IRB USE ONLY
Study Number: 2016-07-0090
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Name of Funding Agency: National Institutes of Health

Assent for Participation in Research

Title: Determinants of HPV vaccination for Hispanic parents from the Texas-Mexico border

Introduction

You have been asked to be in a research study about improving HPV vaccination for adolescent girls living in Hidalgo County. This study was explained to your mother/father/ caregivers and she/he/they said that you could be in it if you want to. We are doing this study to learn how a health education program given to mothers/fathers/caregivers in a clinic effects HPV vaccine initiation and completion rates for adolescent girls in Hidalgo County. Your doctor or nurse will not be part of the research study other than allowing their exam room conversations to be audio recorded. Your doctor or nurse will not know which of their exam room conversations are being audio recorded and will not know that you are participating in the study. To protect your privacy, it is important that you do not tell your doctor or nurse that you are participating in the study.

Who is conducting this study?

The Principal Investigator (PI) is the researcher directing this study; the PI is responsible for protecting your rights, safety and welfare as a participant in the research. The PI for this study is Daisy Y. Morales-Campos, Ph.D., Research Assistant Professor, Department of Mexican American and Latina/o Studies, at the University of Texas at Austin.

The Study Sponsor is National Cancer Institute through the federal grant, Determinants of HPV vaccination for Hispanic parents from the Texas-Mexico border. The National Cancer Institute, a federal agency that promotes scientific research, is funding this study (the sponsor). This organization is providing money to the University of Texas at Austin for the researchers to conduct the study.

What am I going to be asked to do?

If you agree to be in this study, you will be asked to:

- Allow research staff to look at your vaccination record and write the dates when you received certain childhood vaccines (e.g., HPV; meningococcal; tetanus, diphtheria, and pertussis; and flu).
- Allow research staff to audio-record yours and your mother's/father's/caregiver's visit with your doctor or nurse.
- Complete a short exit interview about your visit with your doctor or nurse. This interview will be audio-recorded.
- If your mother's/father's/caregiver's phone number becomes disconnected a community health worker (CHW) may make a visit to your home to get an updated phone number.
- You will be involved in this study for about 12 months.

- You do not have to receive any vaccinations in order to participate in this study.
- If you participate in the study, only use first names when talking with the doctor or nurse. This is to protect your privacy.

What are the risks involved in this study?

The risks encountered in this study are no greater than those experienced in everyday life. We do not believe that there are any emotional or physical risks involved with participating in this study. The main risk associated with participating in feasibility study is a slight risk that a breach of your private information could occur, despite the steps that the PI and research staff will take to protect participants' privacy. Researchers will give you a unique identification number to protect your privacy, including information from your vaccination record. Research staff will remove names and identifying information from all writings of the audio-recordings.

By participating in the study, you may feel pressured to receive a vaccination. You may also feel like your relationship with the clinic has changed due to your participation. However, you do not have to receive a vaccination in order to participate in the study and your participation does not affect your relationship with your doctor or nurse or the clinic.

Do I have to participate?

No, participation is voluntary. You should only be in the study if you want to. You can even decide you want to be in the study now, and change your mind later. No one will be upset.

If you chose not to participate, you will still receive regular clinic services provided by your doctor or nurse. You will still have your medical records checked to make sure you are up to date on your vaccines and will receive recommendations for those vaccines your doctor or nurse believes you need.

If you would like to participate, sign this document and give it to a member of our research team. You will receive a copy of this form so if you want to you can look at it later.

Will I get anything to participate?

You will not receive any reward.

Who will know about my participation in this research study?

The following steps will minimize your loss of private information:

- research staff collecting data will be trained and certified in human subjects research and ethics;
- research staff will assign you a unique identification number and will use it on written materials;
- research staff will securely store electronic records (databases) and audio recordings on a password-protected folder and backed up on a secured UT server with restricted (password-protected) access for only PI, Co-PI, and project coordinator;
- Research staff will send recordings to a professional to write out word per word what was audio-recorded. While the entire exam room visit will be

audio-recorded, the professional will only write out the portions of the recording that pertain to vaccinations.

- Research staff will instruct the professional to only write out first names, although the doctor or nurse may use the parent's/caregiver's and/or child's full name during the audio recording.
- Research staff will erase these recordings after professional writes out word per word what was audio-recorded and we check the writings for error within 12 months from the exam room visit recording.
- the PI will store paper records in a locked file cabinet in her office and the PI has the only key;
- the PI will separately store the master list that links your name to the identification numbers in a locked cabinet in her office; and
- the PI will separately store from de-identified/confidential data the consent/permission/assent documents.

If it becomes necessary for the Institutional Review Board to review the study records, information that can be linked to your child will be protected to the extent permitted by law. Your research records will not be released without your consent unless required by law or a court order. The data resulting from your participation may be made available to other researchers in the future for research purposes not detailed within this consent form. In these cases, the data will contain no identifying information that could associate it with you, or with your participation in any study. Any written materials will not use names or other information that identifies you unless we obtain your written permission.

Whom to contact with questions about the study?

If you have questions now, feel free to ask us. If you have additional questions, comments or complaints prior, during or after your participation or if you feel that you have been harmed contact:

Primary contact:
Jesus Moralez can be reached at **956-720-7750 or** by sending an email to **jesus.moralez@austin.utexas.edu.**

If primary contact is not available, contact
Dr. Daisy Y. Morales-Campos can be reached at **512-232-6891**or by sending an email to **moralescampos@austin.utexas.edu.**

This study has been reviewed and approved by the University Institutional Review Board and the study number is 2016-07-0090.

Whom to contact with questions concerning your rights as a research participant?
For questions about your rights or any dissatisfaction with any part of this study, you can contact, anonymously if you wish, the Institutional Review Board by phone at (512) 471-8871 or email at orsc@uts.cc.utexas.edu.

Signature

Writing your name on this page means that the page was read by or to you and that you agree to be in the study. If you have any questions before, after or during the

study, ask the person in charge. If you decide to quit the study, all you have to do is tell the person in charge. You will receive a copy of the assent form once signed.

_____	_____
Signature of Participant	Date