

**10-1004 NCI\_Phase\_II\_report**

**Pilot Testing of NCI's Spanish-language Informed  
Consent Template for Chemoprevention Clinical  
Trials with Spanish-Speaking Latino Audiences**

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Topline Report

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## **I. Background, Rationale, and Aims of the Study**

### **1.1 Foundational work on which the present study is based**

The National Cancer Institute (NCI) has developed an informed consent (IC) template for use in chemoprevention clinical trials. The template was developed for use by clinical trials' principal investigators, research nurses and other healthcare professionals involved in recruiting patients for participation in clinical trials for NCI grantees conducting chemoprevention trials. NCI's Office of Communication and Education (OCE), in collaboration with NCI's Division of Cancer Prevention (DCP), has linguistically and culturally adapted and translated the template into Spanish for use with Spanish-speaking populations during the consenting process for NCI-funded chemoprevention clinical trials. The first round of formative research was completed in 2010 and it involved conducting in depth interviews with healthcare professionals with extensive experience recruiting Spanish-speakers into clinical trials. The goal of that research was to collect best practices and solicit feedback on the Spanish version of the informed consent template from the perspective of the healthcare professionals using the form. In the second round of research, which is detailed in this report, the IC template was edited and pilot tested with individual participants and dyads first in Chicago in early August 2012, and then in Los Angeles later that month. Suggestions obtained from participants in Chicago for how to improve the IC were implemented in Los Angeles, which allowed for fine-tuning the template and obtaining reactions from a diverse, national sample to the material.

### **1.2 Cultural and Linguistic Considerations in the Informed Consent Process**

Culture affects the way people perceive and interact with the world, the way people interpret cues in daily interactions, and their expectations of behavior in various contexts. Thus, culture has been identified as an important factor that affects individuals' outcomes when interacting with various systems of care (Ayón & Aisenberg, 2010). In particular, the cultural differences between the individual and the medical system have been posited to play a key role in health services outcomes (Institute of Medicine, 2002, 2004). For example, the medical culture is characterized by an expectation of individual logic, efficiency, and understanding of the biological bases of disease in health care decisions, whereas health decisions made by ethnic minority populations may be influenced by cultural expectations of interactions with medical

staff, prior negative experiences of minority individuals with the health care system, and cultural beliefs, attitudes, emotions, and normative behaviors associated with the disease (Buki, 2004; Rajaram & Rashidi, 1998).

With respect to cancer outcomes in Latino populations, previous writings discussing the development of print materials for this population emphasize the importance of taking into account various cultural values, namely *familismo*, *personalismo*, *confianza*, and *respeto*, as well as beliefs regarding fatalism (e.g., Buki, Salazar, & Pitton, 2008). Because of the key role that these cultural factors play in promoting or hindering health behaviors, these will be discussed in more detail in the next sections.

### **Familismo**

There is a growing body of literature that highlights the value that Latino families place on interdependence and collaboration, which is in stark contrast to the value mainstream culture places on independence and individualism (Almeida, Molnar, Kawachi, & Subramanian, 2009). Thus, in working with Latino patients, it is likely that family members will be involved in decision-making processes, as well as in helping the patient navigate treatment (Ellington et al., 2006; Galván, Buki, & Garcés, 2009; Matthews-Juarez & Weinberg, 2004). As noted in the Academy for Educational Development (AED) report, participants stated: “*Hispanics, almost all of them come with family, especially when dealing with cancer*” and “*You are consenting not only the person, but their family.*” Consequently, any research addressing clinical trial decision making in Latino audiences would need to attend, in some way, to the fact that the family would be participating in the consent process as well.

### **Personalismo and Confianza**

*Personalismo* refers to an expectation of forming a personal and social connection with another person, rather than having an institutional relationship (Bernal & Shapiro, 2005). Relationships characterized by *personalismo* display agreeableness and interest. Thus, Latino patients will feel more at ease and comfortable with providers who take the time to develop rapport, to listen to their concerns, and who are respectful of their family members’ contributing roles. Medical staff whose behavior is congruent with *personalismo* are more likely to be perceived as trustworthy

(e.g., someone who warrants *confianza*) than those who treat the patient as one more in a large group and convey an impersonal tone (Buki, Salazar, & Pitton, 2009; National Alliance for Hispanic Health, 2001). The importance of building trust in the consent process was also underscored by consenters who participated in the previous research study. Specifically, according to the AED report, one conserter noted that she worked hard to establish trust with the potential participant first, and then proceeded to explain the form once this personal, trusting relationship had been established. Another conserter explained that she acknowledges previous injustices and abuses toward ethnic minority patients in the health care system to gain participants' trust. Related to this, a conserter in that study also suggested that the Principal Investigator in the clinical trial be taught a few words in Spanish and greet the patient during the consent process, even if briefly, an idea that Latino participants were asked to comment on during the present study. Also, as noted in the AED report, efforts to build trust and take the time to have a personal relationship may result in longer times to obtain consent from Latino participants, and requires more time when other family members are present, as this trust and personal relationship are established with each person attending the meeting. Moreover, the Spanish language also requires more words to express similar thoughts, again requiring more time than would be needed to obtain consent from someone from the majority culture. Participants with lower literacy levels also require more time to explain concepts to ensure they understand them correctly. Taken together, these factors related to establishing a personal relationship, building trust, and ensuring comprehension (which is an example of *personalismo* and building *confianza*), are likely to result in a longer time to obtain consent from Latino participants, especially those who are monolingual Spanish speakers and have low levels of health literacy.

## **Respeto**

*Respeto* (i.e., respect) may influence the interaction between Latino patients and medical staff, as it dictates deferential behavior in various interactions based on authority, age, sex, and social position (Buki, Salazar, & Pitton, 2009). Due to the value of *respeto*, Latino patients in medical settings may be less likely to ask simple questions, may not express doubt when they have it, or may leave the setting altogether and disengage from the system if they have felt the provider did not show adequate levels of *respeto*, as it is expected that medical staff will also show *respeto* in

their interactions with patients (Matthews-Juarez & Weinberg, 2004; National Alliance for Hispanic Health, 2001). Thus, it is critical to ensure a tone of *respeto* is exhibited in any materials that address present and potential future interactions between patients and providers (Buki, Salazar, & Pitton, 2009).

We should note that there have been ethical abuses in research with ethnic minority populations that resulted not only in tragic instances of disrespect, but also in significant physical harm, including death (Trimble, Scharrón-del Río, & Casillas, in press). These negative outcomes reflected an intentional effort on the research team's part to subject patients to potentially harmful medical procedures without the patient's informed consent (Reverby, 2011; Trimble, Scharrón-del Río, & Casillas, 2013). Among Latino populations, two of the most cited cases of egregious ethical violations include a syphilis study with Guatemalan populations in the 1940s (Reverby, 2011), and a research project on birth control with Puerto Rican women in the 1950s (The Pill, n.d.). Because of these historical events, in the present study we made an effort to assess the influence past ethical violations in participants' willingness to join a clinical trial, especially among participants from the most affected regions. Twenty percent of participants were either from Guatemala or Puerto Rico, although we would have liked to have a greater proportion of participants from these areas. Unfortunately, due to the fact that we recruited a convenience sample, we were unable to achieve this oversampling despite concerted efforts to do so. However, when asked about barriers to participation in clinical trials, none of these participants, and none of the participants of other ancestries, spontaneously reported that previous abuses would influence their willingness to participate in a clinical trial. Thus, it appears that media exposure about these events may not have reached these participants or that they did not expect such ethical abuses to occur in the future. However, the potential influence that these events would have on other Latino populations is unknown and would need to be assessed further.

### **Fatalismo**

*Fatalismo* (i.e., fatalism), as it relates to cancer, refers to the belief and subsequent fear that a cancer diagnosis will inevitably lead to death (Matthews-Juarez & Weinberg, 2004).

Consequently, Latinos who believe cancer is fatal may be reluctant to engage in prevention

efforts and treatment, or may delay treatment decisions, as they may believe these efforts will not be effective in preventing death from such a powerful disease (e.g., Buki, Borrayo, Feigal, & Carrillo, 2004). Given these beliefs, it is important to provide information that clearly dispels existing myths (Buki, Salazar, & Pitton, 2009). Thus, in preparing an informed consent form for a Latino audience, it is important to include language that will clearly present side effects of medication and their probability of occurring, as well as to note any benefits the patient or others in the future can be expected to derive from their participation. In addition, it is important to include elements within the informed consent process that can enhance self-efficacy, such as welcoming family members to review the forms along with the patient. These family members may provide social support and hope, as well as help clarify information about the informed consent document and clinical trial that may not have been understood by the patient during the informed consent meeting. By enhancing participants' self-efficacy, they will be more empowered to surmount various cognitive, structural, and cultural barriers to enact change in their lives (Bandura, 1997).

Given the relevance of cultural and linguistic issues to this research, throughout this report we will be noting related factors that may influence the clinical trials consent process with Latino populations. Although presented throughout, cultural and linguistic issues are highlighted, in particular, in the Findings section.

### **1.3 Research Phase II: Pilot Test with the Spanish Speaking Population in Chicago and Los Angeles**

#### **Rationale for the Present Study**

In addition to the cultural factors that were previously reviewed, there were other important reasons that warranted the pilot testing of the Spanish version of the Informed Consent form with a community-based audience. First, in the initial phase, health care providers who engage in consenting Latino patients highlighted the potential usefulness of the form with that audience. In the report of that research, it was noted that these providers identified many strengths in the proposed template: they liked (a) the question-and-answer format of the document, (b) the simplicity of the language, (c) the bullet point format to explain risks, (d) the diagrams and

schemas, and (e) the overall coverage of key issues in the consent process. Most participants also reported that the Spanish-language template would be useful to their organizations, and that templates are something they work with regularly, thus making it easier for them to take this particular document and tailor it to their needs. Specifically, as reported by AED, participants noted the template included “great ideas” and would be a “great tool” for the development of Spanish language Informed Consent forms.

However, the participants also made several suggestions that, when implemented, would best be incorporated into a final template after testing with a potential audience. For example, the consenting staff suggested the form would be strengthened by adding examples to explain more clearly the concepts of randomization, placebo, and risks. Pilot testing several ways to explain these terms with the intended audience is critical, as some examples (e.g., throwing dice to explain randomization) may have greater utility than others (e.g., flipping a coin). Consenting staff also suggested adding a brief description of the study at the beginning of the form, including more information about what insurance will cover during the trial, and adding more graphics. These changes were made, including the addition of colorful graphics to explain the concept of randomization, and feedback from the audience was obtained specifically on these revisions.

Also, the consenters in the previous study discussed at length differences between English- and Spanish-speaking audiences that would warrant the development and testing of a separate, dedicated template. For example, they noted that Latino audiences are less likely to be familiar with the concept of clinical trials and the informed consent process than non-Latino White patients. Thus, a more detailed document would be useful for this audience. Moreover, consenters expressed doubt as to how well their Latino participants really understood the form prior to signing it. Having a form developed specifically for the population provided in the Spanish language would alleviate significantly this concern, helping consenters feel confident that the document adequately facilitated the patient’s decision-making process. Also, few consenters used additional materials to assist them in the consent process, putting a greater onus on the development of a sound, clear, easily understood, and comprehensive Spanish language template.

In addition, there were several issues uncovered in the previous research that suggests the strong need for a Spanish-language, culturally-appropriate template for Latino audiences. First, consenters reported that Spanish language consent forms are typically a translation of an English version, given their limited resources to develop a dedicated form for Spanish-speaking patients. They also reported many Informed Consent models they used had been originally developed by pharmaceutical companies, whose investment and expertise for the development of culturally appropriate forms is likely to be quite limited. Moreover, given the recognition of the need for tailored forms, consenters reported some ability to change the presentation and content of materials in their Spanish consents; in one case, health promoters would pilot test their consent documents make changes as needed prior to using them in their studies. However, consenters also indicated that after IRB approval, they could not make changes to the form. These are compelling reasons to create an empirically-tested, Spanish-language Informed Consent form that has already been pilot tested and clinical trial staff can adapt expeditiously to their needs for a particular study.

Lastly, based on previous research conducted by the NCI related to user-experience with this audience, we also wanted to explore the role of technology in the decision-making process of Latinos who may be considering participating in a clinical trial. This was one topic that was not addressed in the previous study, where the only use of technology mentioned was the sporadic use of videos to help explain a concept presented in the IC. Learning how individuals use technology will be helpful as the work of developing and using IC templates continues to evolve in an increasingly technological world.

### **Present Study Aims**

Prior to disseminating the Spanish IC template for chemoprevention clinical trials, OCE and DCP wanted to explore how the template and IC process may be improved to better meet the needs of potential Spanish-speaking clinical trial participants providing an informed consent. The specific research questions to be addressed by this research are:

- A. What are some strengths of the template? Are there any sections of the template that are difficult to understand? If so, how can they be improved?

- B. What cultural and linguistic elements are important to maintaining cultural and linguistic appropriateness?
- C. What decision making process did participants anticipate undertaking to make a decision about participation in a clinical trial?
- D. What is the role of technology in the consenting process?
- E. What reported factors are expected to influence participants' involvement in clinical trials?

It should be noted that this was an exploratory study with a small sample size, therefore the aim was not to quantify findings but to identify themes that were relevant across participants. The goal was to provide information that can point to ways of improving the informed consent process for cancer prevention trials in the Latino population.

## **II. Methodology**

### **2.1 Participants**

Participants were recruited from Chicago and Los Angeles, and included individuals from various Latin American countries, with one major group each from North, Central, and South America represented in the study. Specifically, the sample included participants from Mexico, Guatemala, Peru, with a smaller number of participants from other countries (see Appendix Q for an overview of the participants' characteristics). Inclusion criteria included: (a) having a family history of cancer, to enhance the participants' ability to assume the role of someone who needs to make a decision about participating in a cancer prevention trial; (b) knowing how to read, so they could evaluate the written document; (c) preferring to read and participate in the interview in Spanish, or having no language preference, to ensure a diversity of experience reflective of the diversity in the Latino population at large; (d) having a broad representation of participants from various Latina/o ancestries, including populations known to have experienced abuse historically in the medical setting (e.g., Guatemalan and Puerto Rican populations), to elicit responses to the IC by those who may be both positively and negatively predisposed to participate in a clinical trial; (e) having broad representation in acculturation levels to the U.S., to ensure the IC is effective in communicating information to Latinos of all acculturation levels; (f) representing various ages, income/education levels, and genders, again to obtain feedback on the effectiveness

of the IC from a wide and diverse group, and (g) representing a variety of experiences in use of technology, from no use at all to daily use, to obtain their reactions to using a digital version of consent document. For participants in dyads all the above mentioned criteria had to be met by the main interviewee, and the companion had to be a family member or close friend who would help the main interviewee make health decisions. In addition, exclusion criteria included working or having worked: (a) for the federal government, (b) on issues of cancer control, prevention, or treatment, (c) in the health field, such as in health promotion, in a clinic or hospital, (d) on advertising, marketing, or public relations, and (e) in the field of human computer interaction or user experience research. In addition, potential participants were excluded if they had participated in a clinical trial before, as their prior knowledge would influence their understanding of the information contained within the IC. It was challenging to recruit such a diverse sample both in Chicago and Los Angeles, with diversity in ancestry being the most difficult to achieve.

As can be seen in Appendix Q, the ages of participants ranged from 24 - 58 years in Chicago and 30 - 58 in Los Angeles. Ages of companions in the dyads ranged from 20 - 48 in Chicago and 30 - 46 in Los Angeles. About half of all participants ( $n = 18$ ) did not have any type of health insurance, with about half in each study site. Participants' household incomes were low, especially when taking into account that the majority of households had at least 3 or 4 members relying on that income.

## **2.2 Procedure**

Participants were recruited through purposeful, rather than random, sampling. In Chicago, participants were recruited with the help of community gatekeepers who knew the community very well, whereas in Los Angeles participants were identified with the help of a professional recruiting agency. Using these two types of recruitment strategies was especially helpful in ensuring that biases present in one type of recruitment would not pervade the entire project. For example, in Chicago recruiters had some difficulty identifying participants with high levels of health literacy, whereas in Los Angeles the opposite was true. Therefore, overall, the sample achieved has very good representation across the various factors that may influence the experience of reading and understanding an IC document.

In each location, a total of 15 individuals were interviewed. Five of those individuals were interviewed individually, and another 5 were interviewed in dyads (for a total of 10 participants in the dyads). Thus, overall, we obtained data from 30 participants. Those who were interested in participating were screened over the phone by the gatekeepers to confirm eligibility (see Appendices A and B for screeners used in Chicago and Los Angeles, respectively), and eligibility was further confirmed at the time of the interviews. In Chicago, the interviews were conducted in a multipurpose room of a non-profit, community-based organization familiar to participants in the Mexican neighborhood Little Village. In Los Angeles, interviews took place in interview rooms available at the professional recruitment company located near the LAX airport. The interviews were conducted primarily by Dr. Lydia Buki, with Silvia Salazar from the NCI assisting in the process by probing additional questions, taking notes, and attending to other issues to ensure the high quality of the study overall. Both Dr. Buki and Ms. Salazar are bilingual and bicultural professionals who have extensive experience conducting data collection regarding health matters with Spanish speaking populations. We allowed 90 - 120 minutes for each interview, which included obtaining demographic information (for demographic questionnaire, see Appendices C and D for English and Spanish versions, respectively), giving the participant time to read the IC template, and conducting an interview afterwards following an interview guide (see Appendices E – H for English and Spanish versions used in Chicago and Los Angeles). Participants in Chicago were compensated with a cash payment of \$75, and participants in Los Angeles with a payment of \$100, consistent with local norms for compensation for research study participation.

In culturally-based research, it is critical to understand how participants are conceptualizing the phenomenon under study. To ensure that the NCI would gather participants' perceptions of two key concepts relevant to the study, participants were asked to provide their understanding of the concept "clinical trials" and their understanding of the concept "informed consent" through two open-ended questions at the outset of the study. After gathering their perceptions, the interviewer informed them of the correct definitions of the concepts that were used for the purposes of the study. Participants were then told by the interviewer to use these definitions when thinking or reading about these concepts for the remainder of the study. Participants were then asked to

imagine that they had been recently diagnosed or had a high risk of being diagnosed with breast or prostate cancer and thus, were invited to participate in a clinical trial. The interviewer explained that as a prospective participant in a clinical trial, the interviewee was being asked to read information about the study through the Informed Consent form. Subsequently, participants were given a copy of the model Informed Consent template, a pencil, pen, post-it notes, and a highlighter, and were asked to review the document and mark any areas that appear confusing, that need greater clarity, or any areas where changes could improve its readability and understanding. For all individual participants, women received a Spanish version of the informed consent template for breast cancer (see Appendices J and L, and for English versions, see Appendices I and K), and men received a Spanish version of the template tailored for a prostate cancer clinical trial (see Appendices N and P, and for English versions, Appendices M and O). After an average of 40 minutes, the interviewers met again with participants to discuss the feedback and ask questions based on the interview guide. The data analysis process began after all the 10 interviews from Chicago were completed to ensure that emerging themes that required additional probing would be addressed with participants in Los Angeles. Qualitative theme analysis methods were used to transcribe, review audiotapes and transcriptions, and identify themes that represented participants' responses.

### **III. Detailed Findings**

To explore potential clinical trial participants' understanding of the informed consent document and process, participants were asked to share their reactions to the document and provide feedback to make it more comprehensible to Spanish-speaking individuals. Although there were individual differences in their responses, they also shared similar reactions. The findings are presented in the next paragraphs organized by research question.

#### **3.1 General reactions, strengths, and ways of improving the NCI Spanish language Informed Consent template.**

- *Participants felt the document was well done.* They understood its main purpose, mentioned it was readable and prepared with care. In other words, they were easily able to focus on the areas they were specifically asked about, rather than focus more broadly

on problems with the form. Many participants remarked on the fact that the Spanish language used, the organization of the material, and the general presentation of the information were carefully crafted. They noted that this made it easier for them to focus on the content of the IC document, which they perceived to be very informative. In addition, it is not unusual for bilingual individuals to compare language versions out of curiosity and when they think the document in its source language may be more accurate than in the translated language. This behavior has been observed in previous studies conducted by the NCI. Yet, bilingual participants in this study mentioned that they did not feel a need to compare the English and Spanish versions because of the high quality of the Spanish language IC. Importantly, participants indicated that the information in the IC would be very helpful to them in making a decision about participating in a clinical trial. More information about ways in which the IC was helpful and ways in which it can be strengthened is included in various sections of this report.

- ***Participants reported difficulty understanding medical terminology.*** The following concepts were difficult to grasp: Informed consent, clinical trial, random assignment, placebo, presentation of risks, and medication names. Overall, participants with lower levels of formal education and limited experience with the health care system (and, consequently, lower health literacy levels) had more difficulty with these concepts than those who reported greater literacy levels or greater exposure to the health care system. It should be noted that all of these terms were translated accurately, yet the material was not conveyed effectively to participants. To make the information accessible to participants, it will be necessary to utilize a plain language approach and adapt certain terms to ensure they are communicated effectively for this audience, consistent with public health education principles published in various government documents (Plain Language.gov, 2011; National Cancer Institute, 2008). Thus, we make several suggestions throughout the document with the goal of making the information easily accessible to potential clinical trial participants. A specific term that many study participants did not understand was the medication name, which many eventually surmised was the name of the medication given the context in which the term appeared. However, most were confused by the use of the medication name in the clinical trial title, as there was not enough

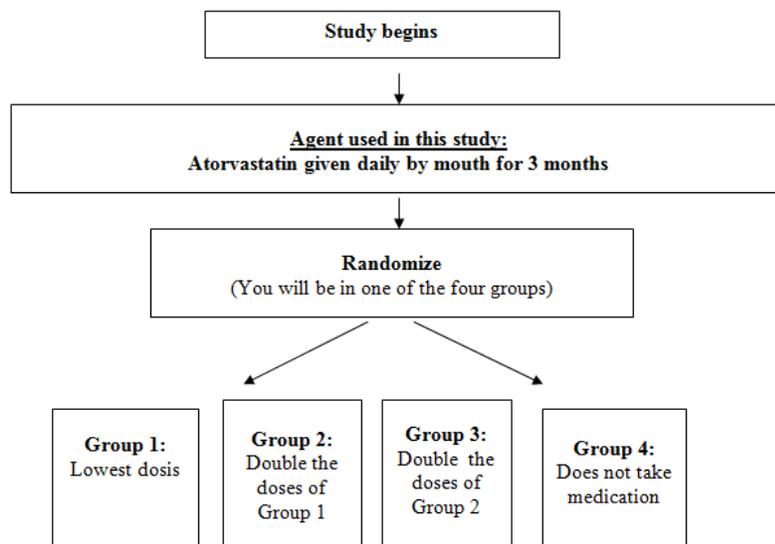
context provided there for them to understand its meaning. In addition, some participants did not understand the word “chemoprevention” in the title of the IC.

- ***When participants did not understand a term, they used reference information they already had to help them make meaning.*** For example, “*clinical trial*” was often confused with “*medical exam*,” partly because the translation of clinical trial into Spanish requires words that could be interpreted to mean a medical exam. There were also linguistic problems with the term “*Informed Consent*,” which initially was translated to read like the English version as “*Consentimiento Informado*.” This is an example of a well done translation where the goal of optimal communication is not achieved. Thus, participants said they preferred the more descriptive phrase that read “*Consentimiento para Participar en un Estudio*” (i.e., Consent to Participate in a Study), as it helped them more easily understand what the document was about. They felt this adaptation would help potential participants understand the purpose of the form more readily.
  
- ***Participants did not understand the purpose of the “pill calendar.”*** Some participants understood that they would receive a calendar that showed the dosage they should take each day, and others thought it was a calendar where they would check off each day that they had taken the medication for the day.
  
- ***To many participants, the notion of random assignment to different groups was confusing.*** Three strategies were used to identify effective ways to explain the concept of random assignment to participants. One strategy involved identifying the best Spanish term to describe the concept of randomization in the text of the IC. There are two terms that can be used to explain this concept in Spanish, “*aleatoria*” (a Spanish scientific term for “random”), and “*al azar*” (a common Spanish term for “random”). Purposefully, we used both terms in the IC in sentences close to each other, and we obtained feedback from the participants about the use of the terms. Participants reported not understanding what “*aleatoria*” meant, and they did not associate this term with “*al azar*” even when presented close together. They suggested using only “*al azar*” because it is a more common term that is easier for them to understand. The second strategy to explain the

concept of randomization included showing an example of random processes when the term was introduced: “Randomization means that you are put into a group by chance (as when throwing dice or flipping a coin).” However, participants indicated that if “al azar” was used, this would be clear enough (consistent with the AED report), and examples would not be needed to explain randomization. The third strategy to explain the concept of randomization involved the use of visual aids to convey the process of randomizing participants into treatment groups. Thus, we showed participants in Chicago the translated version of the diagram presented in the model English IC, obtained their feedback, and subsequently created a revised diagram that was presented to participants in Los Angeles (details about these graphs are discussed in a subsequent section of this report). Participants in Chicago did not grasp the notion of randomization, and in most instances they were unable to explain the graph when we asked them to do it. Part of the feedback they gave included adding details about the purpose of assigning participants to groups with different medicine dosages, so that it would be clear to them that the purpose was to compare outcomes across groups. For example, many participants thought there was a purposeful assignment of participants to groups based on severity of disease. This was especially true of participants in Chicago, where the IC described the groups by numbers (1, 2, 3, and 4). Many participants understood the numbers to mean severity progression, so that individuals in group 1 exhibited the least severity (i.e., cancer at Stage I) or risk and required the least medicine, compared to individuals in group 4, who were thought to have the most severe severity (i.e., cancer at Stage IV) or risk and required the greatest medicine dosage. This made it especially confusing for participants to understand the placebo group, given it was labeled as group 4. One participant thought that she would progress sequentially from one group to another, increasingly receiving greater dosages of the medication. Thus, participants suggested several changes to enhance communication of this information. First, they suggested changing the way groups are labeled to letters. Second, they suggested specifying that the assignment of people into distinct groups is needed to allow doctors to compare reactions to different dosages. Third, they suggested explicitly indicating that across groups the treatment will look the same (e.g., “Participants in every group will take one pill per day”). Lastly, they suggested also stating explicitly that the participant will not know which group s/he is in.

- ***The majority of participants did not understand the notion of placebo.*** Some participants indicated they would be more apt to understand the term if an explanation was provided about why a placebo was necessary during the clinical trial. Also, the use of numbers in the first version of the diagram led many participants to believe the “placebo” group was the one with highest severity or risk that required the highest dosage. To enhance understanding, participants in Chicago suggested adding an example, such as saying that it is like a “*pill without medication.*” We made this change, which indeed made it easier for participants in Los Angeles to understand the concept. Yet, similar to Chicago participants, Los Angeles participants wanted an explanation of the purpose for having a placebo group in the study.
- ***Through iterative testing of diagrams, we found more effective ways to explain the concept of randomization and placebo.*** Based on the model IC, we tailored the diagram used in Chicago to show the process of randomization. This diagram had numbered groups, and given the flow of the arrows, seemed to imply that all treatment groups received the study agent, including Group 4 which received the placebo.

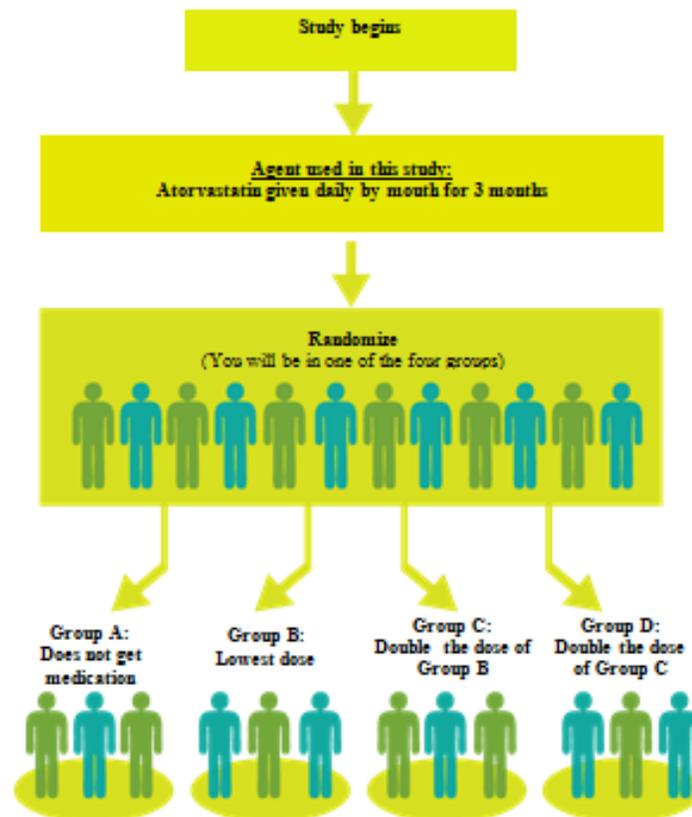
Chicago version



We compiled the feedback given by participants in Chicago and consulted with NCI’s DCP staff, who provided valuable feedback and approved the proposed changes for the Los Angeles version. Thus, based on feedback given by the participants in Chicago and

the DCP, we added stick figures of different colors to show the assignment of people into different groups. In addition, we changed the group identifiers from numbers to letters, and switched the order of presentation such that Group A was now the placebo group. In this way, there was an incremental increase in dosages from Group A to Group D.

### Los Angeles version



The revised diagram was well received, and many more participants understood the concept in Los Angeles compared to Chicago. For future reference, it would be helpful to specifically state on the IC that (a) the participants will not know to which group they have been assigned until the completion of the study, and (b) Group A does not receive [study agent/intervention] rather than the generic term “medication.”

There was a preference for presenting side effects within a table format. In each IC document, we presented some side effects in two formats: tabular form and list form with

bullets. Only cases in which there was more than one risk and side effect we place them in tabular form. We randomized the order of presentation such that we had two versions of each IC, Version A with the tabular format shown for “Likely” side effects, with “Less Likely” and “Rare but Serious” side effects shown in list form with bullets, and Version B, with the “Less likely” side effects in tabular format. This way, we counter balanced and controlled for likelihood of side effect when evaluating the most preferred format. For example, for the prostate cancer IC version A, the side effects were presented as follows:

**Likely** *e.g.*, occurring in more than 20% of participants

<ul style="list-style-type: none"> <li>• Unable to get an erection</li> </ul>	<ul style="list-style-type: none"> <li>• Diminished amount of semen in ejaculation</li> </ul>
<ul style="list-style-type: none"> <li>• Diminished sexual drive</li> </ul>	<ul style="list-style-type: none"> <li>• Increased breast size and/or tenderness</li> </ul>

**Less Likely** *e.g.*, occurring in 20% or fewer of participants

- Skin rash, itching, hives and/or swelling of the lips or face (allergic reactions)
- Testicular pain

**Rare but Serious** *e.g.*, occurring in 2-3% or fewer of the participants

- Development of a more harmful prostate cancer

Although some participants indicated a preference for the list form across cancer types, more participants felt that in tabular form, the risks and side effects were easier to see.

- ***Many participants had difficulty grasping the concept that there are differential probabilities for various risks. Despite the fact that some symptoms were much less likely to happen than others, several participants in Chicago appraised similarly those side effects that were likely to happen, less likely to happen, and rare. In the IC for the breast cancer trial shown in Chicago (see Appendices I and J), risk of side effects was presented as follows:***

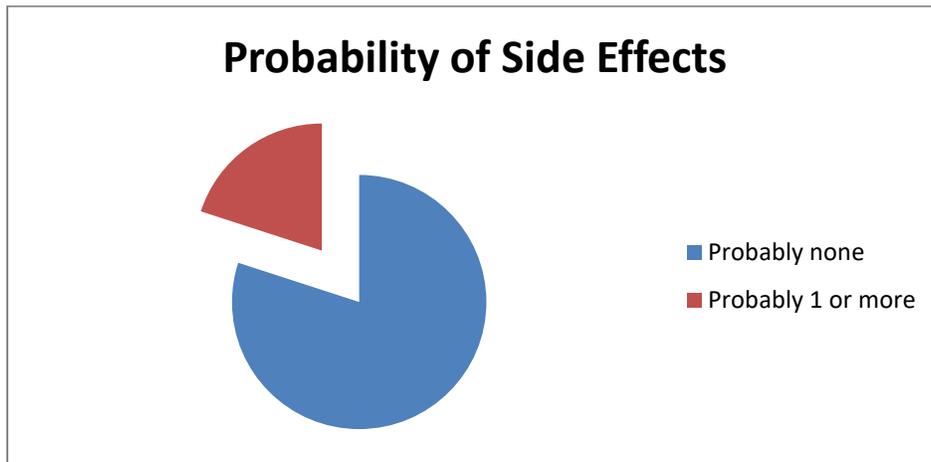
<b>Likely</b>	<i>e.g.</i> , occurring in more than 20% of participants [Risks presented here]
<b>Less Likely</b>	<i>e.g.</i> , occurring in 20% or fewer of participants [Risks presented here]
<b>Rare but Serious</b>	<i>e.g.</i> , occurring in 2 -3% or fewer of participants [Risks presented here]

Participants with low literacy levels, in particular, found it difficult to connect the notion of a percentage of occurrences with the likelihood of something happening to them. To help participants grasp the concept of probability, we revised the presentation of risks in the breast cancer trial IC used in Los Angeles (see Appendices K and L). Based on input from participants in Chicago, the revised document showed, in addition to the probability as a percentage, the number of individuals who may be affected by the side effects based on the probability and the total number of expected participants in the trial. The added wording is underlined below:

<b>Likely</b> , occurring in more than 20% of participants ( <u>in other words, that will occur in more than 13 of the 66 participants</u> ). [Risks presented here]
<b>Less likely</b> , occurring in 20% or fewer of participants ( <u>in other words, that will occur in fewer than 13 of the 66 participants</u> ). [Risks presented here]
<b>Rare, but serious</b> , occurring in 2 to 3% or fewer of participants ( <u>in other words, that will occur in 2 or fewer of the 66 participants</u> ). [Risks presented here]

This new way of presenting the risks elicited much less confusion in Los Angeles participants. Still, one participant gave a specific suggestion for showing risks in a diagram. In Chicago, some participants had mentioned that they would like to see the

risks in visual form, but they were unable to come up with a design. In Los Angeles, in contrast, one participant suggested including first a diagram that would show the probability of having any side effect, and then including a table that would show the side effects listed by probability. This diagram and table, as conceived by this participant, are shown below. It is possible that adaptations will need to be made to the participant’s recommendation to make it most effective. In addition, the figure would need to be adapted to ensure it is Section 508 compliant.



<b>LIKELY - WILL OCCUR IN MORE THAN 13 OF 66 PARTICIPANTS</b>	<b>LESS LIKELY - WILL OCCUR IN LESS THAN 13 OF 66 PARTICIPANTS</b>	<b>RARE - WILL OCCUR IN 2 OR FEWER OF 66 PARTICIPANTS</b>
[Risks presented here]	[Risks presented here]	[Risks presented here]
[Risks presented here]	[Risks presented here]	[Risks presented here]
[Risks presented here]	[Risks presented here]	[Risks presented here]
[Risks presented here]	[Risks presented here]	[Risks presented here]
[Risks presented here]	[Risks presented here]	[Risks presented here]

The diagram and chart are accurate in that for the breast cancer clinical trial featured in this IC, there were no possible risks greater than 20%. However, a different diagram would probably need to be created for different trials, given that the probability of risks will vary.

- *When discussing the potential risks, many Chicago participants did not notice risk of death initially, compared to Los Angeles participants.* When participants were asked about their reaction to death as a potential risk, many participants from Chicago shared that they did not notice that risk mentioned in the form. The IC for Chicago had a sentence informing participants of the risk of death embedded in a larger section discussing the risks of participation in the study. An excerpt is presented here showing this sentence along with the previous and next sentence, for context: “In some cases, side effects can be serious, long lasting, or may never go away. There may also be the risk of death. **You should talk to your study doctor about any side effects that you have while taking part in the study** [sic].” After a slight revision adding a sentence to quantify the risk of death, we tested the new wording in Los Angeles. This revision resulted in most participants recalling the risk of death, a dramatic change from responses we received in Chicago. The revised wording in Los Angeles was as follows: “In some cases, the side effects can be serious, long lasting, or may never go away. There may also be a risk of death. The probability of death is 1 in every 66 persons. **You should talk to your study doctor about any side effects that you have while taking part in the study** [sic].”
  
- *Many of the participants had difficulty discerning who to contact if they had questions about medical problems, study protocols, or their rights as participants.* When participants were asked who they would contact if they had a medical or study question, many easily mentioned that they would contact the clinical trial doctor or staff. However, when we asked participants in Chicago who they contact if they had a question about their rights as participants, most responded that they would contact the clinical trial doctor or staff, despite the fact that the IC clearly stated that they should contact the IRB for these questions. Thus, based on feedback given by participants in Chicago to make the distinction more clear, for the IC used in Los Angeles the contact information for the IRB was presented in a table format with visual aids (shown below). This change made a great difference and helped participants in Los Angeles remember that there was a specific contact provided for them to ask about their rights as participants, and that this number differed from the number they should call should they have medical questions about the study.

## **Chicago version**

### Who can answer my questions about the study?

You can talk to your study doctor about any questions or concerns you have about this study. Contact your study doctor, Dr. Diana Smith, at (555) 555-5555.

For questions about your rights while taking part in this study, call the Institutional Review Board (IRB) at (555) 555-1213.

## Los Angeles version

### Who can answer my questions about the study?

	Questions about the study Dr. Diana Smith at (555) 555-5555
	Questions about your rights as a participant in the study Institutional Review Board (IRB) at (555) 555-1213

Related to this, some participants were unsure if they should call the doctor when experiencing side effects, or whether they should wait to receive the scheduled call as indicated in the IC (at the end of the first month for the breast cancer trial). Although this may not apply to every trial, it seems important for study staff to learn of side effects as soon as they appear, as they may be serious. Thus, we recommend explaining clearly to participants in more than one section of the document that they can and should reach out to the doctor when experiencing side effects. This section of the IC might be a good additional place to include this information, perhaps by having a table with 3 rows with one row showing clearly who to call when experiencing side effects.

### **3.2 Ensuring cultural and linguistic appropriateness in the template.**

This section reports on cultural and linguistic issues that emerged in the course of the study. We highlight the importance of tailoring the process of obtaining informed consent, as well as tailoring the content of the IC, by including cultural and linguistic factors relevant to the Latino population. Issues of culture are presented first, followed by findings on linguistic preferences.

## Cultural Issues

- ***For all participants, family members represented a great source of support in health-related concerns.*** When we asked participants whether family members provided support to them in health matters, emotional support was the most common, and the most important, form of support reported. Instrumental and informational support were also considered important, particularly in terms of understanding prescription and dosages, side effects, and information provided in English. Scheduling appointments, encouraging healthy habits (e.g., exercising and dieting), monitoring health symptoms, and assisting with treatment were other reported means of support. Searching and reading health information on the Internet was mentioned as a family task, particularly for those who were unfamiliar with technology and their children conducted Internet searches for them to obtain information.
  
- ***Participants who came in dyads showed interdependent behaviors.*** Consistent with reports of the importance of family support, in the process of interviewing the participants who came in dyads, we observed that they read the IC together, with family members helping the primary participant understand its content. Some of the observed behaviors included taking turns reading parts of the IC aloud, asking each other questions to clarify the intent of certain portions of the IC, discussing specific parts of the IC such as the process of randomization, and translating words if needed, to ensure the primary participant understood well the content of the form. It should be noted that each dyad was given only one copy of the IC, so some interdependent behavior may have been expected. Yet, the degree to which they interacted with the goal of understanding the material points to family members relying on each other to ensure comprehension of the IC.
  
- ***The ethnicity of doctors and staff was not a salient issue for participants.*** When asked whether they would prefer a doctor (PI of the trial) who is Latino/a, most participants indicated no preference, stating that what they felt was most important for them was to understand the information about the trial. They noted that as long as the IC was clear and there were interpreters to help them understand the trial, they did not have a preference for the ethnicity of the doctors and staff. We also asked whether they would

prefer a doctor who makes an effort to say some words in Spanish while they review the IC. Although there were varying views on this, some participants indicated that this would be positive because it would show that the doctor had made an effort to interact with the potential participants.

- ***Trust issues due to negative experiences with the health care system or doctors were more prevalent in Los Angeles than in Chicago.*** Although participants from both sites reported mistrust towards the health care system, doctors, and medical research, Chicago participants tended to talk more in hypothetical terms and LA participants shared actual experiences they had undergone that had eroded their trust. For example, one participant reported that his wife was diagnosed with breast cancer at an advanced stage because her primary care provider minimized and ignored his wife's symptoms. Participants who were less trustful of the system reported that they would be more careful in reviewing the information on the IC and would conduct additional research before deciding their participation in a trial.

### **Linguistic Issues**

- ***Participants were asked about their preference for a Spanish-language or English-language IC.*** A generational difference was found in regards to language preference. The majority of participants preferred a Spanish version for themselves. Yet, they also wanted to have an English version to share with family members who are more fluent in English, especially their children. This way, they could share information about the trial with them and discuss it together. Consistent with this, younger participants in the dyads preferred receiving an English version of the IC. Participants who were fluent in both Spanish and English reported a preference for receiving health information in English because of their perception that the document in its source language would be of higher quality than the translation. This was not a preference particular to the IC; participants indicated that, in general, their perception is that documents can lose information in the process of translation, and when they have a choice, they prefer to read documents in their original form.

- ***The majority of participants felt it would be helpful to include a bilingual Spanish-English glossary with the IC.*** Specifically, they reported that having a glossary would help them understand difficult terms, differentiate across terms, and learn about the type of medication used in the trial. They expected that by using the glossary, they would better understand the study. A suggestion they made was to include a statement early on in the IC that a glossary is provided, so that they would know it is available for their reference as they go through the document.
  
- ***Linguistic issues emerged in the description of medical procedures.*** In the IC we used as a model for the breast cancer template, which was an IC used in an ongoing breast cancer trial funded by the NCI, participants were given an idea of the amount of blood drawn through an analogy with spoonfuls. We used this as a model for the IC template, which specifically indicated that “Another blood sample will be taken (about 4 tablespoons) for biomarker tests...” Participants were very confused by this, some interpreting that a spoon would actually be placed against their cut arm to measure the amount of blood taken. They also felt it was an odd way of indicating blood volume because “spoons is when you eat.” Some of the recommendations made to deal with this issue included specifying the amount of blood taken in vials, cubic centimeters, milliliters, ounces, or some other measurement. One participant suggested to “just say you will take a blood sample.” We suggest dealing with this by using wording such as “Another blood sample will be taken (the equivalent in volume of about 4 tablespoons) for biomarker tests...”
  
- ***Participants made suggestions for minor changes in wording.*** We made note of these changes and incorporated their feedback in the creation of the model Spanish IC. For example, the Spanish translation for “atorvastatin at different dose levels,” which in the original Spanish translation read “*atorvastatin en dosis a distintos niveles,*” was changed to “*atorvastatin en dosis distintas.*” This change makes the wording more accessible to individuals with low literacy levels.

### **3.3 What is the role of technology in the consenting process?**

- ***Participants were asked about their preference between receiving the IC in print or electronically.*** Most of the participants preferred to receive a printed copy of the document. Some of the reasons reported included: (a) being able to take notes and move back and forth between pages, (b) being accustomed to reading printed medical documents, and (c) finding it more practical to have a physical copy they could see, touch, and take home. There were generational differences, however. Many younger participants, those who were companions to an older primary participant, such as sons and daughters accompanying their mother, preferred to receive an electronic version of the IC. Some of the reported reasons were: (a) being able to make letters bigger, (b) having the ability to more easily move through the pages, and (c) having the material accessible anytime. Among those who reported a preference for an electronic IC, a few stated that they would also like to receive a printed version for their records.
  
- ***Participants did not go on the internet by themselves.*** When asked if they used the Internet to look up information, a majority of participants who said they do not use the Internet went on to explain that they ask their children or grandchildren to look up information for them. Thus, this question would need to be asked from a collectivistic standpoint (“When obtaining information through the Internet, do you search the Internet by yourself or with the help of someone close to you?”) to yield valid data. The participants who reported having assistance to check the Internet still showed behavior congruent with Internet use, as they valued looking for information online, they reported initiating many of the searches (i.e., by asking their family member to help them look something up), and oftentimes looked at the screen with the person who was assisting them. This process of looking up information also shows the interdependence among family members in searching and evaluating available information.
  
- ***Participants accessed the Internet easily.*** Of the 30 participants, 28 reported accessing the Internet through a computer at home. Ten participants also reported having access to the Internet through a computer at work. In addition, 19 participants noted that they access the Internet using their cell phones. These trends are consistent with the recently

documented increase in Latinos' use of technology. Currently, their technology use closely matches, and in some cases is higher, than that of non-Latino Whites (Lopez, Gonzalez-Barrera, & Patten, 2013). Almost 90% of participants ( $n = 26$ ) in this study had used the Internet to search for health information.

### **3.4 What decision making process did participants anticipate undertaking to make a decision about participation in a clinical trial?**

- ***Participants reported that they liked the IC document because it was very informative and detailed about the procedures and their role as participants in a clinical trial, which would help them in their decision making process.*** All participants mentioned that the information contained in the IC was extremely valuable and would help them make an informed decision about participation. In particular, the diagram showing the Study Calendar was very helpful in showing them what their role would be if enrolled in a clinical trial.
- ***Participants shared the process they would follow while making a decision to participate in a clinical trial.*** Many reported that they would consult and/or discuss their thoughts about participation with different people, including family members, friends, previously diagnosed patients, patients who have already undergone the proposed treatment, their primary care provider, and the clinical trial doctor. Some participants specifically mentioned that they would like to obtain a second opinion from other physicians regarding the clinical trial and treatment options that would be available to them should they decide not to participate in the trial. They would also like to consult with the clinical trial staff or doctor about the costs, medical agent, and any preliminary findings they have about the trial.
- ***Participants reported that they would make the decision regarding participating in a clinical trial in consultation with family members.*** Many described an initial phase of information gathering, after which their partner and possibly children would weigh in with their opinions about participation, although the potential participant would make the

decision whether to participate or not. This consulting process was also perceived as providing important emotional support for the affected family member. Participants in dyads reported that they would continue to work together to evaluate the information provided after meeting with the health professional facilitating the consent process, and to this end they thought it would be helpful for each family member helping make the decision to have a separate copy of the IC form in English and Spanish.

- ***The Internet was reported as an important tool in making a decision.*** Participants who did not know how to search the Internet reported co-browsing behavior, such as asking their children or close family members with higher technical skill to search health-related information for them. This co-browsing behavior is consistent with previous findings in usability studies conducted by the NCI, and with national statistics showing that the younger generations have higher technology adoption rates than older cohorts. One of the main reported reasons for doing research on the Internet was to corroborate the information they received from the study staff and that was printed on the IC. For example, participants were specifically interested in learning more about the medication and its side effects. They also reported that they would search more information about clinical trials in general, cancer, and treatment options. Participants with pre-existing conditions stated that they would search information about potential interactions of the treatment with their conditions and medications.
  
- ***Having an IC available in both English and Spanish was perceived as facilitating decision making.*** In most cases, bilingual participants preferred to see the IC in English. Spanish monolingual participants, however, also welcomed having an English version because it would more readily allow their family members for whom English was a primary language to help them understand the information contained in the IC, as well as broker the receipt of additional information, such as through Internet searches. Thus, the availability of an English language IC ultimately was perceived as a facilitating factor that would allow monolingual Spanish speakers to navigate the medical decision making process more effectively.

### 3.5 What reported factors are expected to influence participants' involvement in clinical trials?

- *All participants identified facilitating conditions that may motivate them to participate in a clinical trial.* Most participants reported two main reasons they would participate in a clinical trial: (a) to help find a cure, treatment, or preventive treatment for cancer, and (b) to derive the potential health benefits that participation may bring to them. Other commonly reported facilitating conditions were having a cancer diagnosis, perceiving they were at high risk for developing cancer, having no other treatment options available, and having assistance with financial costs related to participation.
- *All participants felt it was important to include a disclaimer stating that the legal status of participants is not an exclusion criterion for participation in the study.* All participants stated that having this disclaimer may increase participation among undocumented Latinas/os. However, they all reported that undocumented participants would likely still be concerned about their ability to cover any costs related to treating side effects. Participants also shared that undocumented potential participants may fear being found out about their legal status and deported, particularly if the clinical trial is sponsored by a government agency. In those cases, potential participants may fear that the sponsoring agency will share their personal information with the Immigration and Customs Enforcement (ICE) office. Some participants suggested including this disclaimer about undocumented status at the beginning of the IC to ensure potential undocumented participants would see the information up front and put their worries aside while reviewing the rest of the document. This disclaimer would explicitly mention that the clinical trial sponsoring agency is not related to ICE. Participants also suggested it would be helpful to specify whether undocumented participants would qualify for financial assistance to pay for medical costs not otherwise covered during the trial.
- *Participants were asked about their preference for a clinical trial doctor in terms of gender, race/ethnicity, and language fluency.* Most of the participants reported having no preference for the gender or race/ethnicity of the clinical trial doctor, but they did have

a preference for a Spanish-speaking clinical trial doctor and/or staff. All participants agreed that compared to having medical staff of a preferred gender and race/ethnicity, having staff who spoke Spanish was more important to ensure that they could understand the information on the IC. Based on information provided in the formative study by AED, participants were also asked about their preference to have the clinical trial doctor introduce her/himself by saying a few words in Spanish. Some participants reported that they would like such a gesture because it may show that the doctor is making an effort to interact in their language. However, others stated that it would not make a difference in their decision to participate in the trial, and that they would be more attuned to the attitudes held by the doctor than the language she or he spoke.

- ***Participants shared their understanding of the benefits they may accrue by participating.*** Many participants understood that they may not experience a direct benefit from participating in a clinical trial, yet felt that helping future patients through participation in the trial was an important contribution to science. These participants felt it important to help find a cure and support the scientific advancement of prevention and treatment approaches.
  
- ***Participants identified barriers that may prevent them from participating in a clinical trial.*** The two most critical barriers reported related to the participants' concerns about side effects and costs involved in participating in a trial. Some participants reported that it would be helpful to have a financial counselor as a resource so that they could learn in advance the potential costs they would have to incur. However, other participants reported that knowing about this resource would not take away their worry; these participants felt that the sponsoring agency should cover all the costs associated with participation in a clinical trial. In cases where financial counseling and assistance would be available for those without health insurance, participants suggested adding a section in the IC indicating that resources would be available to help those without health insurance cope with any medical costs they would incur as a result of participating in the trial. Some participants reported that being healthy prior to entering a prevention trial would represent a barrier, given that they would be risking their good health. If they became

sick due to a side effect, they worried it would negatively affect their families. Additional barriers included not knowing in advance to which treatment group they would be assigned. Some participants said they would feel more at ease being in the placebo group than being assigned to a treatment in experimental stages. Participants who had been diagnosed with medical conditions expressed concern about taking more medication and the possible interactions between the medical agent in the study and medications they were already taking. Thus, it would be important for clinical trial staff to be familiar with any medical conditions that might be prevalent in the Latino population in their area (e.g., diabetes) and how medication for those conditions may interact with the study agent.

- ***Participants expressed concern about participating in a clinical trial that may present serious side effects and risks.*** Participants who reviewed the breast cancer IC, in particular, were overwhelmed by the number and type of potential risks (70 risks were presented, which were in the model IC for breast cancer provided by DCP, based on an actual trial). Thus, several women perceived that participation in the clinical trial involved more risks than benefits. For some participants, concerns about side effects were tempered by an altruistic attitude related to helping science and future cancer patients.
- ***Participants had differing attitudes regarding the possible risk of death and its impact on their decision to participate.*** For many participants, death was the most serious risk that would prevent them from participating. However, a few participants normalized the risk, indicating that death is a normal risk when taking any type of medication or undergoing medical treatment (e.g., surgery). These participants perceived that being in a clinical trial would not bring with it any unusual risks.
- ***Mistrust towards the health care system acted as a barrier to participation.*** A few participants who had previous negative experiences with the health care system were mistrustful and reported that their decision to participate in a clinical trial would be made very carefully. These participants reported that they would investigate the reputation of the hospital where the clinical trial was being conducted, as well as the background and

reputation of the principal investigator, prior to making a decision about their participation in a trial.

## IV. Conclusions and Recommendations

### 4.1 Conclusions

Through the 2 phases of data collection, we identified some strengths in the document and areas that required additional revision. We noted that the values of *familismo*, *personalismo*, and *respeto* were perceived to influence the consent process, in addition to participants' fear of cancer and side effects. As a result, several linguistic elements emerged that are relevant to the informed consent process.

- ***Participants expected to make decisions about participation in consultation with family members.*** Participants provided support for the findings in the AED report that suggested that family members would be involved in decision making. Both individual interviewees, as well as dyads, reported that their decision making process would engage family members in some way. To facilitate the family member's engagement, they suggested having IC forms available in English and Spanish. Moreover, some family members who accompanied the main participants expressed a preference for having a digital version of the form.
- ***Personalismo and respeto were evident in the IC form.*** By following a question and answer format, the IC modeled questioning behavior in potential participants. The importance placed on ensuring participants understand their role in the study, as well as the expectation that they will ask questions, was underscored by the inclusion of a table with visual icons informing participants of who they should call for what purpose. Thus, the IC has the potential to encourage readers to step outside their cultural comfort zone and ask questions.
- ***Side effects and costs of treatment were key elements in decision making.*** As we expected, participants focused especially on the side effects of treatment. The consideration of how side effects are presented in an IC, therefore, is critical. We found

that unless the side effects were presented in a table format, the possibility of death was clearly spelled out, and the likelihood of the various side effects was not stated in quantifiable ways (e.g., 1 in 66), participants did not understand the probability that they may experience those effects. In addition, given that the majority of participants did not have health insurance, they expressed concern about the possible financial outlays they would need to incur as a result of their participation in the trial.

- ***The template was perceived as effectively conveying much information that would help potential participants make a decision about participation in a CT.*** It is important to note that consenters in the AED study reported some doubt about how well their Spanish language participants understood the IC form. These consenters also perceived a great benefit in having a Spanish template available to them. It is clear from the present research that the template fills a critical need in the IC process by facilitating participants' understanding of the research, a key goal for the National Cancer Institute.
- ***Many participants relied on the Internet to obtain health information.*** The Web was cited as one potential source of information in making a decision about participation in a CT. We found that participants with higher technical skills used the Internet individually, whereas those whose level of technical skill was lower relied on tech savvy family members to help them browse for information on the Web. Almost all participants had access to the Internet either at home, at work, or through their cell phones.

## 4.2 Recommendations

- ***Further incorporate the participants' suggestions into the template.*** Participants provided much valuable information to enhance the effectiveness of the IC, especially with regard to the presentation of the concepts of randomization, placebo, and risk. In addition, some participants provided suggestions for how to write certain words in more informal, simpler language. Some of these suggestions were incorporated between data collection phases, but additional work is needed to incorporate these linguistic changes. Recommended edits and revisions include:

- Qualify difficult medical terms by indicating what they refer to, such as “Phase I of a Prevention Study of the Medication Atorvastatin in Women at Increased Risk for Developing Breast Cancer.” In some cases, the active agent may not be a medication, and another appropriate qualifier might help potential participants understand the meaning of that particular active agent.
- In addition, when the medication has a more common brand name, include that name in parentheses next to the study agent to help the reader understand this new term. For example, Atorvastatin is also known as Lipitor. In this case, the first time that the medication is introduced, we recommend writing “... Atorvastatin (Lipitor)...”
- Change “chemoprevention” to “prevention,” such that the title of the document would read: “Informed Consent to Participate in Breast Cancer Prevention Clinical Trials.”
- Change the literal translation of “Informed Consent” (“*Consentimiento Informado*”) to “Consent to Participate in a Study,” (i.e., “*Consentimiento para Participar en un Estudio*”).
- At the outset of the IC document, we included a description of “clinical trial,” and suggest that this practice continues, as due to linguistic factors, in Spanish “clinical trial” may be interpreted to mean a “medical exam.” The original wording given in this description is the following: “This is a clinical trial, a type of research study. Your study doctor will explain the clinical trial to you. Clinical trials include only people who choose to take part in the study. Please take your time to make your decision about volunteering. You may discuss your decision with your friends and family. You can also discuss this study with your primary care provider’s health care team. If you have any questions, you can ask your study doctor to provide you with a more detailed explanation. You should agree to participate in this study only when you feel you have sufficient information to make an informed decision.” Given the questions that participants asked about the goals of the clinical trial, which came to light when discussing the concepts of randomization and placebo, we suggest having a more complete description of clinical trials, including their goals, to help participants anticipate and understand

the need to compare treatments in the remainder of the document. Thus, we recommend using this wording, which incorporates one sentence from the cancer.gov website that presents the purpose of clinical trials: “This is a clinical trial, a type of research study. Clinical trials are medical research studies that involve people and test new ways to prevent, detect, diagnose, or treat cancer and other diseases. Your study doctor will explain the clinical trial to you. Clinical trials include only people who choose to take part in the study. Please take your time to make your decision about volunteering. You may discuss your decision with your friends and family. You can also discuss this study with your health care team. If you have any questions, you can ask your study doctor to provide you with a more detailed explanation. You should agree to participate in this study only when you feel you have sufficient information to make an informed decision.”

- Include a separate section with visual aids to help potential participants understand who they should call for various purposes (e.g., to ask questions about the study, to ask questions about their rights as participants in the study, to ask questions about side effects, or to report side effects). It may be especially useful to include in the IC the times when a Spanish speaker is available to answer the phones. Otherwise, Spanish monolingual participants would need to call when they themselves have secured an interpreter for the conversation, causing potential delays. This could be especially problematic in cases where participants are reporting serious side effects.
- When describing randomization, use the words “*al azar*” rather than “*aleatoria*.”
- When describing the concept of placebo, indicate that it is, broadly speaking, the type of study agent without the active ingredient for that type of agent, such as “it is a pill without medication.”
- If possible, show a diagram or picture to represent the probability of having a side effect or risk.
- When discussing the risk of death, include a separate sentence describing the probability of this risk.
- If using a “pill calendar,” make clear the nature and purpose of the item.

- Avoid using “*cucharadas*” (spoonfuls) as the measure of blood to be taken. Instead, indicate that the amount of blood taken will represent the equivalent of a given number of *cucharadas*.
  - When presenting information about different dosages, state “<medical agent> *en dosis distintas*,” rather than “<medical agent> *en dosis a distintos niveles*,” as written in the original translation.
  - Other specific edits for readability are included in Appendix R.
- ***Include a bilingual glossary at the end of the IC.*** In addition, participants suggested adding a statement early on in the IC informing readers that this glossary is available. Given the need to report side effects in a timely manner, and the possibility of having difficulty identifying a bilingual staff member when a participant calls to make such a report, we also suggest including a section after the Glossary that provides bilingual translation for each of the named side effects and risks on the IC.
- ***Potential Latino participants should be invited to bring a family member to review the IC with them.*** These family members should also receive a copy of the form in their primary language, as they are likely to serve as a support not only emotionally, but also in terms of providing information that can help the potential participant understand their role and risks in the trial.
- ***Consider having an electronic version of the IC available.*** Although the majority of potential participants preferred a printed version of the IC, many companions in the dyads thought that having an electronic version might be helpful. It may not be too long before the younger generation comes to expect that the information will be available in electronic format.
- ***Include a disclaimer stating that the legal status of participants is not an exclusion criterion for participation in the study.*** Potential participants who are undocumented may be more willing to participate in the study if they know this will not negatively affect their legal status. The disclaimer should be placed early on in the IC.

- ***Include information about potential financial assistance and resources to cover out of pocket medical expenses.*** Potential participants who are low income and/or do not have health insurance may perceive potential financial outlays as a barrier to participation. Having specific information to allay any fears of these potential participants may be helpful in increasing participation in the study.

## V. References

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