UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM
to Participate in Research

Title of this study: Text and Talk: A multi-level intervention to increase provider HPV vaccine recommendation effectiveness – Part 4: Randomized Controlled Trial

Researchers: Stephanie A. S. Staras, PhD
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Before you agree to take part in this study, Dr. Stephanie Staras or her representative will tell you:

- **Why the study is being done and what will happen to you if you take part in the study:**

  The purpose of this research study is to evaluate the efficacy of parent-targeted text messages and a clinician-targeted trainings to increase human papillomavirus (HPV) vaccination.

  If you take part in this study, you will be invited to complete a survey at the beginning of the trial and one year later. We want to understand what other activities your clinic is doing to increase vaccination. Thus, the survey consists of questions about your clinic's vaccination practices.

  A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. 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.

- **How long you will be in the study:**

  Each survey will take about 15-20 minutes to complete, and will be spaced approximately one year apart.

- **How many people will be in the study:**

  90 clinicians, 30 clinic staff, 4,000 11- to 12-year-olds, 4,000 parents of 11- to 12-year-olds.

- **The possible foreseeable risks, discomforts, and benefits of this research:**

  There is a slight risk that your survey responses could be revealed inappropriately or accidentally. Depending on the nature of the information, such a release could upset or embarrass you.

The information gained in the study will not affect your employment. There is no direct benefit to you for participating in this study.
To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You have been informed that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. That is, if you give written consent for the release of information, we cannot withhold that information and we cannot hold responsibility for how that person may use your information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances. If we learn about child abuse, elder abuse, or intent to harm yourself or others, we will report that information to appropriate authorities.

- **Alternatives to being in the study:**

  You can choose not to complete the survey. Not completing the survey will have no effect on you or your relationship with your clinic, your employment, the University of Florida, or UF Health.

- **How your study records will be maintained and who will have access:**

  All surveys will be collected with REDCap a secure on-line data collection system. Surveys will be downloaded onto UF approved PHI storage areas (UF server or UF Dropbox).

  Only certain people have the legal right to review these research records, and they will protect the secrecy (confidentiality) of these records as much as the law allows. These people include the researchers for this study, certain University of Florida officials, and the Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research). Otherwise your research records will not be released without your permission unless required by law or a court order.

  If the results of this research are published or presented at scientific meetings, your identity will not be disclosed.

- **If it will cost you anything to take part in this study:**

  Participating in this study will not cost you or your clinic anything.

- **If you will be compensated for taking part in this study:**

  You will receive $20 per survey after completing the survey for a total of $40 if you complete both surveys. Your payment for participation in this research study is handled through the University of Florida's Research Participant Payments (RPP) Program. Your information which will include your name, and address is protected. Access to the (RPP) Program site is limited to certain staff with the assigned security role. If you have any problems regarding your payment contact the Principal Investigator.

- **When or if you may be told about new findings which may affect your willingness to keep taking part in this study:**

  Participants will be notified in the unlikely event that their information has been compromised.

If you agree to participate in this study, you will receive a signed copy of this document.

You may contact Dr. Staras toll-free at (877) 272-7409 at any time if you have questions about the research or if you think that you have been hurt by the research.

You may contact the Institutional Review Board at the University of Florida Health Science Center at (352) 273-9600 if you have questions about your rights as a research subject or what to do if you are injured.

You may choose not to be in this study or you may quit being in the study at any time and there will be no penalty and no loss of any benefits you are entitled to.
Information collected about you will be stored in locked filing cabinets or in computers with security passwords. Only certain people have the legal right to review these research records, and they will protect the secrecy (confidentiality) of these records as much as the law allows. These people include the researchers for this study, certain University of Florida officials, the hospital or clinic (if any) involved in this research, and the Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research). Otherwise your research records will not be released without your permission unless required by law or a court order.

Once this research study is completed, any information that could identify you **might** be removed from any identifiable private information collected and that, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

Researchers will take appropriate steps to protect any information they collect about you. However there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information such a release could upset or embarrass you, or possibly even affect your insurability or employability.
If the results of this research are published or presented at scientific meetings, your identity will not be disclosed.

Signing this document means that the research study, including the above information, has been described to you orally and/or that you have read this document, and you voluntarily agree to take part.

Signature of Person Obtaining Consent	Date
Consent and Authorization of Participant	Date