1 PURPOSE

1.1 To provide guidelines for the appropriate utilization of Informed Consent with regard to Women's and Newborn's participation in more than one Research project.

1.2 This guidance pertains to subjects or patients who are or have been admitted to Sharp Mary Birch Hospital for Women and Newborns (SMBHWN).

1.3 The guidance begins when the subject(s) meet criteria for more than one research study.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 DEFINITIONS

3.1 Research Informed Consent: A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, along with documentation thereof. This involves a process of information exchange about the trial objectives, potential benefits, risks, alternative therapies available, the subject's rights and responsibilities, and an opportunity to ask questions. The consent must be signed by the patient (or parent/authorized legal guardian) and a copy given to the patient.

4 POLICY STATEMENT

4.1 Clinical trials at SMBHWN present special challenges since they involve the vulnerable populations of pregnant women and newborns. We study disease processes specific to term and preterm newborns who possess unique pathophysiology and can only be studied in this population. Potentially important advances in therapies are needed that could provide great benefit with limited risks.

4.2 There may be justified exceptions to the general principle of participating concurrently in more than one clinical trial. This will be done without compromising the well-being of neonatal intensive care unit (NICU) patients participating in clinical studies.

4.2.1 Protocols undergo careful development with input from experts in neonatal and/or maternal-fetal medicine.

4.2.2 Studies are designed to ensure quality, highest benefit and shield from undue risks such as limiting blood draws and timing with routine procedures.

4.2.3 Consideration is given to subject population, gestational age (GA), type of study, timing of interventions, efficacy and safety concerns.

4.2.4 All Informed Consents and Protocols will have been reviewed and approved by Sharp HealthCare IRB or acceptable research ethics committee.

4.2.5 NICU subjects are closely monitored in an inpatient environment.

4.2.6 Research personnel meet all requirements of Sharp IRB policies.

4.2.7 Those conducting the study are properly trained and experienced in this population.

4.2.8 All participants are informed to the fullest extent possible in language they are able to understand. Parents or Authorized Legal Representatives provide informed consents for newborns.

4.2.9 Participants may decline to participate or withdraw from the study at any time. Some circumstances may require that withdrawal be done gradually for safety concerns.

5 RESPONSIBILITIES

5.1 Principal Investigators, research team staff, and the Neonatal Research Institute (NRI) staff members carry out these procedures.

6 PROCEDURE

6.1 Consideration will be given to the number of studies in each gestational age, type of study, primary and secondary endpoints.

6.2 All studies at SMBHWN with overlapping eligibility will undergo review by the Neonatal Research Institute (NRI) for possible concurrent enrollment.

6.3 Investigators will devise a plan for approaching subjects for more than one study. In most cases the parents will not be approached more than twice; however, there may be exceptions depending on timing of the consent, type of study and parent interest.

6.4 If applicable, approval must be obtained from the sponsor or primary investigators for co-enrollment in each study.

6.5 Documentation of co-enrollment agreement will be stored with regulatory documents.

7 MATERIALS

7.1 None

8 REFERENCES

8.1 ICH E8 Guideline .3.2.2.1

8.2 ICH E11 Guideline

This document is available on www.sharp.com/research, IRBANA or by contacting research@sharp.com.