

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. As a result, a formal, written informed consent process that takes place prior to each procedure/intervention is not practical in this setting and of limited usefulness. In addition, by setting apart specific procedures and activities as warranting special discussions and signatures, they are dissociated from the context of an infant's overall care, potentially distorting parents' perceptions.

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 is 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
- Research protocols

2. *On-going discussions of the infant's condition and care with documentation in the medical record:*

This category of informed consent consists of discussion/education that begins on admission and continues throughout an infant's stay. It covers routine care in the unit and serves as the primary means of establishing and confirming mutually agreed-upon goals for treatment, i.e., "implied consent." 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, some instances of percutaneous central line placement) 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.

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.

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.