Informed Consent

A Colorectal Cancer Educational Intervention in the Latino Community Assessing the Feasibility of Recruitment & Retention Via a Church-Based Approach: Identification of Novel Barriers to Cancer Clinical Trial Enrollment

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University of North Carolina at Chapel Hill
Research Information Sheet
Adult Participants

IRB Study # 22-2980
Title of Study: A Colorectal Cancer Educational Intervention in the Latino Community Assessing the Feasibility of Recruitment & Retention via a Church-Based Approach: Identification of Novel Barriers to Cancer Clinical Trial Enrollment.
Principal Investigator: Dr. José G. Guillem

Purpose of Study:

The purpose of this study is to identify Latino perceived barriers to cancer clinical trial participation and to show that engagement with the Latino communities through the church setting is an option for the recruitment of Latinos.

Eligibility Criteria:

You are being asked to be in the study because you are a Hispanic, Spanish speaking individual 18 years or older. Approximately 60 people will take part in this study.

Being in a research study is completely voluntary. You can choose not to be in this research study. You can also say yes now and change your mind later.

Study Requirements:

Participation in the study includes:

(1) Attending an educational event on a weekday evening. During this event, you will be asked to complete a questionnaire in Spanish assessing your knowledge on colorectal cancer, watch three Spanish educational videos on colorectal cancer, and then complete a questionnaire after watching the videos.
(2) Approximately 30 days later, the study team will contact you to invite you back to St. Thomas More Church in order to complete another questionnaire.
(3) The study team may ask if you want to participate in a one-on-one interview that will help the investigators understand the reasons Latinos may not participate in cancer clinical trials. Participation in this part, if contacted, is not a requirement, but is encouraged.

You can choose not to answer any question you do not wish to answer. You can also choose to stop taking the survey at any time.

Study Risks:

The primary risk associated with this study is a breach of confidentiality. In an effort to preserve confidentiality, the study team has taken precautions to protect the data collected for this research.

Certificate of Confidentiality:

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of some communicable diseases and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Assuring Privacy:

Your personal information will be stored in encrypted, password-protected files and only the study team will have access to them. After you agree to participate, you will be assigned a unique number used for the study.

Audio Recording:

If you are selected for the one-on-one interview and choose to participate, the conversations audio will be recorded. These recordings will be stored until they are transcribed, and then destroyed.

Check the line that best matches your choice:

_____ OK to record me during the interview

_____ Not OK to record me during the interview

Further Communication:

The study team would like to contact you by email or text messages about reminders or notifications about study visits. These messages may be sent or received by the study team's personal electronic devices. There is the risk your information could be shared beyond you and the study team.

If you wish to stop email or text messages, please notify the study team using the study contact information on the first page of this consent form.

_____ Yes, I agree to receiving messages by the study team:

Email:_____

Cell Phone:_____

_____ No, I do not want to receive messages from the study team.

Compensation:

You will receive physical gift cards as a form of compensation for your time. If you complete the first two parts of the study (the educational event questionnaire and the 30-day follow-up questionnaire), you will be given one hundred dollars ($100) and a study T-Shirt. If you complete all three components of the study (educational event questionnaire, 30-day follow-up questionnaire and the one-on-one interview), you will receive an additional fifty dollars ($50) at the completion of the study.

To be eligible to receive this compensation, you will need to fill out a W9 form as is required by UNC policy for any applicable tax withholding obligations.

In order to process payments, the University may share certain identifiable information about you, such as name, contact information, and Social Security Number with third parties that the University retains to process payments on its behalf. If you do not want to agree with sharing

your information with these third parties, then you will be unable to receive compensation for participating in the study. You may still participate in the study without receiving compensation.

Further Information:

If you have any questions about this research, please contact the Investigator named at the top of this form by calling 919-966-8436 or emailing jose_guillem@med.unc.edu. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

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Printed Name of Research Participant

_____

Date of Consent