Verbal Consent Form Template

A Randomized Controlled Trial of a Social Marketing Campaign to Increase HPV Vaccination among Mexican American Children

DIRECTIONS FOR INTERVIEWER/CONSENTING PROFESSIONAL:

"Good morning (afternoon)! My name is _(consenting professional)___ and I work in the Department of Psychiatry & Behavioral Sciences at Memorial Sloan Kettering Cancer Center in New York City. I am approaching you in regards to our clinical study, „**A Randomized Controlled Trial of a Social Marketing Campaign to Increase HPV Vaccination among Mexican American Children**". We would like to ask you to take part in this study because you were born in Mexico or U.S and self-describes as Mexican-American, Spanish is your primary language, are over the age of 18, are willing to accept phone text messages, and have a minimum of one child between the ages of 9 and 17 who has not received the HPV vaccine and you self-identify as the child"s main caregiver.

Would you have a few minutes to hear more about this study? Our conversation will take about 10 minutes.

A clinical research study is completely voluntary and includes only people who choose to take part. Please take your time to make your decision about taking part. If at any time you have questions, please feel free to ask me for further explanation.

During our discussion we will cover information about the research study. Once you understand the study, its risks, and its benefits, and we have discussed your questions, you will be asked if you want to take part.

Do you have any questions so far?

Would you like to hear about our Study?

- **NO- Thank the individual for their time.**
- **YES- Continue with next section.**

Today"s date is _____ **(MM/DD/YYYY)**. My name is _____ and I am verbally consenting you to participate in the study, "_____".

Can you please state your full name? _____

(Please ask them to spell)

STUDY INFORMATION

The Human Papilloma Virus (HPV) is a virus that has been found to cause cancer of the cervix, anus, penis, vulva, mouth and throat. Many of these cancers are seen more often in Latinos than in other groups. The HPV vaccine was developed to prevent most of the cancers often found with this virus. The HPV vaccine is a shot that is meant for children ages 9 – 17 years old. For children 14 and younger, two doses are given over a period of 6-12 months and for children 15-17, three doses are given over a period of six months Many Latino children have not had the vaccine even though it is covered by insurance and free under a government program for the uninsured. The purpose of this study is to see if a social marketing campaign about the HPV vaccine and whether the use of text messaging reminders for Mexican-American parents will make a difference in vaccine uptake rates of their children. A social marketing campaign is an approach used to develop activities aimed at changing or maintaining people"s behavior

for the benefit of individual and society as a whole. Our campaign aims to make people aware of the HPV vaccine and prompt parents to get their children vaccinated.

This campaign will be shown at the Ventanilla de Salud program of the Mexican Consulate. As part of the campaign, we will also look to see if vaccine rates differ for Mexican-American parents who receive text message reminders about the HPV vaccine compared to those who do not receive text messages.

There will be about 200 people taking part in this study at the Mexican Consulate.

This study has no potential conflicts of interest.

Before you begin the study:
We will ask you a few questions (e.g. if you are Mexican or Mexican American, if you speak Spanish, etc) to make sure you can be part of the study. Our study staff will provide you additional details about the study and the HPV vaccine. You can ask questions at any time and we will try to answer them. If you would like to be part of this study, you will be asked to verbally consent. Agreement to be a part of the study will be discussed with parents only . We will not ask your child whether he or she would like to participate in this study, because the HPV vaccine is shown to provide a direct benefit to your child‟s health.

During the study:
If you choose to take part in the study, you will be asked to give information about the youngest child that receives the HPV vaccine. If you chose to vaccinate more than one child, we will ask information about all your children. Please know that your child‟s doctor will provide the vaccine, not us. We can answer questions about the vaccine, but we will also ask that you contact your doctor for more information.

If you chose to take part in this study, we will have you complete two short 5-minute surveys once you agree to participate. One survey will ask about you and your child and the other will ask about the social marketing campaign. After that, you will be randomly assigned to one of the study groups, either the **text message group** or the **group that does not receive text messages**. The group to which you are assigned is decided entirely by chance. Neither you nor your doctor can decide which group you will be assigned to. A month later, we will call to ask you to complete another survey asking about the social marketing campaign again.

We will ask you to complete two or three follow-up surveys by phone to see if your child has received the required dose of the HPV vaccine. Each call will take approximately 5 minutes. Regardless of your study group, these calls will be made:

If your youngest eligible child is 14 years old or younger, you will be asked to complete 2 outcomes surveys, these calls will be made at:

- about 4 weeks after this meeting to see if your child has received the first dose of the vaccine
- 6 months or 12 months after receiving the first dose to see if your child received the last dose of the vaccine
- If the youngest eligible child has not received the dose required, additional calls will be made at 8 and 12 week for each required dose

If your youngest eligible child is 15 through 17 years old, you will be asked to complete 3 outcomes surveys, these calls will be made at:

- about 4 weeks after this meeting to see if your child has received the first dose of the vaccine

- 1 month or 2 months after receiving the first dose to see if your child received the second dose of the vaccine (depends on type of vaccine received)
- 6 months after receiving the first dose to see if your child received the last dose of the vaccine
- If the youngest eligible child has not received the dose required, additional calls will be made at 8 and 12 week intervals for each required dose.

Once you have enrolled into the study, we will give you two documents that will need to be returned to us:

- an HPV study vaccination card for you to fill out after each dose is received
- a postcard with vaccination information that you will give your provider to fill out at the time of the vaccination. He/she will send back the postcard after each vaccine appointment.

Each patient card will have a prepaid, stamped envelope that you will use to send it back. The provider post cards will also have a prepaid stamp.

For those in the text message group, before each vaccine shot, you will receive a text message reminder. You can also send a text message back to the study if you have questions. Participants not in the text message group can call the study team at any time with questions.

You can decide to stop at any time. Let the study staff know if you are thinking about stopping or decide to stop. There are no consequences for stopping.

The study doctor/ principal investigator may stop you from continuing in the study at any time if s/he believes it is in your best interest; if you do not follow the study rules; or if the study is stopped.

Do you have any questions about this study and our discussion so far?

Would you like to hear more so you can decide whether to take part?:

- **NO- Thank the individual for their time**.
- **YES- Continue with next section.**

We do not expect any risks with this study. If you choose to take part in this study, there is minimal risk that you may lose time at work or home and spend more time in the doctor"s office than usual, you may be asked sensitive or private questions which you normally do not discuss. You may skip any questions you do not with to answer, and/or you may feel uncomfortable or stressed answering questions on this topic. If you feel uncomfortable or stressed at any point, you will have the chance to stop. If you become upset because of taking part in this study, the study doctor will refer you to an appropriate mental health worker at the Ventanilla de Salud or in your community.

We believe you may benefit from taking part in this study because your participation will help your child receive all the doses of the HPV vaccine that could prevent your child from getting certain cancers related to HPV. You may also help provide important comments on ways to improve HPV vaccination rates in the Mexican-American population. This study will help researchers learn about how to approach Mexican Americans about HPV vaccination and can help Mexican Americans in the future.

Please remember the choice to take part in this study or not is yours and should be based on what I have explained to you. We will notify you in the future about new information or changes in the study that may affect your health or your willingness to continue in the study.

Do you have any questions about this study and our discussion so far?

There is no cost for taking part in this study. Health insurance covers the cost of the HPV vaccine. In addition, the Vaccine for Children program through the Centers for Disease Control and Prevention (CDC) offers the vaccine free of cost. If you want information on where to receive the vaccine free of cost, we can provide that to you. You may have a co-pay for each provider visit depending on your insurance.

We will give you a $10 gift card after completing this consent form and when you return your child‟s HPV study vaccination cards filled out. This will include a total of up to $40 for study participation, which includes $10 for study enrollment and $10 by mail when we receive confirmation of your child‟s completed HPV vaccination (for each of the 2 or 3 scheduled doses of the HPV vaccine).

It is the responsibility of the research staff at Memorial Hospital to make sure that your records are managed to protect your privacy. We cannot use any of your health information for research unless you tell us that we can. If information from this study is used in any reports or publications, your name and anything else that could identify you will not be used. Access to your medical information (e.g. entire research record and NYS requirement for disclosure of HIV-related information) will be limited to those individuals involved with this study, our Institutional Review Board/Privacy Board whom reviewed this new study to make sure that your rights and welfare are protected, staff of the hospital's clinical research teams, MSK‟s research collaborators, business partners, subcontractors and agent(s), in the United States or other countries, working with MSK to conduct the study, to monitor the study or to analyze the study information for this study or other research about the study intervention, our Data Safety Monitoring Board, and the Quality Assurance Committee. In addition and if necessary, the National Cancer Institute, National Institutes of Health, U.S. Food and Drug Administration, would have access. Your protected health information may also be used for your research treatment, to collect payment for care you receive while on the study (when applicable), and to run the business operations of the hospital. Some of the people or organizations I mentioned may not be subject to privacy laws. This means they could share your information again.

Please remember if you agree to take part in this study, it means you are giving us permission to share your protected health information. We can only share it with the people/organizations I just described. If you withdraw from the study at any time we cannot use or share anymore of your research data. If we have already used or shared your information, it cannot be taken back.

A description of this clinical trial may be available on http://www.ClinicalTrials.gov. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Do you have any questions about this study or your participation?

You can talk to your study doctor about any questions or concerns you have about this study. Contact the study doctor, Dr. Abraham Aragones at 646-888-8058 and/or your study contact Carolina Herrera at 646-888-0045.

For a non-physician whom you may call for more information about the consent process, research patients‟ rights, or research related injury is Jorge Capote, RN, Patient Representative, telephone number: (212) 639-8254.

Are you ready to decide whether or not to participate?

By verbally agreeing to take part in this study, you acknowledge that you understand and accept all of the information provided to you. Do you voluntarily agree to participate in this study? (Participants should state YES or NO) _____.

Will you accept getting text messages (about 1 per week for six months) to your phone as part of the study? If you agree, message and data rates may apply. There will be no purchase necessary to receive the messages. If you would like more information about the messages you can text **HELP**. If you would like to stop getting messages, you can always send a return message that says **STOP**.

- □ Yes
- □ No

AFTER INTERVIEW, STATE PARTICIPANT'S NAME, DATE, AND INTERVIEWER'S NAME ON THE FORM.

_____ _____
PARTICIPANT NAME DATE: MM/DD/YYYY

_____
SIGNATURE OF THE CONSENTING INDIVIDUAL

_____
NAME (PRINT) OF THE CONSENTING INDIVIDUAL