IRB Office Use Only	IRB Approval Date: IRB Consent Version No.:

JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH

ADULT HEALTH CARE PROVIDER INFORMED CONSENT IMPLEMENTATION PHASE – 18 MONTHS

Principal Investigator: Dr. Andreea Creanga

Study Title: Safety Program in Perinatal Care (SPPC)-II/Demonstration Project

IRB No.: IRB00009378

Sponsor/Supporter/Funded By: AHRQ HHSP233201500020I-HHSP23337007T

PI Version Date: 1

Key Information about the Study

- We are asking you to participate in a survey for The Safety Program in Perinatal Care-II (SPPC-II) Demonstration Project, implemented jointly by the Johns Hopkins University (JHU) and the Alliance for Innovation on Maternal Health (AIM). The program aims to demonstrate the value of integrating key components of teamwork and communication with AIM maternal safety bundles developed for obstetric hemorrhage and severe hypertension in pregnancy.
- You are being asked to complete this survey because your hospital's leadership has agreed to participate in this Demonstration Project, and you have received training on teamwork and communication tools and strategies through this project.
- You do not have to join the study; it is your choice and there is no penalty for not joining. Ask as many questions as you need to help you make your decision. Please review the details outlined in the rest of this consent document before deciding.
- If you join, we will ask you to complete a paper or web-based survey. We estimate this survey should take 30 minutes to complete.
- If you join the study, you will receive a $10 Amazon e-gift card as compensation for the time you spent completing this survey. We will use your responses to evaluate the SPPC-II Demonstration Project.

Details about the Study

Why is this research being done?

This survey is a tool to help assess the skills you gained from the SPPC-II teamwork and communication trainings, and to what extent you and your colleagues are currently using these in clinical practice. This information will be used to evaluate trainings and tools developed under the SPPC-II Demonstration Project. We hope knowledge generated through this Project will improve implementation of the AIM program and its impact on teamwork and communication, patient safety culture, and key maternal health outcomes.

What will happen if you join this study?

If you agree to be in this study, we will ask you to complete a paper or web-based survey, consisting of 50 close-ended questions (e.g. multiple choice, yes/no). The survey is estimated to take 30 minutes to complete.

Will research test results be shared with you?

The results of this study will be used for the evaluation of the SPPC-II Demonstration Project, but we do not expect they will be clinically useful for you. Therefore, we will not share these results with you.

What happens to data that are collected in the study?

The data we collect from you will help guide the implementation and evaluation of the SPPC-II Demonstration Project. As a participant, you will not own your research data, and you will not benefit financially from any new product or idea that might arise from our work. Sharing of research data in scientific journals is often done to increase what health researchers can learn. The data you provide us will be shared in aggregate at the state level in such scientific journals. We will protect the data you provide and all sharing of data will be done anonymously (that is, the data will not be linked to your name or the name of the hospital where you work). If you are not comfortable with the use of your data in future research, you may not want to participate in this study.

What are the risks or discomforts of the study?

You may get tired or bored when you are completing the survey. You do not have to answer any question you do not want to answer, and can stop completing the survey at any time.

There is a risk that information you provide may become known to people outside this study. We will protect your information to reduce the chance of this happening. We will not identify your name or the name of the hospital where you work in any reports or publications that use the information you provide.

How will the confidentiality of your data be protected?

Your responses will be kept confidential to the extent permitted by law, including federal government confidentiality statute, 42 USC 299c-3(c). That law requires that information collected for research conducted or supported by the federal government that identifies individuals or establishments be used only for the purpose for which it was supplied unless you consent to the use of the information for another purpose.

Confidentiality will be maintained utilizing computer systems that require passwords for access. Collected information will be stored in a password protected computer not available to anyone not directly involved in this study. All names will be deleted from datasets in order to protect your confidentiality. The name of the hospital will only be retained in the dataset that is shared internally within the study team and collaborating institutions.

What are the potential benefits to being in the study?

You will receive a $10 Amazon e-gift card as compensation for the time you spent completing this survey. Knowledge generated through this Project will improve implementation of the AIM program and its impact on teamwork and communication, patient safety culture, and key maternal health outcomes.

What are your options if you do not want to be in the study?

You do not have to join this study. You do not have to join, it is your choice. There will be no penalty if you decide not to join.

Will it cost you anything to be in this study?

No.

Will you be paid if you join this study?

You will receive a $10 Amazon e-gift card as compensation for the time you spent completing this survey.

What other things should you know about this research study?

This study has been reviewed by an Institutional Review Board (IRB), a group of people including scientists and community people, that reviews human research studies. The IRB can help you if you have questions about your rights as a research participant or if you have other questions, concerns or complaints about this research study. You may contact the IRB at 410-955-3193 or jhsph.irboffice@jhu.edu.

What should you do if you have questions about the study?

Call the principal investigator, Dr. Andreea Creanga at 443-287-1864. If you wish, you may contact the principal investigator by letter. The address is on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3193.

What does your signature on this consent form mean?

Your signature on this form means that you have reviewed the information in this form, you have had a chance to ask questions, and you agree to join the study. You will not give up any legal rights by signing this consent form.

Documenting Participant Choices

What does your signature on this consent form mean?

Your signature on this form means that you have reviewed the information in this form, you have had a chance to ask questions, and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

_____

Signature of Participant (Print Name) Date/Time

_____

Signature of Person Obtaining Consent (Print Name) Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).