

Research Subjects with Limited English Proficiency: Ethical and Legal Issues

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Abstract

In this article, we examine Institutional Review Board (IRB) policies, international guidelines, and federal regulations and guidance for dealing with Limited English Proficiency (LEP) research subjects. We show that federal and international guidance concerning this topic is insufficient, and there is considerable variation in IRB policies. While some IRBs have thorough and useful policies, others do not. Many IRBs do not provide researchers and IRB members with answers to several important questions relating to language barriers in research. We recommend that federal agencies, international organizations, IRBs and researchers take steps to fill in the gaps in guidance and policy to help insure that LEP populations will receive equitable and ethical treatment in research.

Key words

Limited English proficiency, research subjects, informed consent, translation, interpretation, justice

Introduction

Many human subjects in research studies in the United States (US) have limited English proficiency (LEP). According to the 2000 U.S. Census, the country's total population was 281 million and 31 million were born outside the country. 35% of this foreign born population does not speak English well or does not speak English at all (U.S. Census, 2000). Since the census undercounts illegal immigrants, the US population is probably closer to 290 million, with a foreign-born population of about 40 million (13.8%) (Bears Stearns, 2005). If one assumes that two-thirds of the illegal immigrants in the U.S. have LEP, then about 5.5% of the people living in the U.S. have LEP. In some areas of the country, such as California and Texas, the percentage of people with LEP is much higher than the national average. In the United States, Spanish is by far the most common language spoken at home other than English; according to the 2000 U.S. census, 60% of people who speak a language other than English at home speak Spanish, followed by Chinese (4%), French (3%), German (2.8%), Vietnamese (2%), Italian (2%), and Korean (1.8%) (U.S. Census, 2000). However, in some areas of the country these percentages vary. For example, a significant percentage of the population speaks French Creole at home in Louisiana and in Hawaii a significant percentage of the population speaks Hawaiian. These demographic facts confirm what many researchers and institutional review boards (IRBs) already know: a significant and growing percentage of people who may participate in research studies do not speak English well or do not speak it at all.

In light of this significant LEP population and the potential problems their involvement in research could pose for unprepared IRB's, we will examine US federal

guidance, international guidance, and IRB policies concerning language barriers in research. We will also recommend some policies that IRBs should consider adopting in the absence of federal guidance in order to ensure fair and ethical accommodation for all research participants.

Federal Guidance

In the US, the federal government has provided some guidance for dealing with language barriers in research. According to regulations adopted by 17 federal agencies known as the Common Rule, the information given to the research subject (or the subject's representative) during informed consent "shall be in language understandable to the subject or the representative" (45 C.F.R. 46.116 and 21 C.F.R. 50.20). This requirement clearly implies that any discussions occurring during the consent process must take place in a language that the subject can understand: if the subject can only understand Spanish, then discussion must take place in Spanish. The federal regulations also address procedures for documenting consent. The regulations allow researchers to use two different forms of documentation:

The consent form may be either of the following:

- (1) A written consent document that embodies the elements of informed consent required by §46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(2) A short form written consent document stating that the elements of informed consent required by §46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form (45 C.F.R. 46.117(b) and 21 C.F.R. 50.27(b)).

If a subject does not speak English, researchers have the option, under the regulations, of translating the complete consent form into the subject's language and submitting that document to the IRB for approval, or using a short written form translated into the subject's language and submitting that form to the IRB for approval. To use the short form, researchers must discuss all the required elements of consent with the subject (or representative) and submit a summary of what they plan to say to the subject to the IRB for approval prior to using the form. The summary does not need to be translated. A witness must also sign the short form and a copy of the summary. It is also worth noting that federal regulations allow the IRB to waive the requirements for documenting consent if the research is minimal risk and consent procedures would not normally be

required outside of the research context or the main risk of the study would be potential loss of confidentiality and the consent document would be the only record linked to the subject (45 C.F.R. 46. 117(c) and 21 C.F.R. 50.27(c)).

Federal agencies have issued some interpretative guidance pertaining to the documentation of consent. In 1995, the Office of Human Research Protections (OHRP), which was then called the Office of Protection from Research Risks (OPRR), clarified the requirements of the Common Rule by stating that the complete consent document could serve as summary and that the witness to the consent process documented by the short form must be fluent in English as well as the subject's language. The OHRP also published a sample document (or template) for the short form (see Appendix) (OHRP, 1995). In 1998, the Food and Drug Administration (FDA) issued additional guidance for IRBs and investigators:

When the study subject population includes non-English speaking people or the clinical investigator or the IRB anticipates that the consent interviews will be conducted in a language other than English, the IRB should require a translated consent document to be prepared and assure that the translation is accurate. As required by 21 CFR 50.27, a copy of the consent document must be given to each subject. In the case of non-English speaking subjects, this would be the translated document. While a translator may be helpful in facilitating conversation with a non-English speaking subject, routine ad hoc translation of the consent document should not be substituted for a written translation. If a non-English

speaking subject is unexpectedly encountered, investigators will not have a written translation of the consent document and must rely on oral translation. Investigators should carefully consider the ethical/legal ramifications of enrolling subjects when a language barrier exists. If the subject does not clearly understand the information presented, the subject's consent will not truly be informed and may not be legally effective. If investigators enroll subjects without an IRB approved written translation, a "short form" written consent document, in a language the subject understands, should be used to document that the elements of informed consent required by 21 CFR 50.25 were presented orally. The required signatures on a short form are stated in 21 CFR 50.27(b)(2) (FDA, 1998).

The FDA guidance makes some very important and useful points. First, it recommends that investigators use an IRB-approved translation of the complete consent document when the subject population will include non-English speaking people or if the investigators anticipate that consent interviews will be conducted in a language other than English. Second, the guidance also discourages ad hoc translation of consent documents by interpreters. Third, the guidance recommends that investigators use the short form when they do not use the complete form. Thus, a translation of the complete document should be used when the researchers anticipate that they will enroll subjects that do speak English, while the short form may be used to cover the unexpected enrollment of

a research subject. When the short form is used, investigators still must conduct an oral discussion of the research that covers the required elements of consent.

The Office of Human Subjects Research (OHSR), which oversees intramural human subjects research at the National Institutes of Health (NIH), has issued some guidance that is very similar to the FDA guidance. According to the OHSR's guidance, investigators should use a translated, IRB-approved, complete consent document when they expect to enroll non-English speaking subjects. Enrollment may be expected if the investigators are actively recruiting non-English speaking subjects or they are studying a disease or condition that it is likely to attract non-English speaking subjects. The IRB may verify the accuracy of the translated document through a back translation or review by an IRB member fluent in the other language (OHSR, 2005). Investigators may use the short form when they have an unexpected enrollment of a non-English speaking subject. The guidance also recommends that interpreters should be investigators fluent in the subject's language or someone who is independent of the subject (OHSR, 2005).

International Guidance

Surprisingly, international research guidelines provide very little guidance concerning overcoming language barriers in research. According to the guidelines from the Council for International Organizations of Medical Sciences (CIOMS):

Informing the individual subject must not be simply a ritual recitation of the contents of a written document. Rather, the investigator must convey the information, whether orally or in writing, in language that suits the individual's level of understanding. Consent may be indicated in a number of ways. The subject may imply consent by voluntary actions, express consent orally, or sign a consent form. As a general rule, the subject should sign a consent form, or, in the case of incompetence, a legal guardian or other duly authorized representative should do so. The ethical review committee may approve waiver of the requirement of a signed consent form if the research carries no more than minimal risk – that is, risk that is no more likely and not greater than that attached to routine medical or psychological examination – and if the procedures to be used are only those for which signed consent forms are not customarily required outside the research context. Such waivers may also be approved when existence of a signed consent form would be an unjustified threat to the subject's confidentiality (CIOMS, 2002).

Like the federal regulations, the CIOMS guidelines require that consent take place in language understandable to the subjects. The guidelines do not, however, say when a consent form must be used or what type of form (complete vs. short) may be used. The conditions for waiving the need for a consent form are almost identical to the conditions stated in the federal regulations.

The World Medical Association (WMA) Helsinki Declaration has even less to say about language barriers. The Helsinki Declaration states that: “After

ensuring that the subject has understood the information, the physician should then obtain the subject's freely-given informed consent, preferably in writing. If the consent cannot be obtained in writing, the non-written consent must be formally documented and witnessed (WMA, 2001).” The Helsinki Declaration does not say that consent must take place in a language understandable to the subject, or when it must be obtained in writing.

The Guidelines for Good Clinical Practice is a set of rules for conducting clinical trials, which was developed by a working group of the International Conference on Harmonization (ICH) of Technical Requirement of Registration of Pharmaceuticals for Human Use. The ICH recommends that regulatory agencies in the US, Europe, and Japan adopt these rules. Section 4.8.6 of the ICH Guidelines states that “the language used in the oral and written information about the trial, including the written informed consent form, should be as non-technical as practical and should be understandable to the subject or the subject’s legally acceptable representative and the impartial witness, where applicable (ICH, 2004). While these guidelines do not give specific guidance on translating or interpreting documents, they do at least imply that researchers may need to translate or interpret documents other than the consent form, since the consent form is mentioned as one type of “written information” that may be presented to subjects.

Canada, which is officially bilingual, provides an interesting case study in how a nation addresses multiple spoken languages in human research. 59% of the approximately 30 million Canadians list English as their first language, 23% list

French, and 18% list some other language (Wikipedia, 2005). In Canada, three government agencies that sponsor research on human subjects, the Canadian Institutes of Health Research, the Natural Sciences and Engineering Research Council and the Social Sciences and Humanities Research Council, have adopted a uniform set of regulations known as Tri-Council Policy Statement (TCPS), which are similar in spirit and substance to the Common Rule. According to comments on Article 2.1 of the TCPS:

The requirement for free and informed consent should not disqualify research subjects who are not proficient in the language used by the researchers from the opportunity to participate in potential research. Such individuals may give consent providing that one or more of the following are observed to the extent deemed necessary by the REB, in the context of a proportionate approach to the harms envisaged in the research and the consent processes that are to be used:

An intermediary not involved in the research study, who is competent in the language used by the researchers as well as that chosen by the research subject, is involved in the consent process.

The intermediary has translated the consent document or approved an existing translation of the information relevant to the prospective subject.

The intermediary has assisted the research subject in the discussion of the research study.

The research subject has acknowledged in his or her own language, that he or she understands the research study, the nature and extent of his or her

participation, including the risks involved, and freely gives consent (see exception in Article 2.1(c)) (TCPS, 2005).

These comments address the process of obtaining informed consent when there is a language barrier, and for a country with a high rate of non-English speakers, the comments give considerable latitude to the REB (Research Ethics Board, Canada's version of an IRB) in deciding how to deal with translation and interpretation issues. They do not specify when investigators should translate the complete consent form or use a short form. The TCPS does not address questions related to translating or interpreting other documents read by subjects, such as questionnaires.

Accrediting Agencies

Two organizations, the Association for the Accreditation of Human Research Protection Programs (AAHRP) and the Applied Research Ethics National Association (ARENA) have developed programs for accrediting and certifying IRB members and IRBs (AAHRP, 2005; ARENA, 2005). AAHRP has developed accreditation standards for organizations, investigators, IRBs, sponsors, and community involvement, but these standards do not mention policies or procedures for dealing with LEP participants. ARENA has developed a certification exam for IRB professionals, which focuses on federal research regulations, international guidelines, and seminal documents, such as *The Belmont Report* (National Commission, 1978). The ARENA exam does not cover material

pertaining to dealing with LEP participants beyond what can be found in the federal regulations or international guidelines.

Survey of U.S. IRBs

Although US federal agencies and international bodies have provided some useful guidance for dealing with LEP subjects in research, they still have not provided definite answers to at least four important questions:

- (1) What does it mean to “anticipate” or “expect” to enroll non-English speaking subjects?
- (2) Are researchers permitted to exclude non-English speaking subjects?
- (3) Which languages should documents be translated into?
- (4) When should other documents used in research, such as questionnaires, be translated?

These are important questions that investigators and IRBs must answer when conducting or overseeing research involving human subjects with potential LEP.

To understand how some IRBs in the U.S. have responded to these and other issues relating to LEP human subjects, we conducted a survey of policies and procedures available on 30 IRB websites in the U.S., including 23 of the top-ranked medical schools in research, ranked by *US News & World Report* (2005) and the sites of 7 nationally recognized research hospitals and institutions. We choose these institutions based on their geographic diversity and research volume. Most of these institutions are likely to have to deal with dilemmas concerning the enrollment of LEP subjects in research studies. The medical schools in our survey were: Baylor College of Medicine, Case Western Reserve University,

Columbia University, Cornell University, Duke University, Emory University, Harvard University, Johns Hopkins University, Northwestern University, Stanford University, University of California at Los Angeles, University of California and San Diego, University of California at San Francisco, University of Chicago, University of Michigan, University of Pennsylvania, University of Pittsburgh, University of Texas Southwestern, University of Washington, Vanderbilt University, and Yale University. The hospitals and institutions in our sample were: the National Cancer Institute, the Center for Disease Control and Prevention, Memorial Sloan Kettering Cancer Center, the Mayo Clinic, Massachusetts General Hospital, the MD Anderson Cancer Center, and the Fred Hutchinson Cancer Research Center. We only included websites in the survey if we could access the website and relevant material within 30 minutes of searching on the worldwide web. For example, since we were not able to access the Cleveland Clinic's IRB website, we did not include it in our data set, even though the Cleveland Clinic is one of the top research hospitals in the U.S. We analyzed the content of these websites to find answers to the five questions mentioned above as well as several others.

Survey Results

The results of the survey are summarized in Table 1. Most IRB's, we found, provided some general guidance on enrolling LEP individuals in research, but very few offered specific guidance on some important issues, such as defining "expected" or "anticipated" enrollment or translating documents other than the informed consent form. Furthermore, few institutions offered guidelines about

the languages into which documents should be translated, or discussed problems with excluding LEP individuals. None of the websites specifically identified a way to determine which languages a researcher must translate ahead of time, although six institutions did provide pre-translated informed consent templates in a variety of languages other than English. The CDC, for example, provided translations of the short form in 19 different languages (CDC, 2005).

Lack of specific federal regulation or guidance concerning these issues is likely the reason that there are so few IRB policies and so much variability among IRB's. For example, the federal regulations provide specify when to use the complete consent document and the short form, and the IRB policies that we studied mirrored the federal policy. 96.7% of IRBs stated when researchers should translate the complete consent document, and 60% stated when it would be appropriate to use the translated short form. In many cases, IRBs specifically referred to federal policies. But in areas where there are no federal directives, few IRBs provided guidance. For example, there is no federal policy on when to translate other research documents and, not surprisingly, only 6.7% of IRBs discussed this issue. Clearly, IRBs, investigators, and LEP research subjects could benefit from additional federal regulation or guidance in this area.

Another possible explanation for the variability among IRB policies is that different IRBs serve different research institutions and human populations. Different institutions may have different attitudes toward accommodating LEP people, and different populations may have different percentages of potential

research participants with LEP. If an IRB must deal with issues related to LEP participants on a regular basis, it may take steps to develop consistent policies.

Although many websites we examined were not very helpful to investigators and IRB members concerned about language barriers in research, one website was exemplary. The Duke University Health System (DUHS) IRB website provides specific guidance on translating the complete consent form, using the short form, using interpreters, and translating other research documents, like questionnaires and surveys. The website has a substantial passage on dealing with LEP subjects in research, including:

An increasing number of research studies in English-speaking countries include subjects who do not understand the English language. It is imperative that all subjects have an opportunity to understand enough about the study and the elements of consent in order for them to make an informed decision about being a research participant. This means that consent must be obtained using language that non-English-speaking subjects understand. To implement this requires either written translation or oral presentation in the relevant non-English language by a person who is fluent in both English and the other language. The basic requirements are stated in the federal regulations (45 C.F.R. 46), but specific rules for implementation are determined by the DUHS IRB... When subjects who do not understand the English language are involved in research studies that require responding to questionnaires, it is important that those questionnaires are translated into a language that the subjects understand.

Also, it is important that the questionnaires convey the same meaning as the original English version. Otherwise, responses of non-English-speaking subjects will not be comparable to responses of those who speak English (DUHS, 2005).

Table 1: IRB Policies Regarding LEP Subjects

Question	% YES
Does the website discuss translating the complete consent document?	96.7
Does the website explain when to use the short form?	60.0
Does the website discuss language barriers in research?	53.3
Does the website provide guidance on using interpreters?	40.0
Does the website provide guidance on which languages to use in translating documents?	20.0
Does the website discuss the ethical or legal problems with enrolling subjects when a language barrier exists?	20.0
Does the website discuss problems with excluding LEP subjects from research?	16.7
Does the website provide guidance for translating other research materials, such as questionnaires,	6.7

surveys, or brochures?

Does the website define “expected” or 0.0

“anticipated” enrollment?

Discussion

From our survey, it is clear that some IRBs have very little guidance for researchers in dealing with LEP subjects and that most IRBs (in our sample) do not go beyond what is required by the federal regulations. While it is easy to understand why IRBs in the U.S. are reluctant to adopt rules that go beyond what is required by the federal government, due to the lack of a legal mandate, they need to have some fair and reasonable policies and procedures for addressing questions or problems related to language barriers in research. Surprisingly few institutions have clear and easily accessible guidelines for researchers who enroll LEP subjects, leaving a wide array of difficult ethical questions regarding the treatment these subjects should receive. To stimulate discussion toward workable policies, we will offer perspectives on several of these important questions related to enrolling LEP subjects in research.

Excluding LEP Subjects

Researchers might decide to simply exclude LEP people from enrollment in their study as a way of avoiding problems and hassles related to language barriers. Indeed, there is evidence that some researchers have often taken this tactic. In a survey of authors of medical journal articles dealing with patient-provider relations, 40% of the authors had excluded non-English speaking

individuals (Frayne et al, 1996). Among the reasons cited by researchers for excluding LEP people were difficulties translating study documents and problems with recruiting, training and paying bilingual staff. Although one can see why researchers would exclude LEP people to avoid the burdens of translation and interpretation, there are several reasons why they should refrain from exclusions. First, exclusion of LEP people can limit the generality of a research study by excluding people particular with ethnic or cultural characteristics (Frayne et al, 1996). For example, suppose that a researcher plans to conduct a national study on a new hypertension medication and excludes LEP people from the research. The effect of excluding LEP people would be to exclude a disproportionately high number of Latino subjects from the study, since most of the LEP people in the US are Latino. Thus, it might be difficult to apply the results of this study to the Latino population, unless researchers make special efforts to recruit English-speaking Latinos.

Second, intentionally excluding LEP people would be unfair to potential subjects who happen to have LEP. The principle of justice, discussed in *The Belmont Report*, requires fair procedures and outcomes in the selection of subjects (National Commission, 1978). It is unfair to exclude research subjects from a study without a valid scientific or ethical reason. For example, there is a good scientific reason to exclude men from a study on ovarian cancer, and there is a good ethical reason (fetal protection) to exclude pregnant women from a study on a drug that is likely to have harmful effects on the fetus. In some cases, there may be legitimate scientific reasons to exclude LEP people. For example, there are no

good reasons to include LEP subjects in a study on English reading comprehension among people with a 10th grade reading level, because people with LEP will, by definition, not have a 10th grade reading level. In other cases, the nature of the research topic may unintentionally exclude LEP subjects. For example, a study on lung cancer in Vietnam veterans would probably not include any LEP subjects, even though the study would not intentionally exclude these subjects.

Third, intentionally excluding people with LEP may also violate federal research regulations, which state that:

Selection of subjects should be equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons (45 C.F.R. 46.111(a)(3) and 21 C.F.R. 56.111(a)(s)).

Even though the federal regulations require equitable selection of subjects, no federal agency has published any guidance to help IRBs and researchers decide when subject selection is equitable. Historically, ensuring equitable subject selection has involved making sure that vulnerable populations, such as prisoners or economically disadvantaged people, are not unfairly used in research for reasons of convenience or expedience. The regulations not only require investigators to develop extra protections for vulnerable subjects, but they also

mandate that specific classes of vulnerable subjects should not participate in some types of greater than minimal risk research that does not offer the subject any direct benefit. However, many commentators have argued that equitable subject selection also involves making sure that subjects are not unfairly excluded from research (Mastroianni and Kahn, 2001). While researchers in the 1970s routinely excluded women from clinical trials without sound scientific or ethical justifications, such exclusion should be considered unethical and illegal by today's standards (Mastroianni and Kahn, 2001). One could argue that excluding LEP subjects from research without a sound scientific or ethical reason would violate the requirement for equitable subject selection. (A sound scientific reason for exclusion would be that inclusion of LEP people would not promote the aims of the study. A sound ethical reason for excluding LEP people would be to protect them from harm or exploitation.)

Fourth, intentionally excluding LEP people from research may violate the Department of Health and Human Services (DHHS) regulations pertaining to Title VI of the Civil Rights Act. The DHHS regulations require all recipients of DHHS funding to provide meaningful access to programs and activities (DHHS, 2005). Title VI mandates that no person "on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance (42 U.S.C. 200d)." The DHHS has promulgated regulations that forbid recipients from using methods that deny federal benefits on the basis of race, color, or national origin, or have this effect (DHHS, 2005). These

regulations apply to institutions that receive DHHS funding, such as universities, hospitals, or branches of local government. To determine what counts as “meaningful access” recipients of DHHS funding may consider four factors:

- (1) The number or proportion of LEP persons eligible to be served or likely to be encountered by the program or grantee; (2) the frequency with which LEP individuals come in contact with the program; (3) the nature and importance of the program, activity, or service provided by the program to people's lives; and (4) the resources available to the grantee/recipient and costs (DHHS, 2005).

The regulations are intended to provide meaningful access to LEP persons without overburdening businesses, non-profit organizations, or government agencies. It is worth noting that federal agencies, such as the DHHS, are also required to provide meaningful access for LEP people (Clinton, 2000).

Thus, if researchers are working for a branch of the DHHS or are working for an organization that receives DHHS funding, then they must provide meaningful access for LEP people. To decide what it takes to provide “meaningful access” to a study, researchers should consider the number or proportion of LEP people that might participate in a research study, the frequency with which LEP people come in contact with their organization, the importance of the study to those persons, and the resources available to provide access to the study. In most cases, LEP people will frequently come in contact with the organization and the research being conducted by the organization will be important to LEP people. Thus, implementing meaningful access will usually

boil down to consideration of the proportion of LEP people within the entire study population and the resources available to provide access. Though intentionally excluding LEP people will usually be unjustified, it might be justifiable if there are not sufficient resources to provide access to that population and the proportion of LEP people in the study population is low.

Based on federal policies ethical considerations, we believe that investigators should not routinely exclude LEP people from research studies. Investigators are justified in intentionally excluding LEP people only if there is a sound scientific reason for excluding LEP people, a sound ethical reason for excluding LEP people, or if there are not sufficient resources to include LEP people and the proportion of LEP subjects is very low.

Anticipated or Expected Enrollment

The FDA requires investigators to use the complete, translated consent document (as opposed to the short form) when they “anticipate” that they will enroll LEP subjects. The OHSR requires the complete form when a researcher “expects” to enroll LEP subjects. While it is obvious that enrollment of LEP subjects can be expected or anticipated when the target population is LEP subjects, what should investigators and IRBs do in other situations? “Anticipate” and “expect” are vague terms, but investigators and IRBs need terms and phrases that are clear and precise, because vague terms are difficult to apply. One way of thinking about anticipated enrollment would be to consider the total number of LEP subjects that are likely to enroll in a study. We suggest that researchers

expected enrollment of LEP subjects speaking a particular language can be anticipated when five or more of those subjects are likely to be enrolled.

To illustrate our suggestion, suppose that researchers propose to enroll 100 subjects from a population in which 5% of the people speak only Spanish and 0.4% only speak Chinese. After completing enrollment, they are likely to have five Spanish-only subjects but not even one Chinese-only. Given these numbers, it makes sense to say that the researchers expect to enroll Spanish-only subjects but they do not expect to enroll Chinese-only subjects. If the study were larger, then they might expect to enroll Chinese-only subjects. If the study were much smaller, they might not expect to enroll any Spanish-only subjects. When enrollment is set at 100, it would be reasonable to require the researchers to translate the complete consent form into Spanish, but not reasonable to require them to translate the form into Chinese, since this would impose an additional burden on the researchers without a great deal of additional protection for human subjects. All of the subjects, whether Spanish or Chinese speaking, still deserve the same degree of protection, but the benefits of translating the complete consent form are much higher when researchers expect to enroll five LEP subjects (of a particular language) than when they expect to enroll none. If researchers happen to “unexpectedly” enroll a Chinese speaking subject, then they can use the IRB-approved short form, translated into Chinese, combined with an oral presentation of the complete form.

Translation of Consent Forms

Defining “anticipated” or “expected” enrollment of LEP people provides a way of settling questions about the language used for translation of documents. If it is probable that five or more subjects in the population will speak Spanish well but do not speak English well, then investigators should translate the complete consent document into Spanish. If fewer than five subjects will speak Spanish but not English, then investigators may translate the short form into Spanish for each “unexpected” enrolled Spanish speaker. In some areas where there is more than one type of LEP population, researchers may have to translate the complete consent document into more than one language.

Translation of Other Documents

As noted earlier, the federal regulations provide some guidance concerning the translation of consent forms, but they do not provide any specific guidance for translating other documents used in research, such as questionnaires, instructions for using medical devices, brochures, etc. In our survey of IRBs, we found that only a few IRBs provide guidance on this topic. While we recognize that translating other documents places an extra burden on investigators, we believe that investigators have an obligation to translate these documents in order to overcome language barriers in research and help secure genuine informed consent. If a study protocol calls for a document to be orally presented to all subjects without a written counterpart, then investigators do not need to translate the document, and they may use an interpreter to present the document to LEP subjects. For example, researchers should use properly translated and validated self-administered questionnaires, but they do not need to translate the text of an

orally administered survey. If researchers expect to have LEP subjects from a particular language group in their study, i.e. they are likely to have five or more LEP subjects from that language group, then they should translate documents into that language prior to initiating the study. If they have an unexpected enrollment of an LEP person from a particular language group, then they may use the short consent form, and they may translate other documents into that language prior to initiating the study with that person.

There are several reasons for requiring investigators to translate documents read by LEP research subjects. First, failing to translate other documents could place subjects at risk. In many clinical studies, subjects receive written instructions for taking medications, recording or reporting symptoms, using medical devices, and so on. It is important for these subjects to receive accurate written instructions for their own safety. Second, not translating other documents can undermine the integrity of the study's data if LEP subjects fail to follow directions appropriately or do not understand how to answer survey questions. Third, failing to translate other documents can have an adverse impact on the LEP subject's informed participation in research. Informed consent does not end when a subject signs a consent form; it is a communication process that should continue throughout a study. Subjects need to understand information exchanged during research so that they can decide whether to answer survey questions, take medications, participate in procedures, or even withdraw from a study.

While we believe that it is important for investigators to translate all documents read by subjects, we recognize that this goal may be difficult to achieve in some circumstances. If investigators are conducting a study sponsored by a company or organization and they are using written materials prepared by that company, the researchers may not want to incur the responsibility or even the liability of translating those documents. For example, if a medical device company provides written instructions on how to use its device, then the company itself should be responsible for translating those instructions. Therefore, investigators should encourage companies that sponsor clinical studies on their products to provide translated documents. If investigators are conducting a study in which the LEP population does not have a written language, then there is no need to translate any documents (including the consent form).

Conclusion

We have examined federal regulations and guidance, international guidelines, and IRB policies for dealing with LEP research subjects and have found that there is insufficient federal or international guidance concerning this topic. We have also found that there is considerable variation in IRB policies among major biomedical research centers in the US. While some IRBs have thorough and useful policies, others do not. Most IRBs (in our survey) do not provide researchers and IRB members with answers to several important questions relating to language barriers in research. We recommend that federal agencies, international organizations, IRBs and researchers take steps to fill in the gaps in guidance and policy to ensure that LEP populations receive equitable and

ethical treatment in research. The issues that we have identified in this paper are not likely to disappear anytime soon, especially since the LEP population is expected to continue to rise in the U.S.

Although we have advocated for translating the complete consent form as well as other documents when it is likely that a study will enroll five or more LEP subjects from a particular language community, we recognize that translation and interpretation poses significant logistical and financial burdens on researchers. It takes time and money to translate and validate documents, and recruit and retain research staff capable of assisting with translation and interpretation. These costs can place significant burdens on researchers, especially on those conducting smaller studies. The costs of translation and interpretation can also be a significant burden for smaller research institutions. Who should bear these costs? Who should pay helping to ensure that LEP subjects are treated ethically and equitably in research? It is probably the case that many researchers have chosen to deal with these problems by intentionally excluding LEP subjects from research. We have argued, however, that intentionally excluding LEP subjects is unethical and illegal, unless one has a sound scientific or ethical reason for exclusion. Instead of excluding LEP subjects, research sponsors and institutions should work together to address costs related to translation and interpretation, which could become a part of the administrative/overhead cost of conducting research.

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Appendix: Sample Short Form for Subjects Who Do not Speak

English

Consent to Participate in Research

You are being asked to participate in a research study.

Before you agree, the investigator must tell you about (i) the purposes, procedures, and duration of the research; (ii) any procedures which are experimental; (iii) any reasonably foreseeable risks, discomforts, and benefits of the research; (iv) any potentially beneficial alternative procedures or treatments; and (v) how confidentiality will be maintained.

Where applicable, the investigator must also tell you about (i) any available compensation or medical treatment if injury occurs; (ii) the possibility of unforeseeable risks; (iii) circumstances when the investigator may halt your participation; (iv) any added costs to you; (v) what happens if you decide to stop participating; (vi) when you will be told about new findings which may affect your willingness to participate; and (vii) how many people will be in the study.

If you agree to participate, you must be given a signed copy of this document and a written summary of the research.

You may contact ____name____ at ____phone number__ any time you have questions about the research.

You may contact ____name____ at ____phone number__ if you have questions about your rights as a research subject or what to do if you are injured.

Your participation in this research is voluntary, and you will not be penalized or lose benefits if you refuse to participate or decide to stop.

Signing this document means that the research study, including the above information, has been described to you orally, and that you voluntarily agree to participate.

signature of participant date

signature of witness date