DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
ADULT
Improving the **c**linical encounter **t**o enhance delivery of an Individualized Prematurity Prevention Plan (IP3) – The IMPaCT-IP3 Study

CONCISE SUMMARY

The purpose of this study is evaluate an intervention to improve uptake and adherence to Individualized Prematurity Prevention Plans (IP3) in women with a history of preterm birth.

All women who participate in this study will view a narrated power-point presentation, receive additional materials and receive text message reminders during their pregnancy. The content of the presentation and the text messages will be randomly assigned to information about details and medical reasons for the IP3 or general pregnancy information.

Risks include a possible loss of confidentiality and possible charges for text messages based on your cell phone carrier.

If you are interested in learning more about this study, please continue to read below.

You are being asked to take part in this research study because you are pregnant, self-identified as black or African American race, have a history of prior preterm birth, eligible for an Individualized Prematurity Prevention Plan (IP3) and you are planning to deliver your baby at Duke University Hospital. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask them to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research studies.

A grant from the National Institutes of Health (NIH) will sponsor this study. Portions of Dr. Sarahn Wheeler and her research team's salaries will be paid by this grant.

WHO WILL BE MY DOCTOR ON THIS STUDY?
If you decide to participate, Dr. Wheeler will be your doctor for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

WHY IS THIS STUDY BEING DONE?
In the United States, black women are more likely to deliver a baby preterm (before 37 weeks gestation). We worked with a group of black women to understand some of the barriers to uptake and adherence to prenatal care. We've developed an intervention based on their feedback.

The current study is being done to see if we can deliver the intervention that we have developed and to get some initial data on how well it works and patient's feedback on the intervention.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 60 women will take part in this study at Duke.

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WHAT IS INVOLVED IN THE STUDY?
If you agree to be in this study, you will be asked to sign and date this consent form. You will complete a short questionnaire, view a brief (~ 15 minute) narrated powerpoint presentation and complete another questionnaire following the presentation.

You may also be offered additional materials including a letter with a general explanation about your high risk pregnancy that you may choose to share with your employer and information about your employment rights during your pregnancy.

Text messages are also part of the intervention weekly from the time you enroll until shortly after delivery. We will not charge you for these messages, however depending on your cell phone service provider fees may apply. You can elect to stop text messaging at any time.

Initial here if you **DO** want text messages as part of this study _____

Initial here if you do **NOT** want text messages as part of this study _____

We will review your medication history, and medical information over the course of your pregnancy and hospitalization for delivery of your baby.

HOW LONG WILL I BE IN THIS STUDY?
You will be in the study from the time you sign this consent until 12 weeks after the birth of your baby. This is around one year. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

WHAT ARE THE RISKS OF THE STUDY?
There are no physical risks of the study. The main risk includes a possible loss of confidentiality.

Text messages are also part of the intervention. We will not charge you for these messages, however depending on your cell phone service provider fees may apply. You can elect to stop text messaging at any time.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
The information in the presentation contains information that we believe may be helpful to you during you pregnancy. We also hope that your feedback will help us to improve the presentation for women in the future.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

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The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1. there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);

2. you have consented to the disclosure, including for your medical treatment; or

3. the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations.

If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

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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.

WHAT ARE THE COSTS TO YOU?
You or your insurance provider will be responsible and billed for all costs related to your routine medical care, including copayments and deductibles. Routine medical care services are those that you would have received for your condition if you were not participating in this research study. Not all services are covered by insurance. Some procedures or scans may require pre-authorization by your insurance plan. We will notify you if we learn that a service is not covered by your insurance plan as part of the pre-authorization process. If it is not covered, you will be responsible for paying for it. The amount of your out-of-pocket expense will depend on your insurance plan. For beneficiaries with Medicare Advantage Plans, traditional Medicare is billed for the routine cost of a research study. You may have more or higher co-pays than with a Medicare Advantage plan. Please discuss the costs of the study with Dr. Wheeler. At your request, a Financial Counselor in the clinic may provide you with an estimate of costs for routine services.

WHAT ABOUT COMPENSATION?
You will receive $20 after completing viewing the presenation and completing the questionaires during at the study intake. You will receive an additional $20 after completing the exit-interview after your baby is born.

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. Wheeler at (919) 681-5220 during regular business hours and at (919) 970-6606 (pager) after hours and on weekends and holidays.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record. All data that have already been collected for study purposes, and any new information about an adverse event related to the study, will be sent to the study sponsor.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Wheeler in writing and let her know that you are withdrawing from the study. Her mailing address is 2608 Erwin Road Suite 210, Durham, NC 27705.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

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WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Wheeler at (919) 681-5220 during regular business hours and at (919) 970-6606 (pager) after hours and on weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Subject	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time