



Parental Consent Form

A Pilot Study for Newborn Screening of Severe Combined Immunodeficiency
Sponsored by a grant from The Centers for Disease Control and Prevention

How Your Child and Family Can Help

As you look forward to a healthy future with your new baby, you will be glad to know that children born in Texas benefit from a state program called Newborn Screening. This program screens for many treatable disorders in babies. In an effort to improve the health of children, your baby has the chance to assist in a study for Severe Combined Immunodeficiency Disorder, or SCID. SCID is a genetic disorder that although rare, if left untreated can cause death. Your baby is considered a possible participant since he/she lives in the State of Texas, and will already be having the Newborn Screen performed. The Newborn Screen requires a few drops of blood from your baby's heel, but no extra cost or blood will be needed for your baby to help in this study. The laboratory test for SCID can be done with the same sample that will be used for the Newborn Screen.

The Study

The purpose of this study is to evaluate a screening test for identifying SCID in babies and to find out how many children in Texas may be born with this life threatening condition. Babies who have this condition often show no sign of illness at birth, but because SCID prevents the baby's ability to fight infections, most will unfortunately die within the first year of life. However, if SCID is detected early, treatment is available to allow for a normal healthy life. Because SCID is a rare condition, there are still many unanswered questions. The State of Texas requires two separate newborn screens; the first sample is taken at 24 - 48 hours after birth and the second one is taken from babies at 1 - 2 weeks of age. Screening for SCID may also find babies with other types of immune problems. By reading and signing this form, you will allow the Texas Newborn Screening Laboratory to do an extra test for this rare disorder on your baby's newborn screen samples.

Benefits and Risks

The most important benefit for your baby is that if your baby does have SCID, he/she will have the earliest opportunity for detection. The testing for this study has no added medical risks for your child. If the screen results are not normal, your baby's doctor and a pediatric immunologist will be notified and further testing on your baby may be required. This process may cause you to worry, even if it turns out that your baby does not have SCID. Remember, SCID is rare; therefore the chances of your baby having it are very low. Also, keep in mind that with any screening test there is a small possibility that this disorder might not be identified by this test.

Another benefit may include your own satisfaction in knowing that you are helping to answer important questions that may help other babies.

Confidentiality

Records of this study will be kept confidential. Part of the specimen may be tested by another laboratory in the University of Massachusetts, however all identifying information will be removed.

If you decide to allow your baby to participate, you are free to withdraw your child from this research study at any time. Your decision whether or not to allow your child to participate will not affect any testing done with your baby's current Newborn Screen. Please ask any questions that you have before signing this form. If you have any questions later, you may contact Susan Tanksley, Ph.D. or Rachel Lee, Ph.D. in the Department of State Health Services (DSHS) Newborn Screening Laboratory at 512-458-7158. If you have any questions concerning your child's rights as a research subject, you can call the DSHS Institutional Review Board at 1-888-777-5037.

Last Name of Baby (Printed) _____ Baby Date of Birth _____

Specimen Kit Serial ID Number _____

Name of Parent/Legal Guardian (Printed) _____

Signature of Parent/Legal Guardian _____ Date _____

Printed Name and Title of Person Obtaining Consent _____

Signature of Person Obtaining Consent _____ Date _____

