Online Consent to Participate in Research

Title of Research Study: ***Supporting Transitions to Primary care among Under-resourced, Postpartum women: The STEP-UP Trial***

IRB Study Number: STU00217979

Investigator: ***Stacy Bailey, PhD MPH***

Supported By: This research is supported by the National Heart, Lung and Blood Institute (NHLBI)

Collaborating Institutions: AllianceChicago and Cook County Health

Key Information about this research study:

The following is a short summary of this study to help you decide whether to be a part of this study.

The purpose of this study is to test a strategy to connect high-risk, postpartum patients with primary care within community health care settings.
You will be asked to complete 1 interview by phone.
We expect that you will be in this research study for 1 hour
The primary potential risk of participation is you may feel uncomfortable answering some questions. You may skip any question if you feel uncomfortable
The main benefit of being in this study is receiving information and recommendations to promote transitions to primary care.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Here is why you are being asked to take part in this research study:

We are asking you to take part in this research study because you recently gave birth at one of the study clinics and had gestational diabetes or hypertensive disorders of pregnancy.

This is what you should know about being in a research study

- Whether or not you take part is up to you.
- You can choose not to take part. You can also 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.

If you say that "Yes, you want to be in this research," here is what you will do

During the interview, I will ask you questions about your experience with the a new intervention that was added to your clinic and some questions about your background. The interview will take about an hour to complete

If you say that you do not want to be in this research:

You can decide not to participate in this research and it will not be held against you.

You can say "Yes," but change your mind later

You can leave the research at any time and it will not be held against you. We can end the interview at any time. Just let me know if you want to do this. If this happens, I will ask you if any data collected up until that point may be used in the research.

This is what will happen to the information collected for this research

Efforts will be made to limit the use and disclosure of your personal information, including research study records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

Identifiable information that could still be disclosed beyond the research team: The Certificate does not stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate does not stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also does not prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Here is some other information that is useful for you to know

If you agree to take part in this research study, we will email/mail a $75 Visa Gift Card within 2 weeks of completing the interview. You will still receive this compensation even if you choose to end the interview early.

Here is who you can talk to

If you have questions, concerns, or complaints, you can contact the Principal Investigator, Dr. Stacy Bailey, at (312) 503-5595. This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may contact the IRB by phone at (312) 503-9338 or irb@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

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Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by clicking "I agree" or "I disagree" and placing your initials next to the activity.

I agree	I disagree	
_____	_____	The researcher may keep my contact information in order to contact me in the future to see whether I am interested in participating in other research studies by the Center for Applied Health Research on Aging.

Consent:

If you want a copy of this consent for your records, you can print it from the screen.

We will email you a copy of this signed consent form.

If you wish to participate, please click the "I Agree" button.

If you do not wish to participate in this study, please select "I Disagree" or select X in the corner of your browser.

☐ I agree
☐ I disagree

_____ _____
First Name Last Name

_____
Consent Date