IRB Protocol Proposal

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Project Title: Management and Outcome of Very Low Birthweight Infants with Congenital Heart Disease in a Cardiac NICU

A. Study Purpose and Rationale

Infants with congenital heart defects are more likely to have a low birthweight either due to prematurity and/or they are small for gestational age. There is little data, however, about the outcomes of very low birth weight infants (<1000g) with congenital heart defects, making it difficult to create best practice or standard of care guidelines. As the only Children's Hospital in the country with a dedicated Cardiac NICU, we have a large and unique set of data. Very low birth weight (VLBW) infants have the potential for many complications even without cardiac defects. Some of these include retinopathy of prematurity, intracranial hemorrhage, bronchopulmonary dysplasia, necrotizing enterocolitis and infections. Many of these can be further complicated by poor growth and oxygen requirements both before and after surgery, as well as complications secondary to cardiopulmonary bypass. Surgical management frequently taken is to allow infants to grow prior to intervention, however, surgical advances now allow for intervention earlier on smaller infants, which in some studies has suggested may decrease some of the morbidities associated with cardiac surgery in VLBW infants. By investigating risk factors and outcomes in this population, this study could inform decision making regarding optimal time/weight for surgery as well as many other potential factors involved in the care of these infants.

B. Study Design and Statistical Analysis

We plan to conduct a retrospective case series encompassing data from the Columbia Cardiac NICU for infants with Congenital Heart Disease who were born weighing <1000g. We intend to look for trends in complications and successful vs. unsuccessful outcomes that could standardize the care of VLBW infants with Congenital Heart Disease to be used both in our institution and around the country. One such measurement includes outcomes related to time to surgery and weight at time of surgery.

Possible extensions of the study could include comparison of data to matched controls in the Columbia NICU prior to the establishment of a dedicated Cardiac NICU.

C. Study Procedure

No procedures are being performed as a part of this study

D. Study Drugs

No drugs or medications are being administered as part of this study

E. Medical Device

No medical devices are being used as part of this study

F. Study Questionnaires

No questionnaires are being used as part of this study

G. Study Subjects

Study subjects are infants who weighed less than 1000g at birth and were admitted to the Cardiac NICU at Columbia for Congenital Heart Disease.

H. Recruitment of Subjects

There will be no recruitment of subjects for this study

I. Confidentiality of Study Data

Information used in this study will be obtained from Columbia's medical records. All information will be deidentified and kept on a secure server that is encrypted and password protected.

J. Potential Conflict of Interest

There are no potential conflicts of interest with any members of the study team

K. Location of the Study

Data will be obtained from the medical record system and Columbia Medical Center. Data analysis will take place on the Morgan Stanley Children's Hospital campus.

L. Potential Risks

Given that this is a retrospective review of data, this study has minimal risk and should be exempt from IRB review.

M. Potential Benefits

There are no potential benefits to subject participants, however information obtained from this study could inform medical decision making in the future.

N. Alternative Therapies
There are no alternative therapies to this study because there are no interventions being studied.

O. Compensation of Subjects

Subjects of this study will not be compensated in any way.

P. Costs to Subject

There will be no costs to subjects participating in this study

Q. Minors as Research Subjects

All subjects studied in this study are minors, however as it is a retrospective review of data this study poses minimal risk to these subjects.

R. Radiation of Radioactive Substances

There will be no radiation or radioactive substances used as part of this study

S. References

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