IRB USE ONLY
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Approval Date: 08/17/18
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Name of Funding Agency: National Institutes of Health

Consent for Participation in Research

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

Introduction

The purpose of this form is to provide you information that may affect your decision as to whether or not to participate in this research study. The person performing the research will answer any of your questions. Read the information below and ask any questions you might have before deciding whether or not to take part. If you decide to be involved in this study, this form will be used to record your consent.

Purpose of the Study

You have been asked to participate in a research study about improving HPV vaccine initiation and completion rates of adolescent girls living in Hidalgo County. The purpose of this study is determine how a health education program delivered by community health workers and providers to parents/caregivers in a clinic setting effects HPV vaccine initiation and completion rates of adolescent girls in Hidalgo county. Your child's provider will not be involved in the research study other than allowing his/her exam room conversations to be audio recorded. Your child's provider will not know which of his/her exam room conversations are being audio recorded and will not know that you and your child are participating in the study. To protect your privacy, it is important that you and your child do not tell your provider 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 the 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 will you be asked to do?

You are being asked to participate in this study because your child is a Hispanic, female, between 11 and 17 years old; is an established patient at Nuestra Clínica del Valle (NCDV); has never received the HPV vaccine; and lives with you full-time. In addition, you are being asked to participate in this study because you and your child are residents of Hidalgo County and intend to stay in the area throughout the study period.

If you decide to take part in this study, you will be asked to:

- Sign a consent form.
- Fill out a demographic, pre-survey, and medical release form to view your child's vaccination record to confirm their HPV vaccination status, which would take approximately 20-30 minutes to complete.

- Receive brief 5-10 minute one-on-one education session in a private room from a community health worker (CHW). The educational talk will focus on cervical cancer risk factors, how you get screened for cervical cancer, and how to prevent cervical cancer with the HPV vaccine.
- During your daughter's regular appointment with her provider, the provider will recommend vaccines that your daughter is eligible to receive. Your visit with your child's provider will be audio-recorded. You will be asked not to tell your provider that you are participating in this study because s/he will not know you and your daughter are in the study, and to protect yours and your daughter's privacy. ***It is your decision to get the HPV vaccine and return for the remaining doses (standard of care) for your daughter. Your child does not have to receive any vaccine in order to participate in this study.***
- After visiting with your provider, you will be asked to fill out a post survey and to complete a short exit interview with a research staff member about your visit. This interview will be audio-recorded. The post survey and exit interview will take approximately 20-30 minutes to complete.
- Six months after completing the exit interview, a CHW will call you to ask your daughters' HPV vaccine status (self-report), which will take 2-5 minutes. If your phone number becomes disconnected, a CHW will make a home visit to the address provided, in order, to obtain updated contact phone number and ask you about your daughters' HPV vaccine status (self-report).
- If you decide to get the vaccine for your daughter, the CHW will also make reminder calls for your daughters' remaining doses, which will take 2-5 minutes. If your phone number becomes disconnected, a CHW will make a home visit to the address provided, in order, to obtain updated contact phone number and give you a reminder that your daughter is due for her next HPV vaccine dose.
- CHW's will also invite you to a monthly group education session at the clinic for parents/caregivers who want more in-depth information, which last approximately 30-60 minutes depending on group size. These groups are optional to you.
- Your participation in the study will last for 12 months.

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 confidentiality could occur, despite the steps that the PI and research staff will take to protect participants' privacy. Researchers will give you and your child a unique identification number to protect yours and your child's privacy, including information from your child's vaccination record. Research staff will remove names and identifying information from all transcriptions of audio-recordings.

By participating in the study, you may feel pressured to give your child a vaccination. You may also feel like your relationship with the clinic has changed due to yours and your child's participation. However, your child does not have to receive a vaccination in order to participate in the study and yours and your child's participation does not affect your relationship with your provider or the clinic.

What are the possible benefits of this study?

You may not benefit directly from participating in the study, but will learn about cervical cancer prevention, HPV, and the HPV vaccine. You will receive the clinic-based program at no cost to you

Do you have to participate?

No, your participation is voluntary. You may decide not to participate at all or, if you start the study, you may withdraw at any time. Withdrawal or refusing to participate will not affect your relationship with The University of Texas at Austin (University) in anyway.

If you do not participate in study, your child will still receive regular clinic services provided at well-child or other medical visits. Your child will still have their medical records checked to make sure your child is up to date on required childhood vaccines and will receive recommendations for those vaccines the provider deems your child needs.

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 there be any compensation?

Your child will not receive compensation. You (parent/caregiver) will receive an incentive (participant's choice of HEB, Wal-Mart or Target gift card) for completing pre and post surveys ($15 at baseline) and reporting your child's vaccine status ($25 six-months after your exit interview with research staff) at the final six month assessment visit. For the final 6-month assessment, the CHW will schedule a face-to-face visit with you at my home or another location of your choosing. At this assessment, the CHW will ask you about your daughters' HPV vaccine status (self-report), deliver your incentive, and have you sign a receipt to document you received the incentive. If you choose a home visit and you are not home, the CHW will not provide any information to another person or leave the incentive/receipt at your home. You are not required to vaccinate your child in order to report your child's vaccine status and receive compensation. Research staff will pay you to provide verbal yes or no response if your child received the HPV vaccine. If your daughter received an HPV vaccine, research staff will ask you to provide the date that your child received it (if you remember).

How will your privacy and confidentiality be protected if you participate in this research study?

The following steps will minimize your loss of confidentiality:

- 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 HIPAA compliant professional transcription service (e.g., transcribeme.com). While the entire exam room visit will be audio-recorded, the transcription service will only transcribe the portions of the visit pertaining to vaccinations.
- Research staff will instruct the transcription service to only transcribe first names, although the provider may use the parent's/caregiver's and/or child's full name during the audio recording.
- Research staff will erase these recordings after transcription and error checking of transcripts 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.

Participation

If you agree to participate, sign this form and return it to research staff.

Signature

You have been informed about this study's purpose, procedures, possible benefits and risks, and you have received a copy of this form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask other questions at any time. You voluntarily agree to participate in this study. By signing this form, you are not waiving any of your legal rights. You will receive a copy of the consent form once signed.

☐ Yes, I am interested in having the CHW contact me about the OPTIONAL group education sessions.	☐ No, I am NOT interested in having the CHW contact me about the OPTIONAL group education sessions.
☐ Yes, I agree to the CHW visiting my home if my phone number becomes disconnected during the study. The CHW will make the home visit to obtain an updated phone number and remind you about your daughter upcoming vaccine doses (only if you choose to vaccinate your daughter). I understand if I am not home, the CHW will not provide any information to another person or leave any information at my home regarding mine or my daughter's participation in study.	☐ No, I DO NOT agree to the CHW visiting my home if my phone number becomes disconnected during the study.

Preferred Day _____and Time _____to visit.	
☐ Yes, I agree to the CHW making a face-to-face visit with me for my final 6-month assessment. At this assessment, the CHW will ask you about your daughters' HPV vaccine status (self-report), deliver your incentive, and have you sign an receipt to document you received the incentive. I understand my final assessment can be conducted at my home or another location of my choosing. I understand if I choose a home visit and I am not home, the CHW will not provide any information to another person or leave the incentive/receipt at my home. Preferred Location_____, Day _____and Time _____for final assessment visit. ***NOTE: "If the researcher (or CHW) should observe or otherwise learn of child or elder abuse while visiting the participant's home, confidentiality will be broken. The researcher will report the abuse to the appropriate authorities (Child Protective Services or the Texas Department of Family and Protective Services) as required by law."***	☐ No, I DO NOT agree to the CHW making a face-to-face visit with me for my final 6-month assessment. At this assessment, the CHW will ask you about your daughters' HPV vaccine status (self-report), deliver your incentive, and have you sign a receipt to document you received the incentive. I understand if I choose NOT to have a face-to-face visit, I will not receive my incentive because the CHW is unable to get a signed receipt from me.
☐ Yes, I give permission for the CHW to leave a message at the phone number listed as my contact number regarding my daughter's immunization reminders and/or updates on her immunization status.	☐ No, I DO NOT give permission for the CHW to leave a message at the phone number listed as my contact number regarding my daughter's immunization reminders and/or updates on her immunization status.
☐ Yes, I give permission for the CHW to send a text message to the phone number listed as my contact number regarding my daughter's immunization reminders and/or updates on her immunization status.	☐ No, I DO NOT give permission for the CHW to send a text message to the phone number listed as my contact number regarding my daughter's immunization reminders and/or updates on her immunization status.

_____
Printed Name

_____ _____
Signature Date

As a representative of this study, I have explained the purpose, procedures, benefits, and the risks involved in this research study.

_____

Print Name of Person obtaining consent

_____ _____

Signature of Person obtaining consent Date