ATTACHMENT 22B

ENGLISH VERSION

OMB NO. 0925-0046-22
Exp.Date: 2/28/2013

Interview Guide

IDIs for Spanish-Language Informed Consent Template for Chemoprevention Trials
2012

ALL INTERVIEWS WILL BE CONDUCTED IN SPANISH

Interviewer Identification

Name of interviewer_____

Date of interview_____

Interview start time _____ Interview end time _____

Interviewee Identification

Name of interviewee_____

Introduction (5 minutes)

Hi, this is _____ and I am conducting this interview on behalf of the National Cancer Institute. The National Cancer Institute is the US Federal Government's principal agency for cancer research and training. Today we have a representative from the National Cancer Institute, [Insert First Name of Individual], that will be taking notes to make sure we include all of your comments with as much detail as possible.

The purpose of this project is to improve the National Cancer Institute's Spanish-language informed consent form template. The informed consent form is the document is commonly read and signed before people agree to participate in a clinical trial. In this case the clinical trial is about cancer prevention through the use of medications, supplements, vitamins, and foods. It is also know as "chemoprevention". In the English language, the document is called "informed consent form."

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This interview should take us about 60 minutes. Your feedback will be kept secure to the extent provided by law. The findings will be reported to the National Cancer Institute in a summary form and no names or other identifying information will be used.

With your permission, we would like to audiotape today's interview. The recording will be used only to help the National Cancer Institute to write their report of findings. Please let me know if I have your permission to record this interview on this audio device recorder. If so, I will turn on the recorder now.
[If participant agrees – and has signed a consent form – proceed with taping the interview. If participant is uncomfortable or unsure, proceed without taping.]

As mentioned on the consent form you signed prior to our interview, you can stop the interview at any time or chose not to answer any particular question without penalty. There may be questions that I will ask that you may not be able to answer. That is expected and OK. Please just let me know if you do not know the answer to a question and we will move on to the next question. Because we have a limited amount of time there will also be points in the interview where I may move the discussion to another question. If there is time in the end, we can always revisit a topic.

A representative from the National Cancer Institute will be observing this interview in person to let me know if I have covered everything I need to ask during the interview or if they have any follow up questions they would like me to ask you to learn more about your opinions, thoughts and perspectives on the topics we are discussing today. To protect your privacy, I will not use your name. If you prefer for the representative(s) from the National Cancer Institute to **not** observe, please let me know.

Do you have any questions for me before we get started?

I. Warm-up /Background (10 minutes)

First, I would like to hear a little bit about you and your experiences or knowledge about health topics and clinical trials.

1. Can you briefly explain a little bit about how you look for health information?
    - **Probe:** Where is the first place you look for health information? The internet, radio, newspaper, healthcare professional, friend, or family member?
2. Can you briefly describe what you know about clinical trials?
    - **Probe:** What is a clinical trial?
3. Have you ever participated in a clinical trial? Has one of your friends or family members ever participated in a clinical trial?

- **Probe:** Can you share any details about when you, your friend, or family member participated in a clinical trial?

II. Reactions to Informed Consent Template (40 minutes)

As I previously mentioned, the purpose of this project is to understand the opinions and viewpoints of the Spanish-speaking community on this informed consent document. People commonly read and sign these types of documents to give their permission before participating in a clinical trial. In this case, the clinical trial is about a preventing cancer through the use of medications, supplements, vitamins, and foods. It is also called chemoprevention.

For the rest of our time, let's go over some aspects of the template together. As you may have noticed, the template provides some sample text of wording to be used when writing these types of documents.

1. What was your first reaction to the template?
    - **Probes:** Was there anything you particularly liked about it? Was there anything you particular disliked about it?
2. Do you think the template would be helpful to someone like you? To you personally? How so? If no, why not?
3. Overall, what is your impression of the quality of the Spanish-translation of the template?
4. In the template, the Informed Consent Form is referred to as "consentimiento informado". What are your thoughts about this way of referring to the Informed Consent Form in Spanish?
    - **Probes:** In your opinion, how should we refer to the informed consent form in Spanish? Are there any other words you would recommend?
5. There were different sections on the template that discussed the concepts of randomization, placebo and risk. What are your thoughts about the way in which these concepts were explained in the sample text included on the template?
    - **Randomization:**
        - Can you share what randomization means? *[Allow participant enough time to describe and explain]*
        - Do you think concept is clearly explained?
        - If not, how would you explain it differently?

- **Placebo:**
  - Can you share what placebo means? *[Allow participant enough time to describe and explain]*
  - Do you think this concept is clearly explained?
  - If not, how would you explain it differently?

- **Risk:**
  - Can you share what risk means? *[Allow participant enough time to describe and explain]*
  - Do you think this concept is clearly explained?
  - If not, how would you explain it differently?

6. What other suggestions do you have for how this template could be improved to better assist the process of informed consent with Spanish-speakers?

III. Closing (10 minutes)

1. Do you have any other comments that you would like to share about the informed consent template?

Thank you for your time today. The information you provided will be very helpful to the National Cancer Institute as they move forward to better support and facilitate the work of individuals and organizations that work with Spanish-speaking populations in clinical trials, particularly as it related to the informed consent process.