁰ The Report recognizes that some groups require greater protection, due to illness, mental disability, socioeconomic condition or circumstances that severely restrict liberty.⁵¹ Protection of vulnerable populations extends even to the point of their exclusion from research trials. The level of protection should be determined by weighing the risk of harm against the likelihood of benefit to the subject.⁵²

The Declaration of Helsinki provides that "medical research is justified only if there is a reasonable likelihood that the populations in which the research is carried out stand to benefit from the results of the research."⁵³ Echoing the Declaration of Helsinki, the Belmont Report provides that "whenever research supported by public funds leads to the development of

therapeutic devices and procedures, justice demands both that these not provide advantages only to those who can afford them and that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research.”⁵⁴

The history of medical research is marked with countless cases in which vulnerable populations have been exploited for the benefit of other members of society, or society as a whole. In the United States, children, individuals with mental disabilities, African Americans, prisoners and slaves have been exploited in the name of medical research.⁵⁵ One of the most infamous abuses in the United States occurred in 1932. The United States Public Health Service initiated the Tuskegee Syphilis Study, in which 399 poor black sharecroppers, with latent syphilis, for decades were deliberately deceived and denied treatment for their disease.⁵⁶ The Tuskegee study was initiated by the United States government. It provides a glaring example of how vulnerable groups can be manipulated to bear serious burdens and risks for which they derive no benefit. Populations within developing countries, because of their “vulnerable” status, may be prime targets for exploitation.

Another more recent controversy involved the testing of AIDS drugs in Africa. Of the 36.1 million HIV infections worldwide, 25.3 million (77%) are in Sub-Saharan Africa.⁵⁷ Although African nations are severely affected by the AIDS pandemic, and would benefit from any effective treatment, the concern is that most African countries cannot afford the treatment after the research process ends, nor are drug manufacturers necessarily willing to price the treatment within a range affordable to these populations. In addition, local health delivery systems may be ineffective or nonexistent.⁵⁸ This immediately raises questions about the ethical permissibility of testing drugs on these populations, when there are serious doubts about whether access to the drug will continue after the trials end.^{59,60} Ethical requirements and guidelines

such as the Belmont Report and the Declaration of Helsinki would seem to prohibit AIDS research in poor African nations when there is little chance that the population ultimately will benefit.

Economics

Drug manufacturers point to significant economic disincentives to research and develop drugs that treat diseases and conditions primarily afflicting poor nations.⁶¹ Currently, “only 10% of the global health research budget is devoted to diseases that cause 90% of the world's disease burden.”⁶² International health economists suggest there is little monetary incentive for drug companies to expend resources to research compounds intended for diseases prevalent in “poor” nations.⁶³ The return on products intended for developing countries promises to be minimal, far from covering research and development costs.⁶⁴

The economic status of developing nations and the populations within simply cannot absorb the cost of new drugs. Africa, for example, “generates less than one half of one percent of sales by global pharmaceutical firms but accounts for nearly 25 percent of the world's disease burden, as measured by years of healthy life lost to disease.”⁶⁵ Because there is no financial incentive, few large-scale research efforts are targeted at “poor country diseases” for example malaria and tuberculosis.⁶⁶ Absent a viable market for drug products, it is difficult to create an incentive for manufacturers to develop drugs for poor populations. Currently, most of the research funding for diseases affecting developing countries comes from international organizations such as the World Health Organization (WHO).⁶⁷

Not all developing nations lack markets for new drugs. In Asia and Latin America, a new market for pharmaceuticals has been emerging.⁶⁸ Many drug manufacturers are viewing developing countries as opportunities for prosperous drug sales, as the spending powers of some

of these nations expands. Evidence of this change can be seen in the trend among contract research organizations (CROs) (entities that manage foreign trials under contract with drug sponsors) to locate offices in a range of foreign countries.⁶⁹ For example, in 2000, the world's largest CRO, located in thirty-eight countries, opened offices in Chile, Czech Republic, Greece, Norway, Philippines, Romania and Thailand.⁷⁰

Overall, some developing countries are being excluded from the benefits of cutting-edge research because they cannot afford the results of the research enterprise while others are seeing vast growth in their markets for new pharmaceuticals. In a perverse way, economic conditions often exert an inappropriate influence on the standards for human rights protections in research trials.

Conclusion

CIOMS, SIDCER and the World Health Organization recognize that fostering a sustainable system of ethical review and research oversight in developing countries can strengthen the overall research infrastructure. With a stronger and more developed research infrastructure that includes increased oversight experience, better-trained researchers and staff, and an international support network, developing countries will be in a stronger position to embark on research beneficial to their populations. Developing countries have a greater incentive to permit research on vaccines and treatments for diseases that affect their populations than do large drug companies, and would be able to do so assuming increased support from abroad.

As trials overseas increase in number, it becomes increasingly important that the system of ethical oversight be adequate to protect the rights of research participants. By instituting international ethical standards, and not only consulting with but listening to local review entities,

protection of human rights in overseas trials can be more rigorous. Inclusion of and consultation with local IRBs during the protocol review, combined with affirmative steps to strengthen the local review infrastructure are essential ingredients to the integrity of the process. Increasing education, ethical oversight experience, and the exchange of information about human subject research eventually will empower vulnerable populations within developing countries, allowing them to determine the protections that will safeguard their rights and their communities.

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- ¹ Kristen Farrell, *Human Experimentation in Developing Countries: Improving International Practices by Identifying Vulnerable Populations and Allocating Fair Benefits*, 9 J. HEALTH CARE POLICY 136 (2006).
- ² Id.
- ³ Id.
- ⁴ Id.
- ⁵ 45 C.F.R. §46 (2005)
- ⁶ 45 C.F.R. §46.101(a)(2) (2005)
- ⁷ 45 C.F.R. §46.102(e) (2005)
- ⁸ 45 C.F.R. §46.101(h) (2005)
- ⁹ Id.
- ¹⁰ Fed. Reg. Vol. 62, No. 242, Dec. 17, 1997.
- ¹¹ DEPT. OF HEALTH & HUMAN SERVICES: OFFICE OF INSPECTOR GENERAL, THE GLOBALIZATION OF CLINICAL TRIALS: A GROWING CHALLENGE IN PROTECTING HUMAN SUBJECTS, OEI-01-00-00190 (Sep 2001), *availale at* <http://oig.hhs.gov/oei/reports/oei-01-00-00190.pdf> (last vistied April 10, 2007).
- ¹² Id.
- ¹³ Id.
- ¹⁴ 21 C.F.R. 312.120(c)
- ¹⁵ 21 C.F.R. §312.120(c) (2005)
- ¹⁶ Yale IRB: Sample Policy on Int'l Research, <http://irb.yale.edu/policies/international.html> (last visited April 10, 2007).
- ¹⁷ Id.
- ¹⁸ Id.
- ¹⁹ Id.
- ²⁰ See, Leslie London, *Ethical Oversight of Public Health Research: Can Rules and IRBs Make a Difference in Developing Countries*, 92 AM. J. PUB. HEALTH 1079 (2002).
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- ²² London, *supra* note 21.
- ²³ AA Hyder, SA Wali, AN Khan, NB Teoh, NE Kass & L Dawson, *Ethical Review of Health Research: A Perspective from Developing Country Researchers*, 30 J. MED. ETHICS 68 (2004).
- ²⁴ Id.
- ²⁵ Id.
- ²⁶ Id.
- ²⁷ See, Mary Terrell White, *Guidelines for IRB Review of International Collaborative Medical Research: A Proposal*, 27 J. L. MED. & ETHICS 87 (1999).
- ²⁸ Hyder, *supra* note 24.
- ²⁹ Id.
- ³⁰ Id.
- ³¹ See, Patricia A. Marshall, *Human Subject Protections, Intsitutional Review Boards and Cultural Anthropological Research*, 76 ANTHRO. Q. 269 (2003).
- ³² CARL H. COLEMAN, JERRY A. MENIKOFF, JESSE A. GOLDNER & NANCY NEVELOFF DUBLER, THE ETHICS AND REGULATION OF RESEARCH WITH HUMAN SUBJECTS 297, (LexisNexis Group 2005).
- ³³ Marshall, *supra* note 31.
- ³⁴ Id.
- ³⁵ Id.
- ³⁶ Id.
- ³⁷ White, *supra* note 28.
- ³⁸ Council for Int'l Org. of Med. Sciences, *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, http://www.cioms.ch/frame_guidelines_nov_2002.htm (last visited April 10, 2007).
- ³⁹ White, *supra* note 28.
- ⁴⁰ Hyder, *supra* note 24.
- ⁴¹ *International Ethical Guidelines*, *supra* note 39.

⁴² Id.

⁴³ Id.

⁴⁴ Supra, note 39

⁴⁵ Strategic Initiative for Developing Capacity in Ethical Review: About SIDCER, <http://www.who.int/sidcer/en/> (last visited April 10, 2007)

⁴⁶ Id.

⁴⁷ Strategic Initiative for Developing Capacity in Ethical Review: Strategic Plan, http://www.who.int/sidcer/about/strategic_plan/en/index.html (last visited April 10, 2007)

⁴⁸ Id.

⁴⁹ Id.

⁵⁰ Dept. of Health, Education & Welfare, *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research*, 44 Fed. Reg. 23,192, (Apr. 18, 1979)

⁵¹ Id.

⁵² Id.

⁵³ <http://www.fda.gov/oc/health/helsinki89.html>.

⁵⁴ Dept. of Health, Education & Welfare, *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research*, 44 Fed. Reg. 23,192, (Apr. 18, 1979)

⁵⁵ Coleman, *supra* note 32.

⁵⁶ Report of the Tuskegee Syphilis Study Legacy Committee (1966), <http://www.tuskegee.edu/Global/story.asp?S=1141982&nav=CcX1> (last visited April 10, 2007).

⁵⁷ See, Ruqaiyah Yearby, Good Enough to Use for Research, But Not Good Enough to Benefit From the Results of that Research: Are the Clinical HIV Vaccine Trials in Africa Unjust? 53 DEPAUL L. REV. 1127 (2004).

⁵⁸ Id.

⁵⁹ Id.

⁶⁰ Id. at 1141.

Health Care Expenditures of African Countries Involved in
Perinatal HIV Transmission Prevention Trials

Country	Year	Amount Spent per Patient in US dollars
Burkina Faso	1992	22
Cote d'Ivoire	1995	22
Ethiopia	1990	5
Kenya	1992	13
Malawi	1990	11
Tanzania	1990	5
Uganda	1994	10
Zimbabwe	1991	86

⁶¹ *Toiling in tough times: Interview with Professor Sangkot Marzuki, head of the Eijkman Institute for Molecular Biology in Jakarta, Indonesia*, 321 BRIT. MED. J. 778 (2000).

⁶² Id.

⁶³ Id.

⁶⁴ Rachell Glennerster, Michael Kremer & Heidi Williams, *Price of Life*, 148 FOREIGN POLICY 26 (2005).

⁶⁵ Id.

⁶⁶ Id.

⁶⁷ *Toiling in Tough Times*, *supra* note 59.

⁶⁸ Globalization of Clinical Trials, *supra* note 13..

⁶⁹ Id.

⁷⁰ Id.

University of Chicago Social & Behavioral Sciences IRB & Investigator Manual

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Adopted 16 February 2006

International Research at The University of Chicago:

International research often requires additional safeguards to protect the rights and welfare of subjects. These include everything from the use of a translator if the person(s) seeking consent and/or collecting data is not fluent in the subject's language to waiving the requirement to obtain written consent due to local custom or because of risks subjects may face due to social or political conditions. Investigators who will be conducting research internationally should provide the IRB with at least the following information:

- Information about where the research will be conducted (both the geographic location and the performance site, where applicable).
- A copy of local IRB or equivalent ethics committee approval, where possible. Depending on the local context, this may take the form of a letter of approval from a local IRB, a local university department sponsoring the research, a local institutional oversight committee, or an indigenous council. In areas where government-issued research visas are required, a copy of the visa should be submitted.
- Information about the investigator's knowledge of the local research context, including information about the current social, economic, and political conditions. This should include a detailed description of the investigator's personal experience conducting research (or studying or residing) in the region.
- Information about whether there are any additional risks subjects might face as a result of the population being studied and/or the local research context.

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- The language(s) in which consent will be sought from subjects and the research will be conducted, as well as whether the investigator fluent in this language, or whether a translator will be used. If a translator will be used, it should be clear what risks, if any, this might pose for subjects, as well as how they will be minimized.
 - Copies of the translated informed consent documents and instruments, including verification of the accuracy of the translation(s).
 - If the research is federally funded, information about the status of the assurance for the performance site, where applicable.

When composing an IRB protocol for an international research project, researchers should clearly demonstrate that the proposed procedures are appropriate given the culture, norms, and mores of local communities. Whenever practical, researchers should include local community representatives in the design of the research and consent processes to ensure that local concerns about research practices, goals, or uses of collective cultural or intellectual property are considered. Community collaboration in research design demonstrates concern for the ethical principles of justice (by articulating the equitable distribution of research risks and benefits in relation to community needs) and respect for persons (by recognizing the right of individuals to form groups with corporate agency).

http://humansubjects.uchicago.edu/sbsirb/manual/sbsirb_manual.pdf

<http://humansubjects.uchicago.edu/sbsirb/manual/index.shtml>
