# Study Protocol

Title of Project: A Chatbot Intervention for Reducing HPV Vaccine Hesitancy
NCT #: NCT05959564
November 16, 2022

## INITIAL APPLICATION PART 2

### 1. Abstract:

The goal of this project is to test the efficacy of a chatbot intervention for reducing HPV vaccine hesitancy among African American parents. This project has two phases. In phase I, in-depth interviews will be conducted with African American parents to evaluate the feasibility and acceptability of the chatbot intervention. In phase II, an online experiment will be conducted to test the effectiveness of the chatbot intervention with African American parents. Results of this project will inform future communication interventions for reducing vaccine hesitancy among African American parents.

### 2. Subject Selection:

a. **Recruitment:** In phase I, we will recruit participants from local pediatric offices. We will recruit by distributing flyers in the offices. We will obtain permission from the practices to recruit at their offices. A copy of the flyer is attached to this application (we will submit an addendum if additional changes need to be made to the flyer before distribution). In phase II, participants will be recruited from online survey panels (e.g., Prolific, YouGov, Lucid, etc.). Eligible participants will be invited via email to participate in the study. There will also be screening questions at the beginning of the survey to screen participants to ensure they meet the eligible criteria.

b. **Eligibility Criteria:** Participants must be 18 years or older, self-identify as African American, are custodial parents or caretakers of a child under the age of 18.

c. **Rationale:** The burden of HPV-associated diseases (e.g., cervical cancer) is disproportionately higher among African Americans compared to other racial groups. Understanding effective methods of communicating to African American parents about the importance of HPV vaccination is therefore critical.

d. **Enrollment Numbers:** For phase I, we aim to recruit up to 30 participants. For phase II, we aim to recruit up to 600 participants.

e. **Rationale for Enrollment Numbers**: The enrollment numbers ensure we have adequate statistical power to detect small effects of the intervention.

### 3. Procedures:

For phase I, we will conduct in-depth interviews with up to 30 African American parents recruited from local pediatric offices. To facilitate participation, the interviews will be conducted online via Zoom. During the interviews, participants will be asked to interact with a chatbot designed to answer questions about HPV vaccines. Their opinions about the chatbot and suggestions for improvement will be solicited. Each interview session will last approximately 45 minutes. Only anonymized transcription (using Zoom's transcript function) of the interview will

be saved for later analysis. Interviews will not be audio- or video-taped. Each participant will receive a $50 store gift card. The cash incentive is needed to encourage participation in the study.

In phase II, participants will complete an online survey. In the survey, participants will first answer questions related to their attitudes toward childhood vaccines. Then they will be directed to interact with a chatbot designed to deliver personalized HPV vaccine messages (tailed to the participant's personality) or a similar chatbot with non-personalized messages. There will also be a control condition where participants receive no HPV vaccine messages. After interacting with the chatbot, participants will answer questions related to their attitudes toward HPV vaccination, intentions to vaccinate their children, as well as other message response measures. Those in the control will answer the same questions without interacting with a chatbot. The survey will take approximately 10 minutes to complete. Participants who complete the survey will be compensated with a small amount of cash paid through the online survey platform ($1-$2).

**4. Risks:**

There are no known risks associated with this research. Participants may opt to exit the interview or survey if they are not comfortable answering any of the questions.

**5. Benefits:**

There are no direct benefits to participants. This research will result in an improved understanding of the design of effective educational materials about HPV vaccination.

**6. Confidentiality:**

Responses of the participants will be confidential. The transcriptions from the interviews will have no identifying information. The transcriptions will not be linked in any way to personally identifiable information. The questionnaires will not contain any questions that ask for information that could be used to identify the participants. Only approved researchers will have access to the data collected. Hard copy materials will be stored in a locked office. Data collected will be stored in a password-protected computer located in a room with limited access. All research data collected from this study will be stored for 10 years after the study allow the research team to thoroughly analyze the data for research purposes only. The research data will be removed from computer hard disks afterwards.

**7. Consent Process:**

Because this study involves online interviews and an online survey, we request a consent waiver because our research meets the following criteria: (1) this research involves no more than minimal risk to the subjects (no personally identifiable information is collected); (2) the waiver or alteration will not adversely affect the rights and welfare of the subjects (participants can stop their participation at any time during the study). The online consent form (see attached) is identical to a written consent form; (3) the research

could not practicably be carried out without the waiver or alteration (written signatures cannot be collected online). Participants will indicate consent by clicking a radio button. Online consent will be obtained prior to the study. Participants will be permitted to print/save a copy of the consent form for their records; and (4) the subjects will be provided with additional pertinent information after participation through the debriefing process (see attached).

Participants who agree to participate will indicate consent by clicking a radio button in an online questionnaire ("I agree to participate") before the start of the study (for both the online interview and the onine survey). No name will be required. Because the interviews are one-on-one, investigators will know whether or not a participant agrees to participate by examining the instantly recorded responses in the online questionnaire. There is no deception involved in either study.

The title of the IRB application (Chatbot and Vaccine Acceptance) is different from the title on the consent forms (HPV Vaccine Messaging Study). We want to keep the title on the consent forms general because some of the participants will not interact with a chatbot.

**8. Conflict of Interest:**

There is no conflict of interest.

**9. HIPAA Compliance:**

N/A

**10. Research Outside of the United States:**

N/A

**11. Research Involving Prisoners:**

N/A

**12. SUPPORTING DOCUMENTS**

Your Initial Application must include a **completed Initial Application Part 1 (On-Line Document),** the information required in items 1-11 above, and all relevant supporting documents including: consent forms, letters sent to recruit participants, questionnaires completed by participants, and any other material that will be presented, viewed or read to human subject participants.

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**The consent forms in your approved <u>IRBNet PACKAGE</u> must be used. When creating or editing your consent form, please provide the most recent IRBNet package number at the bottom, right corner of the consent form. This ensures you are using the most "up-to-date" version of the form.**

**To find your IRBNet package number, go to the MY PROJECTS tab and click on the title of your project. In the PROJECT OVERVIEW page, your IRBNet package number will be listed at the top, next to your project title.**