University of Kansas Medical Center
RESEARCH PROTOCOL INVOLVING HUMAN SUBJECTS
TEMPLATE WITH GUIDANCE

Version date: 4/18/2016, Version 7

Principal Investigator: Hope Krebill

Study Title: Program Evaluation of HPV Documentary

Co- Investigator(s): Mugur Geana, MD, PhD

I. Purpose, Background and Rationale

A. Aim and Hypotheses

1. HPV vaccination is an evidence-based approach to decrease the number of individuals with HPV related cancers. Unfortunately there is limited evidence on methods to increase vaccination rates. The aim of this brief program evaluation is to assess the increase in knowledge and attitudes toward HPV Vaccination for those who attend the publicly available HPV Documentary: Someone You Love.
2. Hypothses: Individuals who watch the HPV Documentary: Someone You Love and listen to the panel will have increased knowledge and intent to educate others about the importance of HPV Vaccination.

B. Background and Significance

1. Study Significance: The results of this program evaluation will help to determine whether to screen the HPV Documentary in other Kansas and Missouri communities.
2. KUMC is partnering with many organizations to increase HPV vaccination, including development of outreach and research programs. This project is part of greater outreach strategy to increase knowledge by showing the HPV Documentary to the public to inform communities of the low rate of vaccination.
3. Literature Review: Although HPV Vaccination has been available for many years and shown to be effective, it appears that parents remain reluctant to vaccinate their children against HPV when compared to other vaccines[1]. According to the President's Cancer Panel 2012-2013, "there are many reasons parents do not intend to vaccinate their adolescents against HPV: Vaccination not needed, particularly for males, Vaccination not recommended by healthcare provider, Safety concerns, Lack of knowledge about the vaccines or diseases caused by HPV infections, Son or daughter not sexually active, Son or daughter too young to be vaccinated against HPV and Cost of vaccines."

C. Rationale

1. Because there is a lack of knowledge about methods to increase parents' intention for vaccination, it is our intent to evaluate the short term impact of the HPV Documentary.
2. This program evaluation will provide information about change of knowledge and attitudes of those who attend the HPV Documentary screening.
3. By understanding short-term impact of documentary, it will provide pilot program evaluation about approaches to enhance knowledge and attitudes toward HPV Vaccination.

II. Research Plan and Design

A. Study Objectives: The primary outcome of this study is change knowledge and attitudes related to HPV and HPV Vaccination.

B. Study Type and Design: This is a descriptive study, a pretest survey will be completed immediately before the documentary with a -post survey immediately after the documentary.

C. Sample size, statistical methods, and power calculation

1. All who attend the documentary will be asked to complete the survey.
2. No Blinding.
3. 200 potential participants.

D. Subject Criteria (See Vulnerable Populations appendix, if applicable): All adults who attend the documentary in 2015 and 2016 in Kansas City, MO Great Bend, Salina, and Emporia, Kansas are eligible to complete the survey.

1. Inclusion criteria: All adults who attend the documentary are eligible to participate in the project evaluation.
2. Exclusion criteria: Individuals younger than 18 are not eligible.
3. Withdrawal/Termination criteria: This is a program evaluation; the only way to withdraw is to not complete the survey evaluation or to not turn in the completed evaluation.
4. . Participating in research studies in addition to program evaluation is allowed.

E. Specific methods and techniques used throughout the study

1. Laboratory tests: **N/A**
2. Study Procedures: The only study procedures are a pre and a post survey.
3. N/a
4. **N/A**
5. Timeline: The HPV documentary will be shown at a public location, pre and post surveys will be completed immediately before and after the screening.

F. Risk/benefit assessment: All participants have the choice to participate in the pre/post survey.

1. Physical risk: none
2. Psychological risk: none
3. Social risk: none
4. Economic risk: none
5. Potential benefit of participating in the study
    a. This is a program evaluation, attending the screening may increase their knowledge of HPV vaccination, but individuals may attend the screening without participating in the survey.
    b. Outreach organizations will have a better understanding of the impact related to knowledge and attitudes of HPV for those who attend the HPV documentary: Someone You Love.
    c. This is brief program evaluation and will provide initial pilot information about the impact of the documentary.

G. Location where study will be performed:. The documentary will be show at Union Station in Kansas City, MO in May 2015, in Emporia and Great Bend Kansas in November 2015, and Salina, Kansas in January 2016, Pittsburg, Kansas between March 15-June 1, 2016, and Kansas City, Kansas between March 15 and July 1, 2016. The pre/post survey will be completed immediately before and immediately after the screening.

H. Collaboration (with another institution, if applicable): N/A

I. Single IRB Review for a Multi-site study (if applicable): N/A

J. Personnel who will conduct the study, including:

1. Indicate, by title, who will be present during study procedure(s): Hope Krebill and/or MCA Research Nurse, and/or James Coulter, and/or Michelle Springer, and/or Hanluen Kuo, and/or Marilyn Labinski, and/or Susan Krigel and/or Mary Beth Warren
2. Primary responsibility for the following activities, for example:
    a. Determining eligibility: Hope Krebill and/or MCA Research Nurse
    b. Obtaining informed consent: N/A
    c. Providing on-going information to the study sponsor and the IRB: Hope Krebill
    d. Maintaining participant's research records: Hope Krebill
    e. Completing physical examination: N/A
    f. Taking vital signs, height, weight: N/A
    g. Drawing / collecting laboratory specimens: N/A
    h. Performing / conducting tests, procedures, interventions, questionnaires: Hope Krebill and/or MCA Research Nurse
    i. Completing study data forms: Hope Krebill
    j. Managing study database: Hope Krebill

K. Assessment of Subject Safety and Development of a Data and Safety Monitoring Plan

1. Elements of the plan include:
    a. Persons/groups who will review the data (study team; independent safety monitor, data monitoring committee or formal DSMB) N/A
    b. Data/events that will be reviewed N/A
    c. Frequency of review N/A
    d. Types of analyses to be performed N/A
    e. Safety-related triggers that would cause the PI to stop or alter the study N/A
2. N/A
3. N/A

III. Subject Participation

A. Recruitment:

1. All adults who attend the HPV screening documentary at will be asked to complete the pre/post questionnaire.
2. Announcement will be made at the screening asking all interested to complete the pre-post questionnaire.
3. This is a program evaluation, see attached flyers.
4. Recruitment statement: Thank you for participating in this survey. Your feedback is important. Please answer the following questions as honestly as possible. The purpose of this survey is to help us understand the impact of human papillomavirus (HPV) Screening Documentary "Someone You Love". **Completing this survey is completely voluntary**. If you choose to complete the survey, please answer the questions on page 1 before watching "Someone You Love". Please answer page 2 after you finish watching "Someone You Love". We do not anticipate that taking this survey will contain any risk or inconvenience to you except for 10 minutes of your time. All information collected will be used only for research and program evaluation and will be kept confidential. There will be no connection to you specifically in the results or in future publication of the results. You may contact Hope Krebill, hkrebill@kumc.edu , 913-588-3739 if you have questions or concerns.
   We will offer the survey on paper and electronically on the KUMC REDcap database.

B. Screening Interview/questionnaire: N/A.

C. Informed consent process and timing of obtaining of consent
A consent statement will be placed at the top of the survey instrument. Please see attached document. The participants will complete the pre-post questions on their own immediately before and immediately after the screening of the documentary

D. Alternatives to Participation: Individuals can choose not to complete the pre/post survey and still attend the documentary screening.

E. Costs to Subjects: There are no costs related to participation.

F. How new information will be conveyed to the study subject and how it will be documented: As this is a pre/post survey connected to the viewing of the documentary, no new information will need to be conveyed to the study subjects.

G. Payment, including a prorated plan for payment: We are not offering payment for participation.

H. Payment for a research-related injury: There are no risk for research-related injury.

IV. Data Collection and Protection

A. Data Management and Security:

1. Study team will have access to the study data.
2. We will not collect any identifiable information. Anonymous surveys will be kept in a locked file cabinet and placed in a REDcap database
3. Human subjects will not be identifiable.
4. Data will not be coded.
5. Data will not be linked to the subject.

6. Data will be stored on KUMC S drive.
7. Mobile devices for data collection and storage will not be used, but participants may choose to complete the survey on their phone through the KUMC REDcap link.
8. No identifiable data will be sent outside of KUMC.

B. Sample / Specimen Collection: N/A

C. Tissue Banking Considerations: N/A

D. Procedures to protect subject confidentiality: The survey is anonymous, so there is no risk for breach of confidentiality.

E. Quality Assurance / Monitoring

1. Data entry will be double checked by the individual entering the data.
2. There are no plans for ongoing third party monitoring.

V. Data Analysis and Reporting

A. Statistical and Data Analysis: Basic descriptive analysis method will be used for this pre-post survey.

B. Outcome: We are expecting a change in knowledge and attitudes.

C. Study results to participants: The participation is anonymous, so there is no plan to provide results back to participants.

D. Publication Plan: Results will be shared with project team, Kansas Cancer Partnership and the Kansas Foundation, as well as other stake holders for Medical Care as an evaluation report.

VI. Bibliography / References / Literature Cited

1. Freed GL, Clark SJ, Butchart AT, Singer DC, Davis MM. Parental vaccine safety concerns in 2009. Pediatrics. 2010;125(4):654-9. Available from: http://www.ncbi.nlm.nih.gov/pubmed/20194286
2. Accelerating HPV Vaccine Uptake: Urgency for Action to Prevent Cancer. A Report to the President of the United States from the President's Cancer Panel. Bethesda, MD: National Cancer Institute; 2014. A Web-based version of this report is available at: http://deainfo.nci.nih.gov/advisory/pcp/annualReports/HPV/index.htm

APPENDIX I: VULNERABLE POPULATIONS

I. We are not including vulnerable populations.

II. Cognitively or decisionally impaired individuals: **N/A**

III. Children: **N/A**

IV. Pregnant women: N/A

V. Prisoners: N/A

VI. Students and/or Employees: N/A