



INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Participant _____ HSC Approval Number 02-0898

Principal Investigator Spence, Kimberly, M.D. PI's Phone Number (314) 454-6148
Last First Credentials

Title of Project: Precursor Preference in Surfactant Synthesis of Newborns

NOTE: "You" refers to the participant.

You are invited to take part in a research study by Dr. Spence and/or colleagues because your child is intubated and on a ventilator.

Please ask for an explanation of any words you do not understand.

If you do not need treatment right now, you can take home an unsigned copy of this form. It will help you talk about the study with your family or friends before you decide to be in it.

1. Why is this study being done?

To study the production of surfactant, the material that helps babies breathe but is missing in premature babies. This is important because only about half of premature babies respond to surfactant replacement. This suggests that something else unrelated to not producing enough surfactant may be causing some of the breathing problems in premature infants.

2. What am I being asked to do? Your child's participation will involve:

(1) Subject Participation: Your child will receive a 24 hour infusion through their IV of sterile, non-radioactive, stable isotopes, a special form of fat and protein that are tagged so it can be detected in your baby's blood and lung fluid. These isotopes are harmless to your baby and will be administered through an IV that is already in place as part of his/her routine care. During the infusion, 5 blood samples of 1/10 of a teaspoon each (for a total of 1/2 teaspoon in 27 hours) will be collected from a tube that has been placed for blood drawing (as part of routine ICU care). If there is no indwelling catheter for blood draws, 2 to 3 samples will be collected at clinically indicated times. This will prevent extra sticks for study blood draws. In addition, the lung fluid that is obtained from suctioning that is done routinely while babies are on respirators will be saved for the next 2 weeks. At the end of 2 weeks, the study is over. Two weeks later, if your baby is still on a respirator and still has a blood drawing tube in place, we will speak with you about repeating the study. We will measure the levels of the special protein and fat in his/her blood and lung fluid.

(2) Participation Related to Research Only: The research procedures include the 24 hour infusion of the tagged fat and protein and drawing an extra 1/2 teaspoon of blood.

How long will I be in the study?

Your participation in this study is expected to last 2 weeks or until he/she is off the respirator, whichever comes first.

3. What are the Costs?

- (1) Standard of Care: Costs for standard care and procedures necessary for your child's problems are ordinarily paid for by your insurance provider.
- (2) Research Related: The costs of procedures performed solely for the research study (isotope preparations, lung fluid and blood sampling and analysis) are provided at no cost to you.
- (3) Payments to Participants: There will be no payment for participation in this research.

4. What are the Risks? There are certain risks and discomforts that may be associated with this research. They include:

- Research Related
Likely: None

Less likely: Your baby may require blood transfusions as part of his/her routine care. The amount of blood to be withdrawn for this study is small in comparison to that drawn routinely for his/her care. However, it may be enough to cause another blood transfusion. The unit of blood from which your baby receives the transfusion is dedicated to him/her so that there will not be any new risks from exposure to a different unit of blood.

Rare: Because of the severe nature of illness and need for procedures, over 20% of infants in the NICU experience a bloodstream infection. The isotope infusions are prepared in sterile fashion by pharmacists specially trained to make intravenous solutions, thus it would be extremely rare for the isotope infusion itself to cause a bloodstream infection.

Participation in this study may cause all or some of the side effects listed above. In addition, there is always the risk of developing previously unknown side effects.

The investigator is willing to discuss any questions you might have about these risks and discomforts.

Your child's data will be assigned a code number. A master list linking the code number and your identity will be kept separate from the research data. The master list will be kept in a locked file and only the principal investigator and designed members of the research team will have access to the master list. Every effort will be made to protect your research data. There is, however, always the possibility of a breach of confidentiality.

5. Are there Benefits to taking part in the study?

The possible benefits to your child and society from this research are: There will be no benefits to your child from this study. From this study, we may develop a better understanding of how surfactant is made and used in premature babies. This information may lead to better medical care for premature infants.

6. What other Options are there?

Your child's participation in this research study is voluntary. You may choose not to take part in this research study or you may withdraw your consent at any time. Your choice will not at any time affect the commitment of your health care providers to administer care. There will be no penalty or loss of benefits to which your child is otherwise entitled. There are no other alternatives for studying surfactant metabolism in babies.

7. What about Confidentiality?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study explained in this consent form.

In addition to health information that may be created by the study, the research team may access the following sources of your health information to conduct the study using direct and indirect identifiers.

The research team may share your information with:

- Government representatives (such as the Food and Drug Administration or the Office of Human Research Protections) to complete federal or state responsibilities
- Hospital or University representatives, to complete Hospital or University responsibilities
- Your primary care physician if a medical condition that needs urgent attention is discovered

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

All reasonable measures to protect the confidentiality of your child's records and your child's identity will be taken. Your child's identity will not be revealed in any publication that may result from this study. The confidentiality of all study related records will be maintained in accordance with State and Federal laws.

This study is sponsored by National Institutes of Health. Representatives of the sponsor will have access to your research and/or medical records for monitoring the study. The research team will also send study results to the sponsor. Information sent to the sponsor will not include personal identifiers. The sponsor is not required to abide by the HIPAA regulations, but agrees to protect the confidentiality of your information. The sponsor will not be using the data.

You will always have access to your medical record and you may request research data from the principal investigator.

You do not have to sign this form. Your participation in this study is voluntary. If you decide not to sign this form:

- It will not affect your treatment or the care given by your health provider.
- It will not affect your insurance payment or enrollment in any health plans.
- It will not affect any benefits to which you are entitled.
- You will not be allowed to take part in the study.

If you sign this form:

- It will never expire.
- You can later change your mind and not let the research team use or share your information (revoke your authorization).
 - To revoke your authorization, complete the withdrawal letter, found at <http://medicine.wustl.edu/~hsc/hipaa/>, or you may request that the Investigator send you a copy of the letter.

- If you revoke your authorization:
 - The research team may only use and share information already collected for the study.
 - Your information may still be used and shared if necessary for safety reasons.
 - You will not be allowed to continue to participate in the study.

Do you already have contact restrictions in place with WUMC?

Yes No

(Example – no calls at home, no messages left for you, etc.)

Please specify any contact restrictions you want to request for this study only.

8. Who do I call if I have Questions or Problems?

If you have any questions or concerns regarding this study, or if any problems arise, you may call Dr. Kimberly Spence at (314) 454-6148. You may also ask questions, state concerns regarding your rights as a research subject, or express any feelings of pressure to participate to Dr. Philip Ludbrook, Chairman of the University's Human Studies Committee, at (314) 633-7400 or (800) 438-0445. If you have questions or concerns about your privacy and the use of your PHI, please contact Joan Podleski, the University's Privacy Officer, at 866-747-4975.

- 9. Washington University investigators and their colleagues who provide services at Washington University Medical Center hospitals, and facilities recognize the importance of your (your child's) contribution to research studies that are trying to improve medical care. Washington University investigators and their staffs will try to reduce, control, and treat any complications from this research. If you feel that you are injured because of the study, please contact the Investigator and/or the Human Studies Committee Chairman from Item 8. Decisions about payment for medical treatment for injuries relating to your participation in research will be made by Washington University.
- 10. The Investigator will tell you about new information that may affect your decision to participate. The investigator may withdraw you from the study if necessary.
- 11. This research is not meant to diagnose or treat medical problems not specifically stated in the purpose of the research. Participation in a research study does not take the place of routine physical examinations or visits to your personal physician.

I have read this consent form and have been given the chance to ask questions. I will also be given a signed copy of this consent form for my records. I authorize the use of my PHI and give my permission to participate in the research described above, *titled:* Precursor Preference in Surfactant Synthesis of Newborns.

Signature Lines for Minors

Parent or legal guardian's signature Date
(if participant is less than 18 years
of age or not legally competent.)

Relationship to Child

Participant's Signature Date
*The HSC does not require participants to re-sign the
consent form unless a change is made; the investigator,
however, may choose to have participants sign annually.*

Signature of Second Parent Date
*Required when research involves greater than minimal
risk and there are no direct benefits to the child
(45CFR46.406) but it presents an opportunity to
understand, prevent, or alleviate a serious problem
affecting the health or welfare of children, unless one
parent is deceased, unknown, incompetent, or not
reasonably available, or when only one parent has legal
responsibility for the care and custody of the child.*

Signature of person providing Informed Consent Date
(If designee, see guideline [Who May Obtain Consent](#))

Thank you for your important contribution to research studies that are trying to improve medical care.

PARTICIPANT'S ASSENT

The doctor or nurse has told me what will happen if I choose to be in this study. I understand what they have said, and I understand that my parents and I may later change our minds and stop being in the study.

Signature of minor participant Date

ASSENT CONSIDERED INAPPROPRIATE

We believe that requiring the signature of the minor is not appropriate for the following reason(s):

Physician Date

Parent/Guardian Date

The Notice of Privacy Practices is a separate document. It describes the procedures used by WUMC to protect your information. If you have not already received the Notice of Privacy Practices, the research team will make one available to you.

Initial I have been offered a copy of the Notice of Privacy Practices.

This form is valid only if the Human Studies Committee's current stamp of approval is shown below.