

## **Frequently Asked Questions**

### **What is MOMS?**

MOMS, or Management of Myelomeningocele Study, is the name given to the multicenter research study of two approaches to the surgical management of infants with spina bifida. The study will compare surgery before birth (prenatal or fetal surgery) and surgery after birth (postnatal surgery). The study is funded by the National Institute of Child Health and Human Development (NICHD), a part of the National Institutes of Health (NIH), and is coordinated through the Biostatistics Center of the George Washington University in Rockville, Maryland. Surgery will be done at three MOMS Centers around the country: the University of California at San Francisco in San Francisco, California, The Children's Hospital of Philadelphia in Philadelphia, Pennsylvania and Vanderbilt University Medical Center in Nashville, Tennessee. It is a randomized study meaning that neither the study staff nor the study participants will be able to choose whether a given baby has surgery before or after birth. The chance of being assigned to either group is 50:50, like the chances of getting a heads or a tails when flipping a coin.

### **What are the advantages of participating in MOMS?**

You and your baby will be cared for by teams of doctors, nurses, social workers and other health-care personnel with a wealth of experience in managing high-risk pregnancies and treating infants with spina bifida. In addition, at the conclusion of the study doctors may learn if prenatal or postnatal surgery is better. This knowledge could lead to more effective treatment for all babies with spina bifida.

### **How do I find out more about the study?**

The Study Coordinator, who can be reached at (toll free) 1-866-ASK-MOMS (1-866-275-6667), will be happy to answer any questions you, your family or your doctor may have and can explain the study in more detail. If you wish to pursue enrollment in the study, the Coordinator can, with your permission, review your medical records to see if you qualify for a more in-depth assessment at one of the MOMS Centers.

### **What will be my expenses if I participate in the study?**

All travel, meal and lodging costs related to your participation in the study will be paid for, both for you and for your baby's father or another support person. There will not be any additional costs for prenatal care and delivery beyond those you would normally have given that you are carrying a baby with spina bifida. It may be that you do not have health insurance. For women who do have insurance, individual insurance policies vary. Costs you may be responsible for include co-payments and deductibles. The MOMS Center staff will work with your insurance company.

**What do I have to do to qualify for inclusion in the study?**

- In order to be eligible for the study:
- You must be at least 18 years of age.
- You must be a resident of the United States.
- You must be screened and enrolled by your 25th week of pregnancy.
- Your baby must have normal chromosomes (your doctor can test for this).
- The baby must have the Arnold Chiari II malformation of the brain as seen on a sonogram.
- Your baby's level of spina bifida must be at a level appropriate for prenatal surgery. The exact level and whether or not it qualifies for prenatal surgery will be determined at the in-depth screening visit conducted at the assigned MOMS Center.

**There are some things which will prevent your inclusion in the study:**

- Multifetal pregnancy such as twins or triplets
- Maternal insulin dependent diabetes
- Fetal abnormality not related to spina bifida
- Preterm labor in this pregnancy or a history of a short cervix
- Past history of early labor
- Maternal HIV or Hepatitis B because of the increased risk of infecting the baby during the surgery
- Maternal/fetal blood incompatibilities
- Conditions which would make surgery or anesthesia risky for the mother
- Abnormality of the uterus such as multiple large fibroids
- Inability to stay at or return to the MOMS Center as required by the study
- No available support person
- Obesity with a Body Mass Index (BMI) of  $\geq 35$  (Your doctor can check for this)
- Severe curvature of the baby's spine
- Placenta covering the opening of the womb (placenta previa)

**Who will have access to my medical records?**

We need to collect information about you and your baby in order to analyze the results of the study. The information will be available only to the study staff and any necessary agency such as the National Institute for Child Health and Human Development (NICHD). Just like any other hospital record, your study records may be inspected by federal regulatory agencies, state agencies and legally authorized parties. Should the results from the study be published, no information identifying you or your baby will be included.

**What happens if I change my mind about participating after I enroll in the study?**

Your participation in this study is completely voluntary. You are free to withdraw at any time. Withdrawal from the study will not impact the health care available to you. In the event that new information becomes available which may affect the risks or benefits associated with this study, you will be notified so that you can make an informed decision as to whether or not to continue your participation in this study.