



You Are Invited To Join A Study of Brain Development in the Fetus with Congenital Heart Disease with the Developing Brain Research Laboratory



Children's National.



We would like to invite eligible pregnant women to join an important study at Children's National Health System.

What is the study about? We are studying brain development during pregnancy in unborn babies with congenital heart disease. Most of these babies do not develop brain-related problems, but some do. In this study, we will gather information to help us identify future babies at risk for brain-related problems. This in turn will help us develop treatments that prevent such problems and ensure the best possible outcome for babies with congenital heart disease in the future.

Do I qualify for this study? If your baby's cardiologist determines that your baby has congenital heart disease, you and your baby could be eligible for this study. If you are unsure whether you qualify, you should ask your cardiologist or you can call us and we will check with your doctor.

What happens if I join the study? We will perform the following safe and painless studies:

Before your baby is born you will meet with us on two occasions at Children's National.

- We will take special "pictures" (or scans) of your baby's brain using MRI (magnetic resonance imaging).
- We will take pictures of your baby's heart using an echocardiogram
- We will ask you to provide a small sample of your saliva to measure stress hormones.
- We will ask you to provide us with a small sample of blood. The sample will be used to try and identify genetic markers that are different in babies with and without heart abnormalities that may be detected in the mother's blood during pregnancy.
- The appointments will be scheduled between 25-39 weeks of pregnancy.

After your baby is born we will meet with you and your baby on two occasions.

Once before and once after surgery:

- We will take MRI pictures of your baby's brain during natural sleep. This test may already be ordered by your baby's doctor as part of routine clinical care.
- We will perform an echocardiogram, which may also already be a part of your baby's clinical care.
- We will do a brief physical examination of your baby.
- We also will ask you questions about the medical history of you and your baby.
- We will ask you to consider contributing a DNA sample from your baby if their condition allows it by taking a small sample of their blood before and after surgery and by swabbing the inside of his or her cheek to collect cells. The blood will only be collected if it is part of your baby's routine standard care.

When your baby is 18 months old we will evaluate your baby to assess her/his development.

Joining this study will NOT:

- Harm your baby in any way
- Change the way your doctors manage your pregnancy or your baby
- Expose you or your baby to any experimental medicines or procedures
- Cost you or your insurance anything
- Expose you or your baby's identity to anyone else outside the study

How do I benefit from participation? We do not anticipate any direct benefit to you or your baby from participating in this study. Rather, any benefits would be to future babies. If we see anything unusual on the MRI, we will tell you and your doctor, with your written consent.

You will receive:

- Free parking during your visits to Children's National
- \$75 after each fetal MRI visit to compensate you for your time & travel expenses
- MRI pictures of your baby

I want to enroll, what do I do next?

**If you would like to hear more about this study, contact our clinical research team:
Phone: 202-476-3765 or Email: FetalBrain@ChildrensNational.org**