

FETAL HEART & BRAIN PROJECT



Study Purpose

The purpose of this research is to better understand brain development in babies diagnosed with congenital heart disease (CHD) during pregnancy.

CHD is the most common birth defect. Yet, much remains unknown about the effect of CHD on brain development. This research aims to clarify the impact of CHD on the fetal brain. This study also aims to assess whether any fetal brain differences relate to neurologic and developmental outcomes after birth. Through this research, we hope to ultimately improve neurologic and developmental outcomes in children with CHD.

What will be done?

If you agree to participate in this research study, you will have two magnet resonance imaging (MRI) scans during your pregnancy and a follow-up visit when your toddler is 2 years old.

During Pregnancy:

- » The first MRI will be between 18 and 30 weeks.
- » The second MRI will be between 36 and 40 weeks.
- » Each scan will take up to 60 minutes.

After Birth:

- » Your child will meet with a neurologist and developmental psychologist for a follow-up visit to assess your child's neurological development at 2 years of age.
- » A wide range of language, motor and cognitive skills will be assessed during this visit.

You will receive compensation of \$100 for each research-only MRI scan. You will receive a \$50 Amazon gift card and a parking voucher for the two-year follow-up visit.

The research study will take place at:

Boston Children's Hospital
300 Longwood Avenue, Boston, MA 02115



About MRI

MRI is generally considered a harmless imaging technique because it does not involve exposure to ionizing radiation such as x-rays. MRI uses a powerful magnet to make images. Therefore, people with metal implants should not have an MRI. You will be screened for such objects prior to entrance to the magnet room.

The potential risks of MRI are easy to avoid and very rarely cause harm when MRI is performed within established guidelines by trained staff. We will use techniques to ensure that exposure to the magnetic field will not lead to an increase in fetal temperature that might be harmful. There are no known risks to the fetus when MRI is performed with the techniques that will be used in this study. These MRI techniques have been evaluated and tested in adults, children, prematurely born infants and fetuses. We will use techniques similar to those used for clinical MRI scans in pregnant women.

All the data collected from the MRI scans and the neurodevelopmental visit will be handled with confidentiality in accordance with applicable laws and hospital policies.

What are the benefits for me?

- » You will receive the results of each MRI scan and a CD of images of your fetus. The scans for this study are for research purposes only, and are not meant to find medical problems or abnormalities. However, if any abnormalities are noted, you will be notified and encouraged to see your physician.
- » You will receive the results of your child's developmental testing and recommendations from the study's development psychologist.
- » You will be part of a study that has the potential to help improve counseling, early intervention, and treatment for future families whose babies are diagnosed with congenital heart disease.

CONTACT US TO LEARN MORE

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