Information and Authorization Consent Form

Study Title: Audit of neurodevelopmental outcomes at three years of age in very preterm infants (<31 weeks gestational age) or very low birth weight (<1500 grams) admitted to single patient rooms compared to open bay neonatal intensive care unit (NICU)

Researchers: Mike Vincer, MD (Principal Investigator) Affiliation and institution

Funding: Unfunded

Introduction and purpose:

This consent form is a request to use data collected during your child’s attendance in the Perinatal Follow-Up Program. Although the data is collected as part of your child’s ongoing care, we seek to combine your child’s data with that of other children to help us understand the long-term effects, if any, of your child’s early care and placement in the Neonatal Intensive Care Unit.

When your child was born, he/she was admitted to the Neonatal Intensive Care Unit at a time when the Neonatal Intensive Care Unit had both single patient spaces (one baby or siblings in one room) and ‘open bay’ spaces (several babies in one area). Babies were placed according to a formal ‘fair patient allocation system’ in which placement was determined partly by a chance-directed schedule and partly by the existing workload on the area. There is some uncertainty about the best way (single-patient vs open bay) to provide care and its effect on the subsequent development of the children. By comparing our rates of successful developmental outcomes in these two groups, we hope to shed some light on this issue.

You have previously consented to have your child attend the Perinatal Follow-Up Program. During that process we undertook to inform you of particular kinds of research which might result from attending the Perinatal Follow-Up Program. The current request addresses the specific research question of long-term outcome of the single patient room compared with the open bay type of Neonatal Intensive Care Unit. Your allowing us to use your child’s data for this purpose is entirely voluntary (your choice) and does not affect your child’s attendance in the Perinatal Follow-Up Program or participation in other research projects. Informed consent starts with the initial contact about the study and continues until the end of the study.

How will the researchers do the study?
We will collect data from your baby’s chart which describes your baby’s placement on admission, his/her progress in the Neonatal Intensive Care Unit, including clinical findings and diagnostic tests, and the findings in the Perinatal Follow-Up Program.

What will I/my child be asked to do?
You will give your permission to include data already collected to be used in this study. After combining your child’s data with that of other children, your child’s identity will not be available for this study or
revealed in reports. The data will be used to help our understanding of the effects of placement in the ward on subsequent health and development, and this information will be prepared for research publication and dissemination.

**What are the burden, harms, and potential harms?**
This study does not result in changes to your child’s care. There are no harms anticipated as a result of your participation in this study.

**What are the possible benefits?**
There are no direct benefits to your child as a result of participating in this study.

**How will I be informed of study results?**
Study results will be available after publication, estimated to be some time in 2023. Please provide your email address if you wish to receive this summary.

**How will my child’s privacy be protected?**
All study records will be stored in a locked and secure area in the Perinatal Follow-Up Program. Electronic data will be kept on the IWK Health Centre secure server. Study records will not be destroyed.

**What if I have study questions or problems?**
You have the right to ask questions about this study at any time. You can call the Perinatal Follow-Up Program at (902) 470-6737 Monday to Friday from 9:00 AM to 4:00 PM or you can email Dr. Mike Vincer anytime at michael.vincer@iwk.nshealth.ca

**What are my research rights?**
You are free to withdraw from the study at any time without affecting the care you or your child will receive from the IWK Health Centre. Your signature on this form only indicates that you have understood to your satisfaction the information regarding you and your child’s participation in the study and that you agree to participate and to allow your child to participate. In no way does this waive you or your child’s legal rights nor release the investigator, the researcher, the study sponsor, or involved institutions from their legal and professional responsibilities. If you have any questions at any time during or after the study about research in general you may contact the Research Office of the IWK Health Centre at (902) 470-7879, Monday to Friday between 9:00 AM to 5:00 PM.
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PARENTAL OR GUARDIAN AUTHORIZATION - I have read or had read to me this Information and Authorization Form and have had the opportunity to ask questions which have been answered to my satisfaction before signing my name. I understand the nature of the study and I understand the potential risks. I understand that I have the right to withdraw my child from the study at any time. I have been offered a copy of the Information and Authorization letter for future reference. I freely agree to participate in this research study and to allow my child to participate in this research study.

Name of Child (Print) __________________________ Name of Parent/Guardian (Print) __________________________

Date: ____________ Time: __________

Parent signature

STATEMENT BY PERSON PROVIDING INFORMATION ON THE STUDY AND OBTAINING CONSENT & AUTHORIZATION
I have explained the nature and demands of the research study and judge that the Parent/Guardian/Participant named above understands the nature and demands of the study. I have explained the nature of the consent and authorization process to the participant and judge that they understand that participation is voluntary and that they/their child may withdraw at any time from participating.

Name (Print): __________________________ Position __________________________

Signature: __________________________ Date: ____________ Time: __________

Note to parents/guardians: If you would like to be notified of the results of this study, please provide your e-mail address:

E-mail address: __________________________

14/08/2018