OMB: 0910-0497
Exp Date:

CONSENT FOR PARTICIPATION IN FOCUS GROUP

Research: Medication use in pregnancy

Introduction and Purpose:

You have been asked to participate in a focus group as part of a research project. The purpose of the focus group is to better understand how women feel and think about medication use in pregnancy. Your answers may help to inform materials and resources that can help pregnant women. The research is sponsored by the U.S. Department of Health and Human Services and the focus group will be conducted by Bixal Solutions. We will be conducting 4 focus groups around the country with women for this study.

Procedures:

During the focus group you will be joining a small group of other women and asked for your opinions and feedback on taking medications during pregnancy. The focus group will last no more than 90 minutes. You will be asked to (1) review a Medicine and Pregnancy fact sheet and answer questions to determine how easy or difficult it is to understand, and (2) to provide your input on the topic of pregnancy registries.

Risk/Discomforts:

There is no known physical risk to you from being in this study. The risks you take by participating in the discussion are the same as those you encounter in daily life.
You can say you do not want to talk about any topic for any reason. You can also stop being in the focus group at any time.

Benefits:

You will be better informed about a public health issue. You may have a sense of satisfaction from civic participation. Your answers may help us better inform the public and others about a public health issue.

Privacy:

Your comments will be kept private and strictly confidential. These forms will be destroyed once the project ends.

Payment:

You will be given $75.00 cash for your time, effort and travel costs.

Confidentiality:

We will keep the information you give us private and confidential to the extent allowed by law. Your name will not be used in the final report. No statement you make will be linked

to you by name. Only members of the research staff will be allowed to look at identifying records for the purposes of recruitment. Following the conclusion of the focus group, all documents identifying participants will be destroyed to ensure complete anonymity. Any presented or published results of this study will not include your name or any other facts that point to you.

Some of the people working on the project may watch the focus group through a one-way mirror and take notes. The focus group will be audio recorded. All recordings will be destroyed at the end of the project.

Right to Refuse or Withdraw:

It is your choice to be in this study. You can choose not to talk about any topic. You can stop your participation in the focus group at any time without penalty.

Persons to Contact:

You may ask questions or express concerns about this consent form, the study, your rights as a research subject, or report problems at any time before, during or after the study. If you have questions about taking part in testing this discussion group, you may call the U.S. Food and Drug Administration, Office of Women's Health, 301-796-9440.

Your Consent:

I have read this consent form and choose to participate. I had a chance to ask questions and my questions were answered. I was given a copy of this consent form.

_____	_____	_____
Printed Name	Signature	Date

Witness:

I have discussed the above information with the person whose name appears above, and have answered his/her questions to the best of my ability.

_____	_____	_____
Printed Name	Signature	Date

<u>Paperwork Reduction Act Statement:</u> An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The public reporting burden for this information collection has been estimated to average 5 minutes per response to complete the Consent for Participation in Focus Group Form (the time estimated to read, review, and complete). Send comments regarding this burden estimate or any other aspects of this

information collection, including suggestions for reducing burden, to PRAStaff@fda.hhs.gov.