What will a patient have to do to enter the study?

The mother of the low birth weight infant will be required to sign the informed consent which grants her permission to be in the study. The informed consent describes the study and explains that you and your infant are being asked to volunteer for this research study.

Can you leave the study?

You and your infant have the right to leave the study at any time. If you do decide to leave the study, neither you nor your infant's healthcare will be negatively affected. If you leave the study before the final planned study visit, the study doctor may ask you to have a final visit. The study doctors could also ask you to leave the study if they believe it is in you or your infant's best interest, or if you are unable to complete what is needed for the study.

What happens if you or your infant is sent home from the hospital?

When you are sent home, your infant will continue in the study until she/he is sent home. If your infant is sent home from the hospital before reaching 60 days in the study, your infant is no longer in the study. You will remain in the study as long as your infant is in the study.

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What is the study team's responsibility if someone agrees to be in the study?

The study team will check your infant for 60 days or until she/he is sent home, whichever comes first. Medical records will be checked regularly and kept private to the extent allowed by the law. A study ID number will be used rather than you or your infant's name on study records to protect your privacy. Blood that is left over from regularly collected tests will be saved in the hospital's laboratory and used for CMV testing instead of drawing it separately (for the study) from your infant.

Who will make sure that the study is done right?

Several agencies and groups regularly check how the study is being done, and these include: The National Institutes of Health, Emory University Institutional Review Board, and a Medical Safety Monitor Review Board.

Why be in the TT-CMV study?

There is no direct benefit to you or your infant as a result of being in this study since we are just observing both you and your infant. The best reason to volunteer for the TT-CMV study is to be a part of a clinical study designed to provide information about how often CMV is spread to low birth weight infants either through breast milk or through transfusion. The study results may be used to help patients in the future and/or lower the spread of CMV.

Principal Investigator: **Cassandra D Josephson, MD**

Emory University Midtown Hospital

Study Nurse: Lorie A Click, BSN, MN, MPH
E-mail: lclick@emory.edu
Phone: 404-276-1063

Site Investigator: Cassandra D Josephson, MD

Prevention of transfusion-transmitted Cytomegalovirus (CMV) in low birth weight infants.

A National Institutes of Health Funded Research Study

INFORMATION FOR PARENTS & FAMILIES

1.

What is Cytomegalovirus (CMV)?

CMV is a virus that can cause serious illness and/or death in premature infants. Mothers who carry the virus can spread it to their infant in the womb, during birth or in their breast milk. It is common to find CMV in normal healthy people who donate their blood. Another way the virus can spread is through a transfusion of blood from a person who is healthy but carries the CMV virus in their blood, this is called being "CMV positive".

What is this study about?

This study is being done to observe or "watch" mothers and their premature infants to see if the spread of this virus can be reduced by transfusing blood that has no virus (CMV negative), or by using CMV negative blood *plus* using filters that sift out the virus in the blood, making it "CMV safe".

The purpose of this study is to see how well these two ways of making blood "safe" lowers the spread of CMV in premature infants. We also want to describe what happens to premature infants who get CMV negative blood that has been filtered, but still develop CMV infection.

Who can be in this study?

Mothers and their premature low birth weight infants.

2.

How long will you and your infant be observed in the study?

You and your premature infant could be in the study for up to 60 days. When your infant goes home (discharged) either before or at 60 days, this will end the study for your infant.

What will happen during the study?

Your blood will be drawn before or shortly after your infant's birth. If your blood test is negative for CMV, we will draw your blood sample once more when your infant finishes the study to see if you have CMV in your blood. If you choose to breast feed, samples of your breast milk will be collected at specific times, frozen and stored for CMV testing later. We will review your medical history about your pregnancy and any illnesses you have been (or are being) treated for and any medications you may be taking (or have taken) during your pregnancy.

Blood **will not** be directly taken from your infant for this study. We will collect and test for CMV in your infant from the blood left over that is taken for other tests routinely done. Your infant will be tested for CMV in the urine and blood on the first day of life and at specific times during the study. If your infant receives a transfusion or shows signs of CMV infection, more CMV testing will be done. Your infant's medical record will also be looked at during the study for any difficulties your infant may develop as a result of the premature birth, and any medications being given to your infant.

3.

Who is doing the study?

The members of the study team are the study doctors and the study nurses. Members of the study team are specialists in transfusion, neonatology (care of newborn infants), and research.

What are the risks of being in this study?

There is nothing about your or your infant's medical condition that will get worse as a result of you and your infant being in this study. Whether your infant develops CMV or not, is not related to being in the study. The risks related to drawing blood with a needle from the mother's vein are minor pain or discomfort, infection, and rarely, fainting occurs. Should any of these risks occur, you will receive treatment for them. Blood **will not** be drawn from your infant specifically for this study; all other blood collections are part of your infant's routine medical care.

What are the costs?

There are no extra costs to you or your insurance if you decide that you and your infant will be in the study. All tests done specifically for this study, including blood, urine and breast milk testing are paid for by the Sponsor. You will not be paid for either you or your infant being in this study.