

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 beneficial and carry risk. The risk/benefit ratio for each infant is continuously weighed, adjusted, and acted upon. Every effort will be made to inform and consent families regarding procedures in a timely manner. Ideally, these discussions will begin with prenatal counseling and continue throughout the hospitalization.

Family centered care involves collaboration with parents and allowing for their participation 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

There are three common scenarios, under which informed consent is obtained in the NCCC, outlined as follows:

1. *Prior informed consent (with parental signature):*

This formal process should be used in instances that are mandated by law or UNC Hospital policy:

1. Blood product transfusions (includes albumin and IVIG)
2. All operations and other invasive diagnostic or therapeutic procedures involving more than minimal risk
3. Back transport of an infant to another hospital by UNC Air Care
4. Research protocols

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.

2. *Verbal consent (with documentation in the medical record):*

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, providers should 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 circumstances, the justification for proceeding with the procedure and a description of attempts to contact the family should be included in the procedure note.

3. Emergency Procedures (without prior consent)²

Physicians may render treatment (other than surgical treatment) without first obtaining the consent of an authorized representative if:

1. Family cannot be located or contacted
2. The necessity for immediate treatment is so apparent that any effort to secure approval would delay the treatment and endanger the life of the patient
3. An effort to contact the family would result in a delay that would seriously worsen the patient's condition
4. The family refuses to consent to a procedure, and the necessity for immediate treatment is so apparent that the delay required to obtain a court order would endanger the life or seriously worsen the patient's physical condition

Before treatment the attending physician shall obtain and document the opinion of another attending physician that such treatment is necessary to prevent immediate harm to the minor.

Who can give consent?

Informed consent for minors is obtained from the patient's authorized representative. While authorized representatives are often the patient's parents, each situation is unique, and the authorizing representative should be identified early in the hospitalization. Individualized plans can be made in conjunction with the patient's family, the medical team, social work team, and legal team.

It is important to differentiate between custodial rights (taking parental responsibility in care) and medical decision-making rights. Parents might retain medical decision-making rights, even if they do not possess custodial rights in certain situations.

Given the complexity of individual situations in the NCCC (ex: surrogacy, adoption, incarceration, etc), if questions arise regarding the patient's authorized representative, please contact the legal team:

1. During the business day, UNC Hospitals Legal & Risk Management Department can be reached at (984) 974-3041.
2. After business hours, please use the pager number listed in myUNC Health Directory or call the hospital operator and ask for the attorney on call.

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. For procedures, an informed consent discussion between the authorized representative and the provider performing the procedure or their designee should involve a thorough description of the risks, benefits and alternatives of the procedure, The informed consent discussion must be documented in the medical record.
2. During the business day, UNC Hospitals Legal & Risk Management Department can be reached at (984) 974-3041. After business hours, please use the pager number listed in myUNC Health Directory or call the hospital operator and ask for the UNCMC -Risk/Legal on call pager.
3. Parents are given the opportunity to refuse recommended vaccines. 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 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.

Treatment of Minors, UNC Health PolicySTAT ID16848739 <https://unhealthcare-uncmc.policystat.com/policy/16848739/latest/>

Informed Consent, UNC Health PolicySTAT <https://unhealthcare-uncmc.policystat.com/policy/15904269/latest>