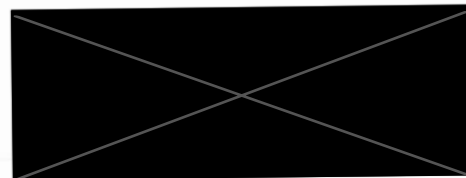


## Cover Page for Informed Consent

Official Study Title:	Kangaroo Care in the Operating Room
NCT Number:	NCT07223775
Document Date:	02/24/2022

## RESEARCH CONSENT FORM

**Kangaroo Care in the Operating Room**  
**Investigators: Angela Martin, MD and Meredith Gray, MD**  
**Contact Phone: 913-588-6287**



You are being invited to join a research study being done at the University of Kansas Medical Center (KUMC) by Angela Martin, MD and Meredith Gray, MD. Being in this study is optional. You can decide not to participate or stop at any time. Regardless of your decision, you will still get the same care from your health care team.

### **Why is this study being done?**

In skin-to-skin contact (also known as kangaroo care), the newborn infant is placed naked on the mother's bare chest at birth or soon afterwards. Skin-to-skin contact improves breastfeeding rates and helped babies adjust to the outside world.

It is standard practice at KU to place the infant immediately on the mother's chest after vaginal deliveries. However, after cesarean birth the baby is handed to pediatric nurses who bring the baby to the warmer for several minutes before determining if skin-to-skin contact is feasible.

We are doing this study to determine if placing the baby immediately on the mother's chest after a cesarean delivery (the way we do after vaginal deliveries) improves maternal satisfaction with the procedure.

### **What am I being asked to do?**

If you participate in our study, you are agreeing to either have your baby go to the warmer first (as is our standard practice) or have the baby placed immediately on your chest for skin-to-skin contact.

In the study, you do not get to choose which option of newborn care you receive. It will be a coin toss (also known as randomization) as to which option you are assigned.

If you do not participate in the study, you will receive the standard practice. After your baby is born by cesarean delivery, the pediatric nurses will evaluate the baby at the warmer for several minutes before determining if skin-to-skin contact is feasible.

### **Are there risks or discomforts to consider?**

Both maternal and infant vital signs are monitored during skin-to-skin contact. If either patient is unstable, then the baby will be handed off to pediatricians to allow for more supervised care of either patient.

### **Are there any benefits to joining the study?**

With immediate Skin-to-skin contact you may experience less pain and anxiety when the baby is on your chest. This intervention may improve your satisfaction with the cesarean delivery experience. There is no payment for participating in the study.

### **How will 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.

Your study information will be labeled with your research ID number. The study team will keep a separate list that matches your name to the research ID number. These steps will lessen the risk that your personal identity and information will be seen by others who shouldn't have it.

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 Drs. Angela Martin and Meredith Gray and the research team. The team may use any and 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.

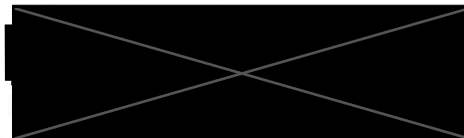
Your participation in this study and your study information may be put into the University of Kansas Health System electronic medical record and combined with your health information from your clinical care. The health system may use and share this information for other purposes described in the Notice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

Your permission to use and share your health information will not expire unless you cancel it. To cancel your permission, please write to Meredith Gray, MD. The mailing address is Meredith Gray, MD, 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 intervention. They are permitted to use and share information that was gathered before they received your cancellation.



### Consent

Please talk to the research team if you have any questions about joining the study. If you have questions about the rights of research participants, you may contact the KUMC Institutional Review Board at (913) 588-1240 or [IRBhelp@kumc.edu](mailto:IRBhelp@kumc.edu).

If you agree to join, please sign and date below. You will receive a signed copy of this form.

[Redacted signature line]

[Redacted signature line]

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