Increasing men's engagement in preventive healthcare through an enhanced cocoon vaccination strategy

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UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES
(v. 06.2023)

Project Title: Increasing men's engagement in preventive healthcare through an enhanced cocoon vaccination strategy

Principal Investigator: Randy Vince

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?
You are being asked to participate in this study because you are a man who visited the birthing center at Ahuja Medical Center.

Things I should know about a research study
- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Introduction/Purpose
This study aims to understand the effectiveness of strategies in the birthing center to increase vaccination and preventive care engagement among men. We anticipate recruiting 450 men for this study.

Key Study Procedures
If you agree to participate in this study, you will be asked to complete a short 5-minute electronic survey. The first survey can be completed now. More detailed information about the study procedures can be found under "Detailed Study Procedures".

Key Risks
Risks of participation in this study are unlikely, but you may feel uncomfortable answering some of the questions. You are free to skip any question you don't want to answer. More detailed information about the risks of this study can be found under "Detailed Risks"

Benefits
There are no direct benefits for you, but the data from this study may help us to understand the effectiveness of strategies to increase healthcare engagement among men.

Alternatives to Study Participation

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Participation in this study is voluntary. The alternative is to not participate.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Detailed Study Procedures
This study involves the following:

- Completing a 5-minute survey electronically that asks questions about your vaccination history, healthcare utilization, and demographics.

Detailed Risks
While unlikely, there is a risk that you may feel uncomfortable with some of the questions in the survey. You are free to skip and not answer any question that you do not feel comfortable answering. There is also a risk of breach of confidentiality. We take measures to protect your information, including storing everything electronically in a secure password protected electronic file..

Financial Information

- There are no costs associated with participating in this study.
- You will receive a $5 gift card upon completion of the **s**urvey.

If you receive USD $600 or more in a calendar year (January to December) from University Hospitals, the IRS will require a Form 1099 to be issued to you. Money paid back to you for study-related travel and other out-of-pocket expenses such as parking and meals are not included on the IRS form since reimbursements are not considered compensation per IRS regulations.

To receive compensation for participation you must provide your SSN or TIN to University Hospitals by completing a W-9 or applicable tax form. You may choose to waive compensation for any reason without affecting your participation. Waiving compensation does not affect payments or reimbursements related to travel so you will still be eligible for these if they are applicable to your study.

Consent to Contact for Future Research
Our study team may have additional research studies in the future. We would like your permission to contact you in the future if we think you could be a potential participant in one of our studies. Please check one of the boxes below that indicates your choice to be contacted for future research.

____ Please contact me by [select all that apply: phone; email] for future research opportunities.
____ Please do not contact me for future research opportunities.

Clinical Trial Information – ACTs or NIH-funded clinical trials
A description of this clinical trial will be available on http:///www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time to find out information about the trial and basic results.

Student/Employee Rights
Choosing not to participate or withdrawing from this study will not affect your employment or class standing, nor will the results be shared with your supervisor.

Confidentiality
Only researchers in this study will have access to your data and contact information. All information will be stored in a secure centralized electronic file.

This study is collecting data from you. We would like to make these available for other research studies that may be done in the future. The research may be about similar diseases or conditions to this study, but it could also be unrelated. These studies may be done by researchers at this institution, other institutions, including commercial entities. Our goal is to make more research possible.

Your deidentified information may be shared with other researchers or databases. If your identifying information is removed from the data or biospecimens you provided, they may be shared without your additional consent. We cannot guarantee anonymity of your personal data even if identifying information is removed.

In addition, with your consent, we would like to share your identifiable or coded data and other biospecimens, with other researchers for future research. Coded data means personal identifiers are removed but a link to your identity exists. We will protect the confidentiality of your information to the extent possible. Coded information may also be submitted to federal or other databases/repositories.

It is your choice whether or not to let researchers share your coded data and biospecimens for research in the future. If you change your mind and no longer wish to have us store or share your identifiable/coded data and biospecimens, you should contact Dr. Sarah Koopman Gonzalez at

216-368-5775. We will do our best to honor your request and retrieve any data and biospecimens that have been shared with other researchers or databases. However, there may be times we cannot. For example, if the data and biospecimens have already been used for new research.

Do you agree to allow for the sharing of your identifiable/coded data?

_____ YES, use my identifiable/coded data in other research studies
_____ NO, do NOT use my identifiable/coded data in other research studies

Privacy of Protected Health Information (HIPAA)

The Health Insurance Portability & Accountability Act (HIPAA) is a Federal law that helps to protect the privacy of your health information (called Protected Health Information or PHI) and by setting rules about how your information may be used and to whom this information may be shared within and outside of University Hospitals. This Authorization form is for the research study entitled "Increasing men's engagement in preventive healthcare through an enhanced cocoon vaccination strategy only." If you do not agree to this authorization, you may not join this study. Your decision to allow this use and disclosure of your PHI is voluntary and will have no impact on your treatment at University Hospitals.

The researchers working on this study, including the Principal Investigator, Randy Vince, will collect the following PHI about you: name and email. This PHI will be used to send you compensation information.

Your PHI could be shared with the Department of Health and Human Services, other Institutional Review Boards, Case Western Reserve University, or with University Hospitals employees who are required to process information for research, compliance or financial reasons.

In the future additional research sites may be added. In this event, your PHI that was collected during this research project may be shared with research personnel at these additional sites. Please understand that if your PHI is disclosed to anyone outside University Hospitals, there is a small risk it may no longer be protected.

Your permission to use and disclose your PHI does not expire. However, you have the right to change your mind at any time and revoke your authorization. If you revoke your authorization, the researchers will continue to use the information that they previously collected, but they will not collect any additional information. To revoke your permission, you must do so in writing by sending a letter to:

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Principal Investigator: Randy Vince

Randy Vince, MD
Urology
11100 Euclid Avenue Cleveland, OH 44106

Summary of Your Rights as a Participant in a Research Study

Your participation in this research study is voluntary. Refusing to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. De-identified data from this study may be published, presented, or otherwise made publicly available. If this happens, your identity will not be revealed. In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating. If you experience physical injury or illness as a result of participating in this research study, medical care is available at University Hospitals Cleveland Medical Center (UHCMC) or elsewhere; however, UHCMC has no plans to provide free care or compensation for lost wages.

Disclosure of Your Study Records

Efforts will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. The University Hospitals Cleveland Medical Center Institutional Review Board may review your study records. If this study is regulated by the Food and Drug Administration (FDA), there is a possibility that the FDA might inspect your records. In addition, for treatment studies, the study sponsor and possibly foreign regulatory agencies may also review your records. If your records are reviewed your identity could become known.

Contact Information

This consent form has described to you what is going to be done, the risks, hazards, and benefits involved. The Principal Investigator Randy Vince can also be contacted at 216-844-3009. If you have any questions, concerns or complaints about the study in the future, you may also contact them later.

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about; concerns regarding the study; research participant's rights; research- related injury; or other human subject issues, please call the University Hospitals Cleveland Medical Center's Research Subject Rights phone line at (216) 983-4979 or write to: The Associate Chief

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Principal Investigator: Randy Vince

Scientific Officer, Clinical Research Center, University Hospitals Cleveland Medical Center, 11100 Euclid Avenue, Lakeside 1400, Cleveland, Ohio, 44106-7061.

Signature

Clicking "Yes" below indicates that you have been informed about the research study in which you voluntarily agree to participate, and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By consenting, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form is available for you as a download. Continue if you decide to participate in the research and:

- You have read the above information
- You voluntarily agree to participate
- You are 18 years of age or older
- You understand that your name and email will be reviewed one time by the study team and that your identifiable information will be used for this study.

____ Yes, I consent to participate in this study.

_____ Name

_____ Email Address