

HIFI CONSENT FORM (Full Study)

Title: A study to compare high frequency mechanical ventilation and standard mechanical ventilation in newborn babies.

We are studying a new breathing machine or ventilator for newborn babies. This new method is called high frequency ventilation and we think it may work better than the standard machines in use now. This study is being done with other hospitals for newborns in the United States and Canada and is being paid for by the National Institutes of Health. Your newborn baby has been chosen because he/she has a breathing problem and needs one of the machines to help him/her breathe.

This study will compare the high frequency ventilators to the standard breathing machines. The type of machine your baby receives will be decided randomly (by chance). Your baby will be treated with that machine for as long as necessary. However, if your baby is not doing well, the other machine will be tried. Except for the breathing machine, your baby will receive the same standard care and other tests as other babies treated in this center. There will be no additional medicines, blood tests or costs. All babies in this study will be examined at nine and eighteen months of age to look for lung problems and to see how well they are growing. These exams are similar to the type of care given to other babies who needed intensive care. The follow-up exam will not add any expense. While your baby may not benefit directly from being in this study, the final results of this research will benefit other babies by showing whether or not the high frequency ventilators are better than standard breathing machines.

The standard breathing machines push air into the lungs at a normal breathing rate, about 30 to 60 times a minute for babies. The high frequency ventilators push a much smaller breath into the lungs at a very high rate, around 900 times a minute (15 times a second). High frequency ventilation has been used in a number of babies and the initial short term results have been encouraging. The direct risks with the high frequency machine are thought to be the same as the risks with the standard breathing machines. These risks include possible damage to the lungs, such as leaks of air (pneumothorax) and long term breathing

problems (bronchopulmonary dysplasia or BPD). The smaller breath used in high frequency ventilation may decrease these risks. Since high frequency ventilation is a relatively new form of treatment, there may be other risks that are not known at this time.

Records on your baby will be kept completely confidential although they may be shared with the U.S. Food and Drug Administration.

Taking part in this study is entirely voluntary. You may refuse to take part in the study or take away your consent at any time during the study and we will continue to give your baby the best medical and nursing care that we can. The _____ will not repay you for injuries that happen because of your baby being in this study. You may call _____ for more information about this or to report problems that come up because of this study.

SUBJECTS STATEMENT

Dr. _____ and/or his coworkers have explained this study to me and answered my questions. I understand the above information and agree to have my baby in the study. If I have any more questions or if I have problems that come up because of this study, I can contact Dr. _____ of his coworker at _____.

Parent/Guardian _____ Date _____

Witness _____