

# Newborn Critical Care Center (NCCC) Clinical Guidelines

## Informed Consent Guidelines

### PURPOSE

The aim of the informed consent process is to offer parents/legal guardians education and involvement in medical decision making for their child. In addition, parental perspectives and choices that are influenced by family values, beliefs and cultural backgrounds are incorporated into care planning and delivery. This process demands that physicians and others on the medical team engage in on-going conversations with parents to establish and confirm mutually agreed upon goals, to discuss the benefits and potential harms of treatments, and to allow parents to participate in decision making to the extent they choose.

### RATIONALE

In the NCCC, routine therapies are both highly beneficial and fraught with great risk. The risk/benefit ratio for each infant is continuously weighed, adjusted, and acted on. Every effort will be made to inform and consent families regarding procedures in a timely manner. Ideally, these discussions will begin in an anticipatory manner with prenatal counseling and continue following delivery and throughout the hospitalization.

A family centered care approach involves information sharing with parents and allowing for their participation and collaboration in the care of their infant. Complete and accurate information is shared with parents in a timely and frequent manner. Dignity and respect are provided to parents by honoring their perspectives and choices that are influenced by their values, beliefs and cultural background.

### GUIDELINES

#### **1. *Prior informed consent with parental signature:***

This formal process should be reserved only for those instances in which it is mandated by law or UNC Hospital policy:

- Blood product transfusions (includes albumin and IVIG)
- Surgical procedures
- Back transport of an infant to another hospital by UNC Air Care
- Research protocols

#### **2. *Verbal consent with documentation in the medical record for procedures:***

Verbal consent should be obtained prior to performing a procedure unless the procedure is conducted emergently. Family consent for procedures should be documented in the procedure note. For procedures that are urgent but not emergent, an attempt should be made to contact the family, but treatment should not be withheld if timely consent cannot be obtained.

Specifically, treatment should not be delayed for the purpose of obtaining consent if the delay will result in significant risk to the infant. For example, attempt should be made to obtain consent for lumbar punctures. However, performance of the procedure and treatment with antibiotics should proceed without consent if the family cannot be contacted in a timely manner. In these circumstance, the justification for proceeding and a description of attempts to contact the family should be included in the procedure note.

### **3. On-going discussions of the infant's condition and care:**

This category of informed consent consists of discussion/education that begins on admission and continues throughout an infant's stay. It also covers medical decision-making about the goals and potential harms of non-routine treatments with unclear risk/benefit ratios. In practice, an attending neonatologist, fellow, nurse practitioner and/or resident should have on-going discussions with parents about their child's diagnoses, prognoses, and management. The aim of these discussions is to seek parental agreement with significant details of a treatment plan that accords with the mutual goal of serving the child's best interests. Benefits, risks and available alternative treatments (including non-treatment when appropriate) should be discussed. Conversations about treatments with unclear risk/benefit ratio (e.g., postnatal steroids for BPD) should precede the initiation of such treatments when possible, to make sure that parents' values and wishes are elicited and incorporated.

Family discussions should be noted in the medical record, with the degree of detail to be determined by the attending, fellow, or nurse practitioner depending upon the level of decision making that has occurred and the perceived medical and legal need for recording specific details. In particular, conversations about whether to withhold or withdraw life-sustaining treatment should be carefully recorded in the medical record as an advanced care planning note.

#### **Notes:**

1. Legal mechanisms are available to seek treatment authority if parents are refusing treatments that appear to be clearly in their child's best interests. The existence and use of such mechanisms should be explained to parents before any legal action is taken.
  - a. During the business day, UNC Hospitals Legal & Risk Management Department can be reached at (984) 974-3041.
  - b. After business hours, please use pager number 216-0813 or call the hospital operator and ask for the attorney on call.
2. Parents are given the opportunity to refuse recommended vaccines (see [Immunization Guidelines](#)). If parents refuse the AAP recommended vaccine schedule, every effort will be made to educate them on the importance of vaccines and continuing an open dialogue on this issue with their pediatrician. All discussions regarding these discussions must to be carefully documented in the medical record.
3. If phone consent is obtained for items requiring written consent, a second provider should confirm consent with the family and sign as a witness on the written consent form.

#### **References:**

French, KB. [Care of Extremely Small Premature Infants in the Neonatal Intensive Care Unit: A Parent's Perspective](#). Clin. Perinatol 44(2017) 275 – 282.