Study of Fetal Chromosomal Aneuploidy and Abnormality
Division: Genetics
Principal Investigators: Brad Tinkle, MD, PhD

What is the purpose of the study?
The purpose of this study is to collect blood samples from pregnant women who have a baby with a known chromosomal aneuploidy (an abnormal number of chromosomes), such as Down syndrome (Trisomy 21), Edwards syndrome (Trisomy 18) or Patau syndrome (Trisomy 13) or other known chromosomal abnormality for further development and optimization of a noninvasive prenatal test. The test can detect an abnormal amount of maternal and fetal DNA in an expectant mother’s blood sample (known as circulating cell free DNA).

Who is eligible to participate in the study?
Women who are pregnant with a baby with a known chromosomal aneuploidy or abnormality may be eligible to participate. About 300 subjects will be enrolled in this study, obtained from sites in the United States and Canada. At this site, we will enroll about 10 individuals.

What does the study involve?
Participants in this study have the option of having their blood drawn between 1 and 5 times for the study, as frequent as once a month, between the 8th and 36th week of pregnancy. Researchers will compare the results of the tests done as part of this study to results of certain tests that pregnant women routinely have as part of their regular health care.

What are the benefits?
There are no direct benefits to subjects from participation in this study. Information gained in the study may help in the development of innovative technology, products and diagnostic tests that may help others.

What are the risks?
There are minimal risks to participating in this study. Risks of having blood drawn include some discomfort, bruising and rarely infection.

Is there any compensation for participating?
Subjects will be compensated with a $25.00 gift card for travel and visit time for the completion of each research visit. Therefore, those who complete a total of 5 research visits will receive 5 $25.00 gift cards with a total value of $125.00.

How will I get more information about the study?
Interested parents will discuss the study with a member of the research team and will be given a parent permission/consent form that further explains all of the details of the study. Study procedures will not be started until the parent(s) fully understands what is involved in the study and has signed a parent permission/consent form.

Status: Recruiting
Site(s): Advocate Children’s Hospital – Oak Lawn and Park Ridge campuses

Who should I contact for more information?
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