A Comprehensive Pre-Natal Intervention to Increase Vaccine Coverage (P3+): Practice, Provider, Patient Level Interventions

Informed consent date: August 5, 2019

NCT02898688

Emory University and University of Colorado
Consent to be a Research Subject / HIPAA Authorization

Title: A Comprehensive Pre-Natal Intervention to Increase Vaccine Coverage: P3Plus-Pratice, Provider and Patient Level Interventions

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University of Colorado Co-Investigator: Sean O'Leary, MD, MPH; University of Colorado School of Medicine

Funding Source: National Institutes of Health

Introduction

You are being asked to be in a research study. This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.**

Before making your decision:

- Please carefully read this form or have it read to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form for your records. Feel free to take your time thinking about whether you would like to participate. By signing this form you will not give up any legal rights.

Study Overview

The patient level intervention is geared to understanding the knowledge, attitudes and beliefs about maternal and childhood vaccination.

Procedures

If you agree to join this study, you will be asked to take part in an intervention that is done via an app at three different times. Today, is the baseline survey that will take about 15-20 minutes. There will also be 2 follow-up surveys to complete via the app when your child is 30 days and 18 months old. We will ask you about your attitudes, beliefs, and behaviors relating to maternal immunizations. You may also receive educational text messages following enrollment in the study. You can disable the text messages at any point. We are recruiting 2200 pregnant women between Colorado and Georgia. Your participation in this study is your choice.

Risks and Discomforts

The risks in this study are likely to be small. There are no foreseeable risks of physical harm. This is always a small chance that confidentiality will be breached. If this happens, we will work with Emory officials to inform all participants and we will take steps to correct the situation. We will keep all information about you private to the extent allowed by law.

Benefits

This study is not designed to benefit you directly. This study is designed to learn more about vaccine information needs and current vaccination system logistics at your practice for pregnant women. The study results may be used to help others in the future. There may be no direct benefit to you as a participant in this study.

Compensation

You will receive a $20 gift card for completing the first survey and then an additional $20 gift card for each of your completed follow up surveys. This will come to a total of $60 in gift cards if you complete all 3 surveys.

Confidentiality

Certain offices and people other than the researchers may look at study records. Government agencies and Emory employees overseeing proper study conduct may look at your study records. These offices include the Emory Institutional Review Board, the University of Colorado Denver Institutional Review Board, the Emory Office of Research Compliance, and the National Institutes of Health (the study funder). Study funders may also look at your study records. Emory will keep any research records we create private to the extent we are required to do so by law. A study number rather than your name will be used on study records wherever possible. Your name and other facts that might point to you will not appear when we present this study or publish its results.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the study.

PHI that Will be Used/Disclosed:
The PHI that we will use or share for the main research study includes:

- Medical information about you including your medical history and present/past medications.

Purposes for Which Your PHI Will be Used/Disclosed:
We will use and share your PHI for the conduct and oversight of the research study. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information.

Use and Disclosure of Your Information That is Required by Law:
We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

Authorization to Use PHI is Required to Participate:
By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your PHI. If you do not sign this form, then you may not participate in the research study.

People Who will Use/Disclose Your PHI:
The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff including research staff and IRB staff at Johns Hopkins University, University of Colorado Denver and University of Georgia will use and disclose your PHI to conduct the study and give you study related treatment.
- Emory may use and disclose your PHI to run normal business operations.
- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- Dr. Saad B. Omer is the Sponsor of the study. The Sponsor may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the University of Colorado Denver IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Government agencies that regulate the research including: Office for Human Research Protections.
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.

Expiration of Your Authorization
Your PHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at:

Saad B. Omer, MBBS PhD MPH
somer@emory.edu
404-727-9814

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the study.

Request to obtain immunization records
We would like to obtain your immunization records from your provider (Ob/Midwife) after your expected date of delivery utilizing medical records from your provider's office. Additionally, we would like to obtain your baby's immunization records from either Georgia's or Colorado's Immunization Information System (IIS). If the information can't be found in your state's IIS system, we would like to obtain this information from your baby's pediatric office.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Voluntary Participation and Withdrawal from the Study

You have the right to leave a study at any time without penalty. You may refuse to do any procedures you do not feel comfortable with, or answer any questions that you do not wish to answer.

Contact Information

Contact Saad B. Omer, MBBS PhD MPH at 404-727-9814 or somer@emory.edu:

- if you have any questions about this study or your part in it,
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

Consent & Authorization

Please, print your name and sign below if you agree to be in this study. By signing this consent form, you will not give up any of your legal rights. We will give you a copy of the signed consent, to keep.

_____

Name of Subject

_____ _____

Signature of Subject Date Time

_____ _____

Signature of Person Conducting Informed Consent Discussion Date Time