# Human Papillomavirus Mitigation and Cancer Prevention across the Lifespan in a Mexican-Origin Population

**Protocol Number:** 1441487

**National Clinical Trial (NCT) Identified Number:** NCT06098690

**Principal Investigator:** Eva M Moya, PhD, LMSW

**Sponsor:** The University of Texas at El Paso, Border Biomedical Research Center

**Grant Title:** Implementing Innovative and Strategic Approaches to Prevent and Mitigate the Deleterious Effects of HPV Across the Lifespan of Hispanics of Mexican Origin: Community Intervention

**Grant Number:** 2U54MD007592-26

**Funded by:** National Institutes on Minority Health and Health Disparities (NIMHD), a component of the National Institutes of Health (NIH)

**Version Number:** 1441487-21

2024-05-02

## (B) Ethical Considerations

| | | |
|---|---|---|
| **1** | Will this project be conducted anonymously?<br>**(In person studies and/or collection of IP addresses are not anonymous)** | ☐Yes ☒No |
| If YES, how will anonymity be preserved throughout the duration of the study? | | |
| **2** | Does the study protocol include children as research subjects? | ☐Yes ☒No |
| **3** | Does the study protocol include a protected group(s)? **(UTEP employees, UTEP students)** | ☒Yes ☐No |
| **4** | Does the study protocol include **prisoners**, **fetuses**, **pregnant women, human in vitro fertilization**, or persons with **impaired decision making**? | ☐Yes ☒No |
| **5** | Does the study **specifically** select economically/educationally disadvantaged individuals? | ☐Yes ☒No |
| **6** | Does the protocol involve more than minimal risk? | ☐Yes ☒No |
| **7** | Does the protocol involve deception? | ☐Yes ☒No |
| If YES, will the participant be informed at the time of **initial consent** that they will be **unaware** and/or **mislead** regarding the true nature and/or purpose of this study? | | ☐Yes ☐No |
| Clarify how the deception is **not likely** to be **embarrassing** or **offensive** to participants. Why it is not likely to result in **adverse** or **long-lasting** effects **(provide literature, as needed)**: | | |
| **8** | For research conducted **outside** of the **UTEP** campus, is the Principal Investigator (PI) and/or member(s) of the research team affiliated with the external site, institution, or organization? | ☒Yes ☐No |
| If YES, explain: Dr. Kristin Gosselink, C-PI is instrumental in overseeing Project Aim2 and she is affilitaed with UTEP. Former faculty with UTEP. | | |

## (C) Project Hypothesis, Objectives, or Goals

**Briefly** state the purpose of the study (research questions and/or study objectives).

**PHASE III - AIM 3.C**

Community Randomized Control Trial (RCT)

**Community RCT Culturally Tailored HPV Psychoeducational Multimedia Intervention**. During years four (2022-2023) and five (2023-2024), a sample of vaccine naïve (unvaccinated or under-vaccinated) adult community members ages 18 – 45 years old from the El Paso Region will be recruited to participate in a human papillomavirus (HPV) multi-media intervention.

**Hypothesis.** Young and middle-aged adults who view culturally tailored multimedia stories encouraging HPV vaccination will report stronger vaccine intentions and, subsequently, significantly higher vaccination completion rates when compared to young and middle-aged adults exposed to a standard HPV vaccination fact sheet and generic HPV vaccine videos.

**Goal.** The overall goal of the study is to increase in HPV, HPV vaccine, and HPV-associated cancer knowledge, attitudes, and practices (KAP).

## (D) Background

**Briefly** describe why the study is important to individual subjects or society at large in **laymen's terms** (non-scientific and non-technical language understood by someone with no scientific background). Do not describe experimental procedures in this section. Description should be limited to no more than two to three paragraphs. **Avoid technical jargon**.

Please see protocol package# 1441487-14

## (E) References/Literature Review

List 10, or less, references that are pertinent to the study.

Please see protocol package# 1441487-14

# (F) Research Method, Design, & Proposed Statistical Analysis

**Brief** overview of research methodology (e.g., experimental, correlational, qualitative) and specific study design and proposed analysis of the research data.

This project has three consecutive phases:

Phases completed:

Phase I includes **Aim 1** (n=600) and sections **A-B** of **Aim 3** (n=75)
Phase II includes section A of **Aim 2** (n=100)

Current Phase:

Phase III includes section **B of Aim 2** (n=150) and **C of Aim 3** (*n* = 100)**;** totaling *N* = 1025 participants over the project lifetime.

**PHASE III - AIM 3.C**
Community Randomized Control Trial (RCT)

**Methods**

**Trial Design.** A randomized control behavioral trial using a parallel group design will be used to examine the effectiveness of the culturally tailored HPV psycho-educational multimedia intervention from baseline to immediately post-intervention (day 0) and at 1 month post-intervention. Community members who are HPV vaccine naïve or under-vaccinated (given vaccine recommendations) will be randomly assigned to one of two conditions: 1) experimental condition in which they receive the tailored multimedia intervention, and 2) active control condition, in which they receive standard materials (standard CDC fact sheet videos).

1.) **Experimental Intervention.** Culturally tailored HPV psycho-educational multimedia intervention materials will be deployed using Research Electronic Data Capture (REDCap) web tool repository. Materials will use the same health messages for adults (e.g., increase HPV vaccine acceptability, uptake, screenings, access to care, and increasing health literacy); however, will vary in delivery format (i.e., multimedia scripts depending on gender preference) in a bilingual fashion (English and Spanish) among adults 18-45 years-old.

2.) **Active Control Intervention.** Standard CDC fact sheet videos will be deployed using Research Electronic Data Capture (REDCap) web tool repository. Materials selected will use similar topics discussed in the experimental group; however, will be provided in multimedia formats (e.g., digitized into a video and read-out-loud by artificial intelligence) in a bilingual fashion (English and Spanish) among adults 18-45 years-old.

**Expected Outcomes.**

- Increase in knowledge scores about HPV, the HPV vaccine, and HPV-associated cancers on the knowledge attitudes and practices (KAP) survey. Measured at baseline (pre-test/assessment), immediately post-intervention (0 months), and at 1-month post-intervention.
- Increased intention to self-vaccinate and complete the vaccine series among unvaccinated adults (ages 18 - 45 years old) on the KAP survey. Measured at baseline (pre-test/assessment), immediately post-intervention (0 months), and at 1-month post-intervention.

- Increased vaccine uptake and completion of the vaccine series among unvaccinated adults (ages 18 - 45 years old) on the KAP survey. Measured at baseline (pre-test/assessment), immediately post-intervention (0 months), and at 1-month post-intervention.

**Expected Outcomes and Interpretation.** Upon completion of the intervention, it is expected that community members who are HPV vaccine naïve (or under vaccinated) and allocated to the Experimental Group (i.e., culturally tailored HPV psycho-educational multimedia intervention) will report increased levels of vaccine intentions and subsequent vaccine uptake and dose series completion compared to those allocated to the Control Group.

**Randomization**

**Sequence Generation.** After determining eligibility, randomization of participants to treatment groups (experimental group vs. control group) will take place, while controlling for the potential bias introduced by factors of sex and age. To achieve this goal, we will utilize a randomization software (e.g., table within REDCap) to create balanced treatment groups based on these factors and reduce the effect of selection bias.

**Analytical Methods.** Approximately 100 adults (ages 18 – 45 years old) will be randomly assigned to one of two conditions:

Group 1 – the experimental condition, in which they receive the tailored multimedia intervention.
Group 2 – the active control condition, in which they receive standard materials (standard CDC fact sheet videos).

Power.

Group I: The proposed sample size of 50 (n=50) participants provides 80% statistical power to detect a small to moderate size difference in vaccine intentions between the intervention and control group (assuming a standardized mean difference of 0.40 in the population, a two-tailed significance test, and alpha equal to 0.05).

Group II: The proposed sample size of 50 (n=50) participants provides 80% statistical power to detect a small to moderate size difference in vaccine intentions between the intervention and control group participants (assuming a standardized mean difference of 0.40 in the population, a two-tailed significance test, and alpha equal to 0.05).

Analysis Plan. All statistical analyses will be conducted using R (V. 4.0.3) and will use two-tail alpha to reject null hypotheses at 0.05. Prior to conducting analyses, data will be screened to ensure that statistical assumptions are met and any transformations or adjustments to the model will be employed. We may employ multiple imputation procedures in order to handle missing data for nominal variables. Descriptive statistics will be reported for demographic variables including age in years, sex, and gender.

Primary Outcome. Chi-square analyses will be used to assess associations between variables reported on the pre-test (baseline), and post-test knowledge, attitudes, and practices (KAP) scales/surveys. T-test analysis will be used to examine differences between experimental group and control group; dependent on statistical assumptions, further t-tests may be conducted to examine differences between two age groups (18 - 26 years old and 27 - 45 years old), and sex for both groups. Multilevel modeling may be used to assess changes in proportions from baseline per participant overtime (time-points [0 and 1-month post-intervention]) reported on the post-test KAP survey questionnaires.

Intervention Effect. Multilevel modeling may be used to assess differences between group proportions reported from baseline overtime (time-points [0 and 1-month post-intervention]) on the knowledge, attitudes, and practices scales/surveys.

Intervention Impact. Finally, multilevel modeling may be used to assess differences between group proportions reported at 0 and 1-month post-test. cc

CONSORT Flow Diagram: Progress through the phases of this planned randomized trial (i.e., enrolment, intervention allocation, follow-up, and data analysis) will be visually represented using the Consolidated Standards of Reporting Trials (CONSORT) flow diagram shown below.

## (G) Sample

Identify the sources of potential participants, derived materials, or data.

Define the study sample (number of subjects to be enrolled, characteristics of subjects, inclusion, and exclusion criteria).

**PHASE III - AIM 3.C**

Community Randomized Control Trial (RCT)

**Participants**

**Sample Size.** A sample size of N=100 was a conservative estimate considering the Central Limit Theorem, planned approach to analysis, and anticipated attrition for this parallel (two) group design. Group I (experimental group) sample size will be n=50 (mixed gender participants between the ages of 18-45 years-old). Group II (active control) sample size will be n=50 (mixed gender participants between the ages of 18-45 years-old).

Power.

Group I (experimental group): The proposed sample size of 50 (n =50) participants provides 80% statistical power to detect a small to moderate size difference in vaccine intentions between the intervention and control group (assuming a standardized mean difference of 0.40 in the population, a two-tailed significance test, and alpha equal to 0.05) (40).

Group II (active control): The proposed sample size of 50 (n =50) participants provides 80% statistical power to detect a small to moderate size difference in vaccine intentions between the intervention and control group participants (assuming a standardized mean difference of 0.40 in the population, a two-tailed significance test, and alpha equal to 0.05) (40).

**Recruitment & Retention.** Recruitment is expected to take take place over 4 months (i.e., February 2024 – June 4 from IRB approval for participant recruitment). Participants will be active in the project for approximately 3 months – from time of recruitment to deployment of the pre-test, post-test, and at 1-month follow-up time-points.

Sampling Plan. Researchers will use a purposive sampling to recruit participants primarily in-person at dedicated venues and events, and via multimedia outlets (e.g., print, email, and video content on social platforms). Specifically, participants will be stratified given sex/gender (e.g., male, female, other) and age groups (e.g., ages 18-45 years) to ensure representation in both experimental and control group. The study sample will consist of

100 (n = 100) young to middle-aged adults from 18-45 years-old. The research team will complete such recruitment with flyer distribution and outreach initiatives. Recruitment will be initiated by the research team members in key locations in El Paso County and surrounding areas/colonias of San Elizario, Socorro, Montana Vista, Anthony (TX). Flyers will be mainly distributed around partnered health clinics, higher educational institutions, supermarkets, parks, and local community-based, private, and non-governmental organizations , and will include and not limited to electronic/social media outreach ( i.e., Facebook, Instagram, Messenger, WhatsApp). The partner agencies identified have a trajectory in working with the population of interest and have agreed to collaborate in the proposed project by facilitating the identification of potential participants as well as the inclusion of established letters of support (see attached letters of support [LoS] NIH Research Project Protocol – LoS).

Inclusion criteria: Adults between the ages 18 and 45 years old, who have not completed the HPV vaccine series (unvaccinated or under vaccinated), and currently living or working in El Paso, TX.

Exclusion criteria: Previously having participated in Phases I or II of the larger research project [cross-sectional phases], ages less than 18 years old or greater than the age of 45 years old, does not plan to be living or working in the El Paso region within the next 6-months following or is unable to participate in the full intervention and follow-up time-points, or unable to complete participation and activities in the English or Spanish language.

**Incentives:** Participants will be compensated for their time with an online (e-gift card) or physical gift card (if applicable) of $30.00 value after completion of the initial intervention and surveys (pre-test, intervention, and post-test survey questionnaire). Participants will receive an additional gift card of $10.00 value for participation in three follow-up survey sessions (post-test survey questionnaire). The total amount of compensation participants may receive is $40.00 if they participate in and complete all components of the research study.

Specifically define the procedures that will be used to recruit, screen, and follow study participants.

Potential participants will be invited to join the study by completing an electronic screening questionnaire provided through the REDCap platform. Participants will be deemed eligible and invited to join the study if they are adults between the ages of 18 and 45 years old, who have not completed the HPV vaccine series (unvaccinated or under vaccinated), and currently living or working in El Paso County, TX. Once consented, participants who agree to take part in the study, will be asked to: complete a 5 minute demographic questionnaire, a 15 minute survey (pre-test), followed by an 15 minute video activity (intervention), and concluding with a 15-minute survey (post-test). See further below for full description of each phase of the study (pre-test, intervention, post-test, and follow-up). The research team will follow-up with participants to complete a similar 15-minute post-assessment survey that will be emailed/electronically sent to them 1-month after their participation in the intervention.

The survey questionnaire will be provided through a secure REDCap link, set up with anonymity assurance enabled, which does not allow for the collection of IP addresses or participant location. The survey will be completed electronically using their own personally owned computer, tablet, or cell phone if study equipment/materials are not available or appropriate. They will be allowed to complete the surveys and the training component on their own time. Once an activity for any single day is initiated, it must be completed within a limited and defined amount of time on that day (i.e., 24 hours upon initiation). Once participants complete the first activity on the on the initial study day, and a follow-up survey will be given a month after the intervention session via a REDCap link. To assist with follow-up and survey completion, we will be integrating Mosio, a two-way text messaging platform that directly linkgs to REDCap that

the leading text messaging software for clinical research. Mosio improves subject enagement and adherence in research studies with automated text messages. Mosio is a secure platform that is hosted on HIPAA-compliant servers and follow HIPAA technical and administrative guidelines to ensure confidentiality in research.

Is there a possibility of coercion or undue influence? ☐Yes ☒No

If YES, describe whether some, or all, the participants are likely to be vulnerable to coercion or undue influence, and if so, what additional safeguards are included to protect their rights and welfare.

N/A

What is your rationale for using participants whose ability to give voluntary informed consent may be in question.
Participants include students in one's class, people currently undergoing treatment for an illness or problem that is the topic of the research study, people who are cognitively impaired, and vulnerable populations.

N/A

The following sections outline types of research activities. Please check the box(es) **ONLY** if **ALL** activities involving human subjects fall into one or more the applicable categories.

## Behavioral Study Activities

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|---|---|
| ☒ | Research conducted in established or commonly accepted educational settings, involving normal educational practices. **(EX1)**<br>This category may include research on effectiveness as well as comparisons about educational strategies, techniques, curricula**,** or classroom management. Educational tests, such as cognitive, diagnostic, aptitude, achievement tests<br><br>Notes: The research must **not** adversely impact students' opportunity to learn required educational content.<br>The research must **not** adversely impact the assessment of educators who provide instruction.<br>A study information sheet or abbreviated consent document should be used. |
| ☒ | Research that **ONLY** includes surveys, interviews, focus groups, or observation of public behavior with adults who can consent for themselves and covering **benign** topics. **(EX2) (LIM)**<br><br>Notes: The term "benign" describes activities that are brief, not expected to cause physical or emotional harm, persistent discomfort, be experienced by the subject as embarrassing, or be offensive, and not likely to have a lasting adverse impact.<br>Interventions are **not** allowed.<br>A study information sheet or abbreviated consent document should be used. |
| ☒ | Research involving **benign** behavioral interventions in conjunction with the collection of information from an **adult** subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection. **Benign** research on perception, cognition, motivation, communication, social behavior, behavioral games, or **minimal risk** performance tasks. (**EX3) (LIM)**<br><br>Notes: A study information sheet or abbreviated consent document should be used. |
| ☐ | Secondary research not requiring consent. Secondary research use of identifiable private information or identifiable biospecimen originally collected for other purposes. **(EX4)**<br>Notes: When the identifiable private information or biospecimens are publicly available.<br>The information is recorded by the investigator in such a way that the identity of subjects **cannot readily be ascertained**, and the investigator **does not** contact the subjects or try to re-identify subjects. |
| ☐ | Taste/Food quality evaluation and consumer acceptance. **(EX6)** |

General Notes: The above research may involve randomization between groups if disclosed to participants. The above research may be **audiotaped**, if the subject agrees, if identities are not shared, and the confidentiality of the information is properly protected.

Exempt category 5 is not listed as it applies to projects conducted or supported by, or subject to, the approval of Federal department and agency heads. Please contact the IRB office if you feel your project meets these criteria.

UTEP will not implement exemption categories 7 & 8 at this time.

## Biomedical Study Activities

| | |
|---|---|
| ☐ | Prospective collection by non-invasive procedures such as ultrasound, MRI without contrast, Doppler, MEG, EEGs, ECGs, eye tracking |
| ☐ | Moderate exercise, muscular strength testing, body composition assessment in healthy adults **(XP4)** |
| ☐ | Non-invasive collection of biospecimens **(XP3)** |
| ☐ | Non-invasive tests (body composition, BP, pulse) **(XP4)** |

| | Technology Type | If Yes, Answer the Required Questions | Examples |
|---|---|---|---|
| ☒Yes ☐No | Mobile technology | Who does mobile technology belong to?<br>☐ Sponsor provided device, not owned by UTEP.<br>☑ Study participant owned device.<br>☑ UTEP provided device.<br>Identify: Study will rely on participant owned devices (i.e., cell phone, computer, tablet, etc.), if participant does not own a personal device, participatn will be allowed to complete on study team electronic devices | iPhone, Android devices, iPods, tablets, or other wireless devices. |
| ☒Yes ☐No | Social Media | Provide Link(s):<br>www.facebook.com<br>www.instagram.com<br>www.whatsapp.com<br>www.mobile.twitters.com<br><br>Purpose: recruitment, promotion (advertisement) | Facebook, Twitter, or Instagram. Provide links to pages/profiles that will be utilized for research. |
| ☒Yes ☐No | Website survey, or similar tool | Name of website survey, or similar tool you are using:<br>QR Code Generator<br>REDCap (Research Electronic Data Capture) Software<br>MOSIO or Twillio | QuestionPro, Qualtrics, surveys on external websites |
| ☒Yes ☐No | Cloud based storage<br>A cloud computing model in which data is stored on remote servers accessed from the internet, or "cloud." | Identify:<br>Microsoft One drive: www.office.com | Google Drive, iCloud, Microsoft OneDrive, etc.<br>**See institutional policy for use of DropBox in research.** |
| ☐Yes ☒No | Wearable Technology | Name of the device: | Examples of wearable biosensors include accelerometers, activity trackers, wireless heart rate |

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|---|---|---|---|
| | | | monitors, pulse oximetry sensors, and glucose sensors. |
| ☒Yes ☐No | Phone, Video or Web Conferencing | Name of the conferencing system: Blackboard Collaborate<br>Webex<br>Zoom<br>Skype for Business<br>Microsoft Teams<br>Apple FaceTime<br>WhatsApp Video Conference<br>Jamboard (google for education)<br><br>The recording captures.<br>☑ Images ☑ Audio ☑ Video | Microsoft Teams, Zoom, Adobe Connect, Skype for Business, FaceTime, etc. |
| ☒Yes ☐No | Text/secure messaging | What type of messaging will be used:<br>☑ Text ☑ Email ☑ Other<br>Purpose: Messaging through reminder application, for purposes of study reminders and access to insentives | Outlook, text, etc. |
| ☒Yes ☐No | Mobile Applications | Name of the application: Reminder App or similar application that can be used to send messages to participants to remind them of vaccination schedule or provide general vaccine information (e.g., REDCap, MOSIO/Twillio). | Apps created by the PI, Apple health, Garmin connect, Fitbit, etc. |

## (H) Informed Consent

The formal consent of each subject must be obtained before that subject is subjected to any study procedure.

Describe how participants will be fully informed of this research prior to their participation and how their voluntary consent will be documented.

**Procedures for obtaining consent.**
Once the participant is deemed eligible and agrees to participate, the SIS will be provided before participation. No personal identifiers will be included; participant IDs will be randomly generated and assigned with information securely stored separately from gathered data. Data will also be securely stored and analyzed via REDcap and with the support of the UTEP Statistical Consulting Laboratory. Respondents will be randomly assigned to control and treatment groups prior to completing pre/post assessments and intervention activities. Participants will also be made aware that participation in voluntary and that they can opt out at any time. Recruitment and participation of subjects will be completed in accordance with UTEP's Institutional Review Board (IRB) Guidelines for human subject research (please see **study information sheet [SIS] for Aim 3.C**).

If you anticipate enrolling subjects whose primary language is not English, how will you obtain informed consent in the language of those participants.

For participants who are not fluent in English, we have prepared Spanish documents/files that mirror all English documents, to ensure that not only the intervention is bilingual, but also culturally tailored to our local community's needs.

Identify who will be involved in the consent process and where this will occur.

Recruitment and participation of subjects will be completed in accordance with UTEP's Institutional Review Board (IRB) Guidelines for human subject research and completed completely online by the participant via the REDCap platform (please see **Appendix E study information sheet [SIS] for Aim 3.C**).

If applying for a **waiver of documented consent**, specifically state this and provide justification.

**PHASE III - AIM 3.C**

Community Randomized Control Trial (RCT)

**Waiver of documented consent.** Participants will be provided an information sheet (SIS), a wavier/alteration of ICF for Aim 3.C activities as this study:

- The proposed research involves no more than minimal risk to the participants, as stated in the SIS and protocol
- The wavier/alteration will not adversely affect the rights and welfare of the participants as they will be provided all information of participating in the study minus complete detail of the intervention materials to be tested
- The Community Culturally Tailored HPV Psychoeducational Multimedia Intervention is solely educational in nature. This phase of the research (RCT) could not be carried out practicably without using participant information in an identifiable form to be randomly assigned (masked/unaware of group assignment) to an intervention or control group to test the effectiveness/differences of outcomes between the groups.
- Participants will be provided contact/study website information to obtain additional pertinent information/findings following their participation in the study

If the study involves **deception**, describe the procedures for re-consenting and debriefing the participants.

N/A

## (I) Detailed Study Procedures

Outline step-by-step what will happen to the human subjects in this study.

What will you ask your participants to do?

During the years 4 (2022-2023) & 5 (2023-2024) of the project, instruments for Phase III will be developed for the randomized control trial portions of the project. See below for specific details.

**PHASE III - AIM 3.C**

Community Randomized Control Trial (RCT)

**Intervention Materials.** Participants will be randomly assigned to one of two conditions:

**1)** Experimental condition in which they receive the Tailored Psycho-Educational Multimedia Intervention, and
**2)** Control condition in which they receive the General Educational Intervention.

An online platform will be developed to deploy the interventions (both the experimental and control conditions). The platform will include access to videos (using visual and audio) accessible by smartphone/tablet or computer/laptop. It

is expected that participants will take approximately 10 minutes to view all video content assigned depending on group allocation and gender preference.

Experimental group materials. The experimental [treatment] group will receive the Tailored Psycho-Educational Multimedia Intervention, to include three of four tailored videos depending on gender preference. Health messaging themes will include:

1) A plain language information on HPV and its relation to cancer
2) The HPV vaccine and eligibility; and
3) Ways to access and obtain the HPV vaccine in the El Paso County.

Control Group materials. The control group [active comparator] will receive the General Educational Intervention, which consists of general standardized untailored health messages via digitized Centers for Disease Control and Prevention (CDC) HPV for adults fact sheets.

**Intervention Measures.** All the survey questionnaire measures/instruments will be available both electronically and in hard copy to both control and experimental group in the participants language of preference (English & Spanish). See attached survey questionnaires for more details (screening, informed consent, pre-test, and post-test instruments).

Screening questionnaire. Questions will ask if they meet eligibility criteria: between the ages 18 and 45 years old, have not completed the HPV vaccine series (unvaccinated or under vaccinated), are currently living or working in El Paso County, plan to stay in the region for the next 6 months, and language preference (English or Spanish language).

Demographics. A demographic instrument will be used to obtain information such as age in years, biological sex, race/ethnicity, medical health insurance status, socioeconomic status, employment status, engagement in health services, and other related information.

Pre-test. Prior to delivery of the intervention materials participants will be asked to complete complete a 15-minute pre-assessment survey. A modified version of the Vaccine Attitudes, and Knowledge Scale (VAKS) will be developed, tested, and deployed to assess HPV knowledge, and HPV vaccine behaviors. All measures will be administered via technology mediums to community participants.

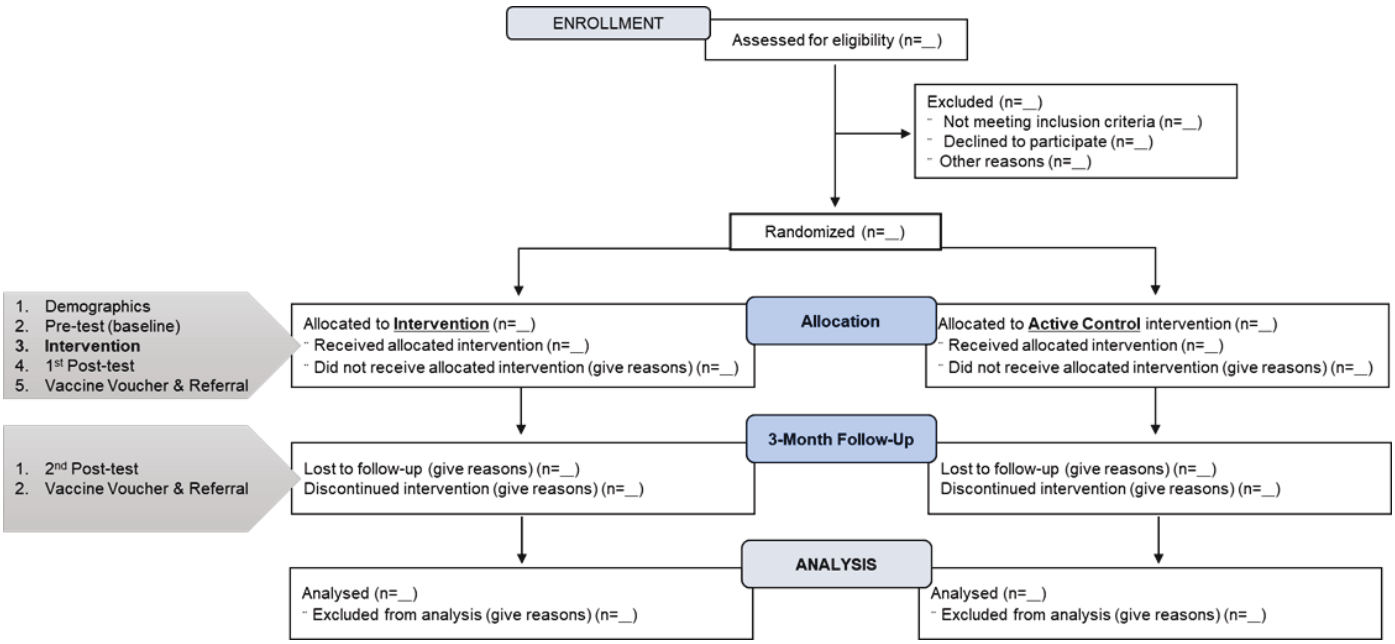
Post-test. Following delivery of the intervention and at 1-month post intervention, participants will be asked to complete a 15-minute post-assessment survey. A modified version of the pre-assessment will be administered to assess 1) knowledge scores about HPV and HPV vaccines, 2) intention to self-vaccinate and complete the vaccine series, and 3) vaccine uptake and completion of the vaccine series. All measures will be administered via technology mediums to community participants.

**AIM 3.C (RCT Culturally Tailored HPV Psychoeducational Multimedia Intervention).** If participants agree to enroll in the study, they will be asked to complete the following online activities: a survey questionnaire about background information and information related to HPV, view informational videos (the intervention) on HPV, and additional survey questionnaires about their experience during the research study. If participants choose to get vaccinated, they will be referred to one of our partner vaccine providers (i.e., Project Vida or Tiempo de Vacunarte) or provided healthcare

navigation. Participant's involvement will include a total of approximately 60-minutes over one month. All activities will be completed electronically using a mobile or electronic device (such as a smart-phone, laptop, desktop computer, or other device) and an internet connection. Activities will include:

First day of study activities (45-minutes): a demographic questionnaire, two survey questionnaires (pre and post-test), informational videos (intervention), and a text message or phone call at 2 weeks about experience and reminder for follow up at 1 month. To assist with follow-up, Mosio will be used as it is a helpful platform that directly links to REDCap to improve subject enagement and adherence clinical research studies thought the use of automated text messages.

- Follow-up activity after 1-months (of 15-minutes): one post-survey questionnaire.




When and where will they do it?

Recruitment will be initiated by the research team members in key locations in El Paso County, TX. Flyers will be mainly distributed around partnered health clinics, higher educational institutions supermarkets, parks, and local community-based, private, and non-governmental organizations, and will include and not limited to electronic/social media outreach ( i.e., Facebook, Instagram, Messenger, WhatsApp). The partner agencies identified have a trajectory in working with the population of interest and have agreed to collaborate in the proposed project by

facilitating the identification of potential participants as well as the inclusion of established letters of support (see attached letters of support [LoS] NIH Research Project Protocol – LoS).

Participants will complete the survey online using personally own computers, tablets, or cell phones (if study equipment/materials are not available/appropriate).

How long will it take them to do it?

Involvement will last about 45-mintues on the first day, with a one 15-minute follow-up session at 1-month after the initial study day. Total contact time is ~60-mintues to compete all research activities across a 1-month period (two contact points).

Describe the type of research information that you will be gathering from your subjects, i.e., the data that you will collect.

Anonymous, self-administered surveys, which will not contain any identifying information, will be collected from all participants in order to maintain confidentiality. All survey data reported will be in aggregate form only.

**Identify the measurement/instrumentation.** For surveys, focus groups, or interviews – clarify whether question items and measures are standardized, published, or designed specifically for this project.

**Demographic Survey Questionnaire.** Following randomization, participants will be administered a ~5 minute pre-assessment survey prior to participation in the educational portion of the intervention. The assessment will include information about the respondent's age in years, biological sex, race/ethnicity, medical health insurance status, socioeconomic status, employment status, engagement in health services, and other related information.

Pre-test. Prior to delivery of the intervention materials participants will be asked to complete a ~15-minute pre-assessment survey. A modified version of the Vaccine Attitudes, and Knowledge Scale (VAKS) will be developed, tested, and deployed to assess HPV knowledge, and HPV vaccine behaviors. All measures will be administered via technology mediums to community participants.

Intervention. Participants will be randomly assigned to one of two conditions: 1) experimental condition in which they receive the Tailored Psycho-Educational Multimedia Intervention, and 2) control condition in which they receive the General Educational Intervention. An online platform was developed to stream video or digitized materials for both the experimental and controlled conditions. It is expected that participants will take approximately 10 minutes to view all video content assigned depending on group allocation and gender preference.

Post-test. Following delivery of the intervention and at 1-month post intervention, participants will be asked to complete a ~15-minute post-assessment survey. A modified version of the pre-assessment will be administered to assess 1) knowledge scores about HPV and HPV vaccines, 2) intention to self-vaccinate and complete the vaccine series, and 3) vaccine uptake and completion of the vaccine series. All measures will be administered via technology mediums to community participants.

Will you be audio or video recording during any portion of this project? ☐ Yes ☒ No

If **yes**, this information must be described in all pertinent sections and the ICF(s).

Will subjects be **compensated** (payment, incentives, extra credit, etc.)? ☒ Yes ☐ No

If **yes**, details should be included here.

Incentives will be offered in the form of gift cards from local vendors at each stage:

1) Upon completion of the initial contact point (day that demographic survey, pre-test, intervention, and post-test is delivered), participants will receive a $30 gift cardll be provided.
2) At completion of second contact point, after completion of the follow-up assessment, the participant will be provided with a $10 gift card (to total $40 for completion of the entire study).

## (J) Privacy and Confidentiality

Describe how the project team will protect the privacy and confidentiality of study participants.

**Privacy** can be defined in terms of having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. **Confidentiality** pertains to the treatment of information or data that an individual has disclosed in a relationship of trust with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure. Ensuring privacy of participants is different from confidentiality of data.

Individuals participating in the study will be informed verbally by the person obtaining consent and/or in print/electronic writing through the consent form, that personal identifying information will not be documented in any materials that will be used to collect data (i.e. questionnaires). They will also be informed that consent forms containing initials and/or signature, will never be attached to the questionnaire; only those including de-identifiable information (e.g., participant number, electronic/verbal acknowledgement). Every effort will be made to keep participant information confidential and may only be disclosed if required by law. Organizations that may inspect and/or copy research records for quality assurance and data analysis include, but are not necessarily limited to:

- National Institutes of Health/National Institute of Minority Health and Health Disparities
- UTEP Institutional Review Board
- Burrell College of Osteopathic Medicine Institutional Review Board
- QuestionPro® survey software
- REDCap database and survey software
- DocuSign
- Microsoft Office 365
- Zoom
- Electronic Devices (personally owned or study equipment)

Because of the need to release information to these parties, absolute confidentiality cannot be guaranteed.

## (K) Data Handling, Record Keeping, and Data Analysis

Describe how the project team will collect, manage, and analyze data.

All data will be de-identified. No identifying data will be obtained. Hard copies of study records (informed consents and project surveys/questionnaires) will be kept in a secured and locked filing cabinet in the locked office of Dr. Eva Moya (College of Health Sciences School of Nursing office# 437) for up to 5-years after completion of the study. Only the research team will have access to the data. Electronic data will be password protected and stored on external drives or cloud-based storage (i.e., Microsoft OneDrive and Drobox) that only the research team will have access to. Project staff will be extensively trained in maintaining confidentiality of research data. Surveys will contain no identifying data. The signed and/or initialed consent forms will be stored separately from the moment of signing and/or initialing. UTEP will provide centralized and secure office space for research staff, and safe/secure storage of equipment, research supplies, and data. Electronic data will be kept on password-protected/encrypted desktop/laptop computers and external storage drives. All research team members who have access to the surveys for data entry or analysis will have participated in

UTEP and CITI responsible conduct of research/research ethics with human participants training, and will undergo rigorous additional training as part of their work. All data and consent forms will be archived in UTEP storage until they are destroyed based upon University guidelines.

Describe the type of research information that you will be gathering from your subjects, i.e., the data that you will collect.

Anonymous, self-administered surveys, which will not contain any identifying information, will be collected from all participants in order to maintain confidentiality. All survey data reported will be in aggregate form only.

Describe provisions that will be made to maintain **confidentiality** of the data. Will it contain subject names or images? (e.g., surveys, video, audio tapes, database).

Only the research team will have access to the data for analysis. The results of this research study may be presented at meetings or in publications; however, findings will be reported in aggregate form (i.e., no identifying information will be reported).

Describe the security plan for data, including **where** data will be stored, and **for how long**, noting that you may not keep identifiable data indefinitely (i.e., password protection, encrypted, locked filing cabinet, etc.)

All data will be de-identified. No identifying data will be obtained. Hard copies of study records (informed consents and project surveys/questionnaires) will be kept in a secured and locked filing cabinet in the locked office of Dr. Eva Moya (Colleges of Health Sciences and Nursing #429) for up to 5-years after completion of the study. Only the research team will have access to the data. Electronic data will be password protected and stored on external drives or cloud-based storage (i.e., Microsoft OneDrive and Drobox) that only the research team will have access to. Project staff will be extensively trained in maintaining confidentiality of research data. Surveys will contain no identifying data. The signed and/or initialed consent forms will be stored separately from the moment of signing and/or initialing. UTEP will provide centralized and secure office space for research staff, and safe/secure storage of equipment, research supplies, and data. Electronic data will be kept on password-protected/encrypted desktop/laptop computers and external storage drives. All research team members who have access to the surveys for data entry or analysis will have participated in UTEP and CITI responsible conduct of research/research ethics with human participants training, and will undergo rigorous additional training as part of their work. All data and consent forms will be archived in UTEP storage until they are destroyed based upon University guidelines.

**Identify the measurement/instrumentation.** For surveys, focus groups, or interviews – clarify whether question items and measures are standardized, published, or designed specifically for this project.

**Demographic Survey Questionnaire.** Following randomization, participants will be administered a ~5 minute pre-assessment survey prior to participation in the educational portion of the intervention. The assessment will include information about the respondent's age in years, biological sex, race/ethnicity, medical health insurance status, socioeconomic status, employment status, engagement in health services, and other related information. The questionnaire has been designed for this project.

Pre-test. Prior to delivery of the intervention materials participants will be asked to complete a ~15-minute pre-assessment survey. A modified version of the Vaccine Attitudes, and Knowledge Scale (VAKS) will be developed, tested, and deployed to assess HPV knowledge, and HPV vaccine behaviors. All measures will be administered via technology mediums to community participants. The questionnaire has been designed for this project.

Intervention. Participants will be randomly assigned to one of two conditions: 1) experimental condition in which they receive the Tailored Psycho-Educational Multimedia Intervention, and 2) control condition in which they receive the General Educational Intervention. An online platform was developed to stream video or digitized materials for both the

experimental and controlled conditions. It is expected that participants will take approximately 10 minutes to view all video content assigned depending on group allocation and gender preference. The interventions have been designed for this project.

Post-test. Following delivery of the intervention and at 1-month post intervention, participants will be asked to complete a ~15-minute post-assessment survey. A modified version of the pre-assessment will be administered to assess 1) knowledge scores about HPV and HPV vaccines, 2) intention to self-vaccinate and complete the vaccine series, and 3) vaccine uptake and completion of the vaccine series. All measures will be administered via technology mediums to community participants. The questionnaire has been designed for this project.

| Will you be audio or video recording during any portion of this project? | ☐ Yes ☒ No |
|---|---|
| If **yes**, this information must be described in all pertinent sections and the ICF(s). | |
| Will subjects be **compensated** (payment, incentives, extra credit, etc.)? | ☒ Yes ☐ No |

If **yes**, provide details here.

Incentives will be offered in the form of gift cards from local vendors at each stage:

3) Upon completion of the initial contact point (day that demographic survey, pre-test, intervention, and post-test is delivered), participants will receive a $30 gift card will be provided.
4) At completion of second contact point, after completion of the follow-up assessment, the participant will be provided with a $10 gift card (to total $40 for completion of the entire study).

| Will you maintain a subject list that has direct identifiers linked to a unique study ID/code? | ☐ Yes ☒ No |
|---|---|

If **yes**, how will you secure this linked subject list?

Click or tap here to enter text.

Will **UTEP study personnel** electronically transmit identifiable **data** or identifiable **samples** to a **non-UTEP recipient**?

| If **yes**, provide the type of data and plans to secure them. | ☐ Yes ☒ No |
|---|---|

Click or tap here to enter text.

What will happen to the **identifiable data** at the end of the study?

| | | |
|---|---|---|
| [redacted] | ☐ | Identifiers permanently removed and destroyed. |
| [redacted] | ☐ | Recordings transcribed without identifiers and destroyed. |
| [redacted] | ☐ | Identifiable or coded (that can be linked) data are retained. |

## (L) Risks

Most studies pose some degree of risk, even if the risk is minimal. A common risk is the loss of the confidentiality of participants' responses.

Describe **any** potential risks (physical, psychological, social, legal, or other) and assess their likelihood and seriousness

There are no known risks directly associated with participation in this study. This research study is considered "minimal risk", which is "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." (45 CFR 46.303(i)).

Describe the procedures for protecting against (or minimizing) any potential risks and include an assessment of their effectiveness.

Anonymous information, which will not contain any identifying information, will be collected from all participants in order to maintain confidentiality. All survey data reported will be in aggregate form only. The informed consent document will include a description of the purpose of the study, the anonymous nature of data collected, the reporting

of data only in aggregate form, and researcher contact information in the event they have additional questions about the study. Participants will be reminded that they have the right to end their participation in the study at any time by not completing the survey.

If the study involves a procedure that introduces a physical risk, specify arrangements for providing medical treatment if it should be needed.

N/A

If the study involves a procedure that introduces a psychological risk, such as the recall of a traumatic event, specify arrangements for providing psychological treatment if it should be needed.

N/A

Were there alternate and potentially less risky methods that were considered as possible methods; why were they not used?

The risks involved with participating in this study are no greater than people experience when voluntarily discussing potentially sensitive topics. Overall, we evaluate the risk to benefit ratio for this study to be very favorable. There are no known risks directly associated with participation in this study.

If the research methods impose risks on the subjects, include evidence that may justify their use (such as previous experience with the procedures).

N/A

Could the information obtained or recorded about subjects place them at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, insurability, or reputation? ☐ Yes ☒ No

## (M) Benefits

Describe and assess the **potential benefits** to be gained by participants (if any) and the benefits that may accrue to society in general because of the planned work. Discuss the risks in relation to the anticipated benefits to the participants and to society.

Potential benefits to participants include the opportunity to provide input that will help researchers develop HPV risk reduction programs tailored to the priority population. Results from this research will inform and enhance future interventions and enhance HPV prevention services and treatment within the El Paso community. There are no known risks associated with this research. However, sometimes when people talk about personal information such as HPV, they may feel uncomfortable or upset. This research study is considered "minimal risk", which is "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." (45 CFR 46.303(i)). **Importance of knowledge to be gained.** Knowledge generated by the study will help inform educational platforms, training for future health professionals, research among underserved populations, non-profit program curricula, and potential policy changes**.** Anticipated gains in knowledge resulting from this research study or as an extension of results from the proposed research will be described. In addition, the investigator will discuss why the anticipated risks associated with the proposed research are reasonable in light of the increase in knowledge that stands to be gained from or result from the proposed studies.

**Note:** Monetary compensation and extra credit **are not** a benefit.

## (N) Research Resources

Please describe your research resources.

Discuss the staff, space, equipment, and time necessary to conduct research and how these needs are met.

**Office space.** The PI and Co-Investigators have ample personal office space (approximately 125 sq. ft. each) including both office-type workspace and secure data storage space ranging from 200-400 additional sq. ft each.

**Hardware and Software.** All faculty and professional staff have access to standard laptop or desktop computer and through both wireless and hard-wired connections with access to Microsoft Windows 8, Microsoft Office, Banner/Goldmine, Adobe Acrobat Reader, BIS/Define, Avira Antivirus Professional and more. Office computers are connected to laser printers and scanners. A wide variety of software for research support (word processing, relational database, data analysis, power analysis) is available. Multiple university computer laboratories provide hardware and software support, and access to laptops, scanners, projectors, and other resources. Investigators and the Stat Lab also have, a variety of software the software available for use in the Statistical Consulting Laboratory include SAS v9.2, Splus v7.0 (Windows/Unix), Mathematica v5.0 (Windows), Minitab v14.0 and MatLab v7 (Windows/Unix). SPSS and EpiInfo are also available on an internal network free of charge to university personnel and students.

The PI and the Co-investigators have percent effort covered by the UTEP and/or grant funding that allows them to work on research projects because they are seen as a benefit to the UTEP.

| Please include a description of the proximity of any resources such as emergency facilities, emergency care or medical/psychological care, and any support services. |
|---|
| N/A |
| If the study necessitates Environmental Health & Safety (EHS) or Institutional Biosafety Committee (IBC) oversight and approval, please describe here. |
| N/A |

## ASSURANCES – Conflict of Interest and Fiscal Responsibility

All UTEP researchers (faculty, staff, and students) and outside collaborators who will be conducting human subjects' research (intervention and/or interaction) must complete human subject research ethics training to conduct research with human participants.

| | |
|---|---|
| Do you or any person responsible for the design, conduct, or reporting of this project have an economic interest in, or act as an officer or director of any outside entity whose financial interests may reasonably appear to be affected by this project? | ☐ Yes ☒ No |
| If **yes**, explain any potential conflict of interest. | |
| Click or tap here to enter text. | |
| Do you or any person responsible for this project have existing financial holdings or relationships with the sponsor of this study? | ☐ Yes ☒ No |
| If **yes**, explain any potential conflict of interest. | |
| N/A | |

## Principal Investigator Certifications:

With this submission I certify that:

| | |
|---|---|
| ☒ | I agree to fully comply with the ethical principles and regulation regarding the protection of human subjects in research. |
| ☒ | I agree that the information provided in this form and all other supporting documents are accurate and complete. |
| ☒ | I accept responsibility for making sure all study personnel involved in the project have been appropriately trained. PI affirms responsibility for keeping training records on file for all study personnel. |
| ☒ | I understand that any changes in procedure with affect to participants must be submitted to the IRB for written approval prior to their implementation. Furthermore, I understand that any adverse events and significant changes in risk for participants must be immediately reported in writing to the UTEP IRB. |

Copies of all required documentation of consent (if applicable) and any related to this research are securely stored as outlined above in the Health Sciences and School of Nursing (HSSN).

University of Texas at El Paso (UTEP) Institutional Review Board

**Study Information Sheet**

**Protocol Title**: HPV (Human Papillomavirus) Mitigation and Cancer Prevention across the Lifespan in a Mexican-Origin Population

**Principal Investigators**: Drs. Eva M. Moya, Kristin L. Gosselink, Margie M. Padilla, and Gabriel A. Frietze

**UTEP Border Biomedical Research Center**

**Sponsor**: National Institutes of Health/National Institute of Minority Health and Health Disparities (NIH/NIMHD) Grant #2U54MD007592

## Introduction

You are being asked to voluntarily take part in the Cuídate El Paso research project described below. Please take your time making a decision. Before agreeing to take part in this research study, it is important that you read and understand the description of the study and what to expect if you do agree to participate. If you do agree to be part of the study, you will be asked to sign this form electronically at the end, and you will receive a copy for personal use. If you need to speak with a study team member, contact us directly at cuidateep@utep.edu or by phone at (915) 747-6313 (or using the contact information listed under "**Who do I call if I have questions or problems?**" at the end of this form) to answer any questions you may have about the study.

## Why is this study being done?

You have been asked to take part in a behavioral research study in El Paso, TX about the human papillomavirus (HPV) and the HPV vaccine. The purpose of this study is to increase HPV vaccination access and vaccine completion among eligible adults in El Paso and the surrounding areas.

Approximately 100 vaccine-eligible adults will be recruited in El Paso using either a recruitment flyer, by email, direct outreach by project research team members, or by word of mouth.

You are being asked to participate in this study because you are between the ages of 18 and 45 years old, are currently living or working in El Paso, and you have not completed the HPV vaccine series.

## What is involved in the study?

If you agree to take part in this study, you will be asked to complete online activities that include: a survey questionnaire about your background information and information related to HPV, informational videos on HPV, and additional survey questionnaires about your experience during the research survey. If you choose to get vaccinated, we will refer you to one of our

partnered vaccine providers (e.g., Project Vida or Tiempo de Vacunarte) or we can additionally provide navigation to help you connect with an unaffiliated vaccine provider that you find most appropriate for your situation.

- First day of study activities (45 minutes): two survey questionnaires, informational videos, and a one-month follow-up text message about your experience
- First follow-up activity at one month (15 minutes): one survey questionnaire about your experience

If you agree to join this study, your involvement will include a total of approximately 60 minutes over one month. All activities will be completed electronically using a mobile or electronic device (such as a smart phone, laptop, desktop computer, or other device) and an internet connection. You can also contact a study team member directly at cuidateep@utep.edu or (915) 747-6313 for further assistance and to help identify accommodations that will work best for you. Please note that if you request an alternate form of the study materials (e.g., hard copy or voice/telephonic version), your participation in this study would then involve distanced and/or virtual research interactions with our research study team; privacy and confidentiality are not guaranteed due to the nature of the research environment in that case.

**Risks and Benefits**

There are minimal known negative outcomes (risks) with joining this study. This study does not include any greater risks than those involved in daily activities. However, sometimes when people talk about personal information relating to topics such as HPV, they may feel uncomfortable or upset. If this happens, please use the information listed under "**Who do I call if I have questions or problems?**", and we will connect you with a study team member trained in providing behavioral health and social services, who will then connect you with services that best fit your needs.

Potential positive outcomes (benefits) of joining this study include the opportunity to provide input that can help researchers have better understand what is known about HPV in our community. Findings and knowledge from this research can also improve HPV education, information tools, and related services in the El Paso, TX region.

**What other options are there?**

You have the right to not join or participate in this study. There are no drawbacks to declining or not wanting to join this study.

If you choose to take part, you have the right to skip any questions or stop at any time. If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them.

**Will I be paid to participate in this study? What are my costs?**

You will be compensated with an online gift card of $30.00 value after completion of the initial session for participating in this study (this includes the two-week follow-up text); you will receive an additional gift card of $10.00 value for participation after completion of the follow-up survey session. The total amount of compensation you may receive is $40.00 if you participate in and complete all activities of the research study.

This study only supports vaccine delivery by our partnered vaccine providers: Tiempo de Vacunarte and Project Vida. If you qualify and use one of our partnered vaccine providers, there will be no direct costs to you to participate in the research study. If you choose a different vaccine provider, there might be a cost associated with your participation (e.g., using personal insurance, doctor visit, co-pay, etc.) which this research study will not cover.

**What if I want to withdraw, or am asked to withdraw from this study?**

Joining or participating in this research study is voluntary. You have the right to choose not to take part in this study. If you do not take part in the study, there will be no penalties or drawbacks. If you choose to take part, you have the right to stop at any time. Also, a research team member may decide to stop your participation without your permission if they believe being in the study may cause you harm or if it is determined that you do not truly qualify for the study. If you withdraw or are asked to withdraw from this study, you will not receive the remaining compensation.

**What about confidentiality and my personal information?**

Your part in this study is confidential (only you and the study staff that recruited you [if applicable] will know of your participation). Your responses will be de-identified as your name is never included on any of the study documents or materials. All records and information will be maintained in a secure location. Electronic information will be password-protected and stored under the supervision of the lead research investigators. All members of the research team will consider your information confidential to the extent permitted by law. Your records may also be reviewed for audit purposes by authorized University or other agents who will be bound by the same laws of confidentiality. Because your name is not on any of the study documents, your information will remain de-identified. Every effort will be made to keep your information confidential; we will only provide personal information if required by law. Organizations that may inspect and/or copy your research records for quality assurance and data analysis include, but are not necessarily limited to:

- National Institutes of Health/National Institute of Minority Health and Health Disparities
- UTEP Institutional Review Board
- REDCap database and survey software
- DocuSign
- Microsoft Office 365
- Zoom

- Electronic devices (personally owned or study equipment)

Because of the need to release information to these parties, absolute confidentiality cannot be guaranteed. Also, the results of this research study may be presented at meetings or in publications up to five years after the study's completion; however, your identity will not be disclosed in those presentations or publications.

**Who do I call if I have questions or problems?**

You may ask any questions you have now. If you have questions later, you may contact Dr. Eva Moya (emmoya@utep.edu) or a study team member (cuidateep@utep.edu).

You may also contact the Human Subjects Protection Office to speak to someone outside of the research team if you have questions or concerns about your rights as a research participant. The UTEP Institutional Review Board (IRB) can be reached at (915) 747-6590 or irb.orsp@utep.edu.

**Authorization Statement**

I have read each page of this form about the study (or it was read to me). I understand that my participation in this study is voluntary, and I choose to be in this study. I am aware that I can stop being in this study at any time, without facing drawbacks or negative outcomes. I will get a copy of this consent form now and can get information on results of the study later if I wish (if completing online, please feel free to print a copy for your records).

___ Yes, I agree to participate in this research project by completing a survey questionnaire about my background information and information related to HPV, viewing informational videos on HPV, being referred to an appropriate vaccine provider, and completing additional survey questionnaires about my experience during the research study.

___ No, I do not agree to participate in this research study.