IRB USE ONLY
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Parental Permission for Children/Adolescent 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 (as the parent of a prospective research study participant) information that may affect your decision as to whether or not to let your child participate in this research study. The person performing the research will describe the study to you and answer all your questions. Read the information below and ask any questions you might have before deciding whether or not to give your permission for your child to take part. If you decide to let your child be involved in this study, this form will be used to record your permission.

Purpose of the Study

If you agree, your child will be 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 is my child going to be asked to do?

If you allow your child to participate in this study, she will be asked to:

- Allow research staff to look at her vaccination record and write the dates when she received certain childhood vaccines (e.g., HPV; meningococcal; tetanus, diphtheria, and pertussis; and flu).
- Allow research staff to audio-record the visit with her provider.
- Complete an audio-recorded exit interview with research staff about her visit with her provider.
- Notify her that if your phone number becomes disconnected, a community health worker (CHW) may make a visit to your home to get an updated phone number.
- She will be involved in this study for about 12 months.
- Your child does not have to receive any vaccination in order to participate in this study.
- If you child participates in the study, only use first names when talking with the provider. This is to protect you and your child's privacy.

What are the risks involved in this study?

The risks encountered in this study are no greater than those your child may experience 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 or your child may not benefit directly from participating in the study, but you will learn about cervical cancer prevention, HPV, and the HPV vaccine. You and your child will receive the clinic-based program at no cost to you..

Does my child have to participate?

No, your child's participation in this study is voluntary. Your child may decline to participate or to withdraw from participation at any time. Withdrawal or refusing to participate will not affect their relationship with The University of Texas at Austin (University) in anyway. You can agree to allow your child to be in the study now and change your mind later without any penalty.

If your child does 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.

What if my child does not want to participate?

In addition to your permission, your child must agree to participate in the study. If your child does not want to participate they will not be included in the study and there will be no penalty. If your child initially agrees to be in the study they can change their mind later without any penalty.

Will there be any compensation?

Your child will not receive compensation.

How will your child's privacy and confidentiality be protected if s/he participates in this research study?

The following steps will minimize your child's loss of confidentiality:

- research staff collecting data will be trained and certified in human subjects research and ethics;
- research staff will assign your child 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 child's 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 child's research records will not be released without your consent unless required by law or a court order. The data resulting from your child's 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 your child, or with your child's participation in any study. Any written materials will not use names or other information that identifies participants unless we obtain participant's 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 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

You are making a decision about allowing your child to participate in this study. Your signature below indicates that you have read the information provided above and have decided to allow them to participate in the study. If you later decide that you wish to withdraw your permission for your child to participate in the study you may discontinue his or her participation at any time. You will be given a copy of this document. You will receive a copy of your child's assent form once signed.

_____
Printed Name of Child

_____ _____
Signature of Parent(s) or Legal Guardian Date

_____ _____
Signature of Investigator Date