**Cover Page for Informed Consent**

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# RESEARCH PARTICIPANT CONSENT FORM

## Labor and Delivery Doula Program to Reduce Perinatal Morbidity and Mortality in Kansas

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- We are asking you to be in a research study.
- Research is done to answer a scientific question. Research studies may or may not help the people who participate.
- Joining this study is completely voluntary. If you say yes, you can quit the study at any time.
- You can still get medical care and other services from the University of Kansas Medical Center even if you are not in the study.
- The research team will explain what happens if you decide to join the study. This conversation is called "informed consent."
- Informed consent includes a chance to get your questions answered before you make your decision. Please ask as many questions as you need to.
- This consent form explains the study. Take as much time as you need to decide.
- If you decide to be in the study, you will be asked to sign this form.

Dr. Martin is doing the study at the University of Kansas Medical Center (KUMC) and 40 research participants will be in the study.

### Why is this study being done?

We are doing the study to learn how to provide the best possible care for Black birthing people at the University of Kansas Health System. A doula is a professional labor assistant who provides physical and emotional support to you and your support people during pregnancy, childbirth, and the postpartum period. 20 people will receive routine pregnancy care at the University of Kansas Health System and 20 will receive doula-enhanced care in addition to routine pregnancy care at the University of Kansas Health System. Outcomes between the two groups will be compared to determine if doula-enhanced care improves perceived communication and quality of care.

## How long will I be in this study?

The study will be around a year in length ranging due to the length of pregnancy and postpartum, how early you enroll during your pregnancy and how closely pre and postnatal visits are together.

## What will I be asked to do?

Patients, once enrolled in the study, will be randomly assigned to one of two groups. Group assignments are random, like flipping a coin or rolling the dice.

- Group 1: Doula-Enhanced Care Group.
    - This group will receive doula-enhanced care along with routine pregnancy care at the University of Kansas Health System.
    - This care entails three prenatal visits with a doula, having the doula present during labor and at the delivery, and three postnatal visits with the doula.
    - The Doula will also attend on physician prenatal appointment and one physician postpartum appointment as a support person at the University of Kansas Health System.
- Group 2: Routine Pregnancy Care Group.
    - This group will receive routine pregnancy care at the University of Kansas Health System.
- You will have a 1 in 2 chance of receiving doula-enhanced care (Group 1) and a 1 in 2 chance of being assigned to the control group (Group 2).
- The research team will be able to access your electronic medical records from the time you enter the study until 6 weeks postpartum to compare you and your baby's health with other participants.

If you decide to be in the study, the researchers will ask you to do the following:

- Follow through on your routine pregnancy care and attend every appointment
- Meet with a doula three times before delivery if you are assigned a doula and three times after delivery
- Fill out 3 surveys, no matter which group you are assigned. One survey after enrollment, one survey after discharge from delivery and one survey at a postnatal visit. Each survey will take approximately 10 minutes to fill out. You will choose between taking the survey in person during your visit or taking it at home on a link sent via email.

## What are the risks of being in the study?

There are no physical risks involved in collecting information about you. There is a small risk of breach of confidentiality. For that reason, your information will be protected as described in the Privacy section below.

## Are there benefits or compensation for being in this study?

You may or may not get the personal benefit of Doula enhanced care from being in this study. Participants who are randomized to doula-enhanced care will have the benefit of working one on one with a doula and receive personalized care for 3 prenatal visits, 3 post-natal visits and during birth. Researchers hope this study may be helpful in improving routine pregnancy care for Black-birthing patients.

In appreciation of your time, you will receive $20 for survey one, $25 for survey two, and $40 for survey three. If you complete all regularly scheduled visits and surveys, you will receive up to $85. If you leave the study early, you will be paid only for the surveys you completed.

You will be given a ClinCard, which works like a debit card. After a study visit, payment will be added onto your card by computer. The money will be available within 1 business day. You can use the ClinCard at an ATM or at a store. No one at KUMC will know where you spent the money. You will be given one card during the study. If your card is lost or stolen, please call (866) 952-3795.

The KUMC Research Institute will be given your name, address, social security number, and the title of this study to allow them to set you up in the ClinCard system. Study payments are taxable income. A Form 1099 will be sent to you and the Internal Revenue Service if your payments are $600 or more in a calendar year. If you do not provide a valid social security number or tax identification number, 30% of your payments will be set aside by KUMC and sent to the IRS for withholding on your behalf.

Your personal information used to pay you will be kept on a secure computer. It will be removed from the computer after the study is over and the money on the card has been used. Your information will not be shared with other businesses. It will be kept completely confidential.

## Will I have any costs for being in the study?

There a no cost for your participation in the study. You will be responsible for the costs of prenatal care, labor and delivery care, and postnatal care. If you are assigned a doula, the doula will be provided at no additional cost.

## Will the researchers get paid for doing the study?

The institution (KUMC Research Institute, Inc.) will receive payments from the sponsor, BioNexus for conducting this study. Payments will be used for research purposes only.

## What other choices do I have if I don’t want to be in the study?

You can choose not to be in the study. You can decide to leave the study at any time. Leaving will not affect the treatment or services you get at KUMC. The University of

Kansas Health System can refer you to doula services in the greater Kansas City area.

**How will my confidentiality and privacy be protected?**

The researchers will keep your identity confidential, as required by law. Absolute confidentiality cannot be guaranteed because persons outside the study team may need to look at your study records. The researchers may publish the results of the study. If they do, they will only discuss group results. Your name will not be used in any publication or presentation about the study.

If you sign this form, the research team will collect, use, and share your private health information as described below. If you decide not to sign this form, you cannot be in the research study.

Study data includes information from your study activities and from your medical record. Your health care providers may release your private health information to Dr. Martin and the research team. The team may use all of your information needed for the study. Your medical records may contain your name, address, phone, date of birth, social security number, or other identifiers. Others at KUMC might need to look at your research records. They include KUMC Research Institute, the Institutional Review Board or other committees and offices that review and monitor research studies.

Your participation in this study and your study information may be put into the University of Kansas Health System electronic medical record and combined with your health information from your clinical care. The health system may use and share this information for other purposes described in the Notice of Privacy Practices.

You may not be able to see your records relating to the study until after the study is over and the results are known. Any research information that is put in your medical record will be kept indefinitely.

The research team will share your study data with people outside KUMC. These groups or agencies may make copies of study data for audit purposes. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may not protect it. These groups may include:

- Federal agencies that oversee human research (if a study audit is performed)
- The Department of Health and Human Services Public Health Services
- Experts who inspect the study information to see if the study is being done correctly and if it is still safe to continue
- Other groups that help manage or provide services to support the study
- Ethics committees that review the study for other locations
- The study sponsor, BioNexus, who provided funding for the study.
- The consulting Doula Organization, Uzazi Village.

Your permission to use and share your health information will not expire unless you

cancel it. To cancel your permission, please write to Dr. Angela Martin. The mailing address is Dr. Angela Martin, University of Kansas Medical Center, 3901 Rainbow Boulevard, Kansas City, KS 66160. If you cancel your permission, you will be withdrawn from the study. The researchers will stop collecting any additional information about you unless they need information about a side effect of Doula enhanced care. They are permitted to use and share information that was gathered before they received your cancellation.

The researchers may publish the results of the study. If they do, they will only discuss group results. Your name will not be used in any publication or presentation about the study.

**What if I decide to leave the study?**

If you no longer wish to take the surveys or meet with a doula, you can choose to withdraw your permission for researchers to use your health information. If you want to withdraw your permission, please contact Dr. Angela Martin using the contact information on the first page of this document. If you withdraw permission to use your health information, you will be withdrawn from the study. If you miss more than two prenatal visits or change facilities for your prenatal care, you will be terminated from the study. The researchers are permitted to use and share information that was gathered before they received your cancellation.

**Will I be told about research results?**

At the end of the study, we will send you a letter with a summary of the results.

**How will my research information be used in the future?**

In the future, researchers at KUMC and at other locations might re-use the information from this study for other research. If that happens, information that could identify you will be removed first. You will not be asked if you agree to the future research that has identifiers removed.

**Who can I talk to about the study?**

Dr. Angela Martin or other members of the study team should answer all your questions before you sign this form. They will also tell you if they learn anything new that might affect your decision to stay in the study. You can talk to the researchers if you have any more questions, suggestions, concerns, or complaints. If you have questions about your rights as a research subject, or if you want to talk with someone who is not involved in the study, you may contact the KUMC Institutional Review Board at (913) 588-1240 or IRBhelp@kumc.edu.

## CONSENT

Dr. Martin or the research team has given you information about this research study. They have explained what will be done and how long it will take. They explained any inconvenience, discomfort or risks that may be experienced during this study.

By signing this form, you say that you freely and voluntarily consent to participate in this research study. You have read the information and had your questions answered.

***You will be given a signed copy of the consent form to keep for your records.***

_____
Print Participant's Name

_____ _____ _____
Signature of Participant Time Date

_____
Print Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date