



***RECOMMENDATIONS FOR  
THE ETHICAL INVOLVEMENT  
OF LIMITED ENGLISH-SPEAKERS  
IN RESEARCH***

by

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## **Introduction**

The ethical principles guiding current human protection from research risk are based on The Belmont Report, written in 1979 by The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.<sup>1</sup> These basic principles are Respect for Persons, Beneficence and Justice.

Respect for persons is the principle upon which the concept of informed consent is based. It indicates that persons should be treated as autonomous agents who should make their own decisions and that persons with diminished autonomy, for example persons with severe mental illness, should be protected. Beneficence is the principle that research should not cause unreasonable harm and that any harm resulting from research should be minimized while maximizing its benefits. Justice addresses the problem of who should receive the benefits of research and bear its burdens. It indicates that all persons should equally share the likelihood of exposure to the risks and benefits of research.

While in theory these principles guide the protection of all humans from research risk regardless of their race, religion or national origin, the National Council on Interpreting in Health Care is concerned that Limited English-Speaking (LEP) persons may not always benefit from these protections. The Council has outlined the following guidelines to help health care administrators, research scientists, and Institutional Review Board (IRB) members better understand how to involve LEP persons in research in an ethical manner.

## **Respect for Persons: Providing Informed Consent for LEP Persons**

The Federal office that regulates the protection of human subjects in research, The Office of Protection from Research Risks, has provided guidelines for obtaining consent from subjects who do not speak English. One of those states that informed consent information should be presented “in language understandable to the subject.” While the guidelines encourage that consent information to be provided in a written form in the language of the potential subject “whenever possible”, this is not required.<sup>2</sup> Oral presentation of informed consent in conjunction with a short form written consent document stating that the required elements of the full consent have been presented orally is allowable. The stated requirement for interpretation is that the person interpreting be fluent in both English and the language of the subject. A witness (which can be the interpreter) and the person obtaining consent must then sign the English language consent form, and the witness and the research participant must both sign the short consent. The research participant is then given the full consent in English to review at home.

The NCIHC believes that this policy is inadequate because it may not always result in informed consent according to the Belmont Principles. There are several important problems that could arise when consent is obtained in this manner. First, while the stated requirement is that the interpreter be fluent in both English and the language of the subject, it does not indicate what type of interpreter should be used. Family members and friends, for example, may say they are fluent in both languages and yet may make errors in interpretation or consciously omit or add information to sway a family member’s choice, seriously jeopardizing the informed consent process. Second, without a consent document in their own

language, research participants do not have an opportunity to review and confirm what they were told in the consent process. This is especially important for LEP persons because they often belong to cultures in which the family plays a more important role in decision-making than in Western cultures. Due to this, they will need the consent document to review with their families at home. Third, this process is especially inadequate given that a substantial sub-group of limited English-proficient populations have diminished autonomy as undocumented residents. Undocumented persons may be coerced to participate in research by being made to feel that their status will be exposed if they do not agree to participate in a study or that their status will improve if they do participate. This is much more likely to happen without notice if undocumented LEP persons are consented without adequate interpretation or given a standard document in their language explaining their rights as a research participant.

These potential problems in providing informed consent can be avoided by implementing the following NCIHC recommendations. First, a qualified health care interpreter or member of the research staff with documented fluency in both English and the person's language should be the only people allowed to obtain consent. While this cannot guarantee informed consent, it will greatly increase the probability that potential research participants will get the correct information about the study and its risks and benefits, have their questions answered adequately, and have their rights to confidentiality respected. Second, all informed consent and research documentation, including the full consent form, must be in the patient's language. It must be translated by a professional translator and back translated until the English and target language version are equivalent in meaning. Directly translating materials without back translation has shown to be an inadequate method of translation, leading to errors in meaning.<sup>3,4,5</sup> In addition, such materials should be written at the 6<sup>th</sup> grade reading level or lower. Third, research participants should be given copies of the study documents both in their preferred language and in English, to allow for subsequent review by family or friends who speak either language.

Finally, Institutional review boards should consider altering the standard informed consent process when research involves LEP persons. They should consider adding an explanation of what informed consent is and an indication of what it is not at the beginning of the consent process. The process of informed consent is a foreign concept to members of many cultures and consequently some LEP persons may be fearful of what it means. A brief explanation would help immigrants understand the process as well as reassure them that a consent form is not a legal document that obliges them to any particular course of action or a contract that takes away any of their rights. Researchers should also be open to the idea that, in contrast to our Western tradition, informed consent with the individual participant may not always be appropriate. In some cultures, participants may want to transfer the consent process to a family member and that informed consent may involve family members in a more direct way.<sup>6,7</sup>

### **Beneficence: Protecting from Risk**

One important component of protecting research participants from risk is by providing them with the opportunity to report adverse events or misconduct on the part of the research staff.

The Federal regulations stipulate that research participants be given the telephone numbers of the person responsible for the research and of the IRB chair so they can report potential harm including adverse side effects, concerns about their participation and misconduct on the part of the research investigator. This protection requires that limited English-speakers be able to make these calls in their primary language. The NCIHC takes the position that LEP research participants should be able to call and speak to research and IRB staff in their language at any time during the study. This could be done in a number of ways. At a minimum the research staff must have made some arrangement with an interpreter service to provide for communication to participants and a method by which participants can call and speak to the IRB chairman in their language. This could be done by providing the hours and number of an interpreter service and to make an arrangement with that service to take the initial call from LEP research participants and then arrange an interpreted conversation with the research staff or IRB chair.

### **Justice: Allowing Access to Research Benefits**

The principle of justice addresses the problem of who should receive the benefits of research and bear its burdens. The federal guidelines and IRBs have long emphasized the protection component of this principle and erred on the side of protecting minority populations from sharing undue research burden. This emphasis is appropriate given past exploitative practices such as those linked to the Tuskegee syphilis study, but it has had the consequence of excluding minority persons from research from which they or their community could potentially have benefited.<sup>8,9</sup> Recently, the pendulum has swung the other way for many minority populations, but not for Limited English-speaking populations. LEP persons are routinely excluded from research,<sup>10</sup> reducing their likelihood of benefiting from research.

The NCIHC takes the position that research investigators should always consider including LEP persons in their research and that IRB members should remind them to do so. In addition to making research more just, taking this step could potentially improve research validity. LEP persons make up a substantial component of the U.S. population in all geographical areas. Representative samples in most areas are not representative if LEP populations are systematically excluded. This means that research excluding them may not be generalizable to them. In addition, LEP persons often have poorer health status than the dominant U.S. population and face language barriers in trying to access medical care. Because so much of the basic health research has not included LEP populations though, we don't know how this poorer health status affects their responses to medication, interventions, etc. Their inclusion will help us understand how to better care for them. We suggest that the IRBs obtain their local census data from the internet so that they can help investigators know how to enroll a truly representative sample appropriate to the research being conducted.

### **Conclusions:**

Using the Belmont Report and its three important guiding ethical principles of Respect for Persons, Beneficence, and Justice, we have outlined several steps that both research scientists and Institutional Review Boards should take to enhance the ethical involvement of Limited-English-speaking persons in research. They include providing interpretation through a

qualified health care interpreter, providing appropriately translated informed consent materials in the LEP person's language, enabling research participants to have ongoing contact with the research and IRB staff in their language, and making research opportunities accessible to LEP persons. The National Council on Interpreting in Health Care takes the position that research involving LEP persons may be unethical unless these recommendations are implemented.

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