COMIRB
APPROVED
For Use
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Principal Investigator: Sean O'Leary
COMIRB No: 19-1312
Version Date: 06/07/2019
Study Title: Adapting Motivational Interviewing for Maternal Immunizations (MI4MI)

You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

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Why is this study being done?

This study plans to learn more about how obstetrician-gynecologists (ob-gyns) talk to their patients.

You are being asked to be in this research study because you are a pregnant woman.

Up to *50* people will participate in the study.

What happens if I join this study?

If you join the study, you will participate in an audio-recorded visit with your ob-gyn and complete an audio-recorded interview sometime after your visit.

You will also be invited to participate in a second interview 3-4 months after today's visit.

What are the possible discomforts or risks?

Discomforts you may experience while in this study include discomfort about being audio-recorded.

Other possible risks include loss of confidentiality.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about how ob-gyns talk to pregnant women about their medical care.

Who is paying for this study?

- This research is being paid for by The National Institutes of Health.

Will I be paid for being in the study? Will I have to pay for anything?

You will be paid $50 in the form of a gift card for completing the visit and interview today. If you participate in a second interview in 3-4 months, you will receive a second $50 gift card.

It will not cost you anything to be in the study.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

Who do I call if I have questions?

The researcher carrying out this study is Sean O'Leary. You may ask any questions you have now. If you have questions later, you may call Sean O'Leary at 303-724-1582.

You may have questions about your rights as someone in this study. You can call Sean O'Leary with questions. You can also call the Multiple Institutional Review Board (IRB). You can call them at 303-724-1055.

Who will see my research information?

We will do everything we can to keep your records a secret. It cannot be guaranteed.

Both the records that identify you and the consent form signed by you may be looked at by others.

- Federal agencies that monitor human subject research
- Human Subject Research Committee
- The group doing the study
- The group paying for the study
- Regulatory officials from the institution where the research is being conducted who want to make sure the research is safe

The data we collect will be used for this study but may also be important for future research. Your data may be used for future research or distributed to other researchers for future study without additional consent if information that identifies you is removed from the data.

The results from the research may be shared at a meeting. The results from the research may be in published articles. Your name will be kept private when information is presented.

As part of this study, we will audio-record a visit between you and your doctor. These audio-recordings will be kept secret by those conducting this study. The recordings will be protected on a password-protected server. They will be kept for seven years and then erased.

Some things we cannot keep private. If you give us any information about child abuse or neglect we have to report that to <state Social Services or other agency>. Also, if we get a court order to turn over your study records, we will have to do that.

Certificate of Confidentiality

This study has been issued a Certificate of Confidentiality from the federal government to help protect your privacy. The Certificate prohibits the researchers from disclosing your name, or any identifiable information, document or biospecimen from the research, with the exceptions listed below. A certificate provides protections against disclosing research information in federal, state, or local civil, criminal, administrative, legislative or other proceedings.

These protections apply only to your research records. The protections do not apply to your medical records.

The researchers may disclose your name or identifiable information, document or biospecimen, under the following circumstances:

Optional Procedure Consent Language for Blood and Tissue
To those connected with the research,
If required by Federal, State or local laws,
If necessary for your medical treatment, with your consent,
For other scientific research conducted in compliance with Federal regulations,
To comply with mandated reporting, such as a possible threat to harm yourself or others, reports of child abuse, and required communicable disease reporting, or
Under other circumstances with your consent.

A Certificate of Confidentiality does not protect information you or a member of your family voluntarily release.

Agreement to be in this study

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I know that being in this study is voluntary. I choose to be in this study: I will get a copy of this consent form.

Signature:_____ Date:_____

Print Name:_____

Consent form explained by:_____ Date:_____

Print Name: _____

Investigator:_____ Date:_____

Consent witnessed by:_____ Date:_____

Print Name:_____