

10A NCAC 13B .5503 INFORMED CHOICE

(a) The potential donor must be free to make an informed independent decision, which has been termed informed choice. Informed choice addresses the decision process of the potential donor as he or she determines whether or not to donate. Informed choice has several aspects. First, the potential donor must know he or she has a choice, meaning he or she can freely decide either to donate or not to donate an organ. Second, the potential donor must be aware of both the risks and benefits of donation. The potential donor must be able to weigh the positive aspects of the donation as well as take into account the technical aspects such as the surgery, recovery, financial impact and any unexpected but potential consequences that may result such as a change in the patient's life, health, insurability, employment or emotional stability.

(b) The person who consents to be a live organ donor shall be:

- (1) Legally competent;
- (2) Willing to donate;
- (3) Free from coercion, including financial coercion, actual or implied;
- (4) Medically suitable;
- (5) Informed and able to express understanding of the risks and benefits of donation; and
- (6) Informed of the risks, benefits and alternative treatment regimens available to the recipient.

(c) A statement signed by the potential donor that his or her participation is completely voluntary and may be withdrawn at any time shall be placed in the medical record.

(d) Understanding

- (1) The potential donor shall be able to demonstrate that he or she understands the essential elements of the donation process with emphasis on the risks associated with the procedure;
- (2) With the potential donor's permission, the donor's designee, family or next of kin shall be given the opportunity to openly discuss the donor's concerns in a safe and non-threatening environment; and
- (3) The potential donor shall understand, agree to, and commit to postoperative follow-up and testing by the facility performing the surgical removal of the organ and subsequent organ transplant.

(e) Disclosure

- (1) The donor surgical team and the IDAT shall disclose any facility affiliations to the potential donor;
- (2) The potential donor shall have a period of reflection appropriate to the acuity of the clinical condition of the recipient and reaffirmation of the decision to donate subsequent to the completion of the medical work-up and final approval to proceed by the IDAT. After the period of reflection the potential donor may sign the consent for the donation procedure;
- (3) Non-English speaking candidates and hearing impaired candidates must be provided with a non-family interpreter who understands the donor's language and culture;
- (4) A member of the IDAT shall witness the potential donor signing the consent documents for removal of the donor organ; and
- (5) The overall donation process and experience shall be explained to the potential donor and shall be provided in writing to include:
 - (A) Donor evaluation procedure;
 - (B) Surgical procedure;
 - (C) Recuperative period;
 - (D) Short-term and long term follow-up care;
 - (E) Alternative donation and transplant procedure;
 - (F) Potential psychological benefits to donor;
 - (G) Transplant facility and surgeon-specific statistics of donor and recipient outcomes;
 - (H) Confidentiality of the donor's information and decisions;
 - (I) Donor's ability to opt out at any point in the process;
 - (J) Information about how the facility performing the transplant will attempt to follow the health of the donor; and
 - (K) Need for the donor to review potential personal insurability for future insurance coverage.

(f) The IDAT shall make the potential donor aware of the following risk factors:

- (1) Physical
 - (A) Potential for surgical complications including risk of donor death;
 - (B) Potential for organ failure and the need for future organ transplant for the donor;

- (C) Potential for other medical complications including long-term complications and complications currently unforeseen;
 - (D) Scars;
 - (E) Pain;
 - (F) Fatigue; and
 - (G) Abdominal or bowel symptoms such as bloating and nausea.
- (2) Psychosocial
- (A) Potential for problems with body image;
 - (B) Possibility of transplant recipient death;
 - (C) Possibility of transplant recipient rejection and need for re-transplantation;
 - (D) Possibility of recurrent disease in a transplant recipient;
 - (E) Possibility of post surgery adjustment problems;
 - (F) Impact on the donor's family or next of kin;
 - (G) Impact on the transplant recipient's family or next of kin; and
 - (H) Potential impact of donation on the donor's lifestyle.
- (3) Financial
- (A) Out of pocket expenses;
 - (B) Child care costs;
 - (C) Possible loss of employment;
 - (D) Potential impact on the ability to obtain future employment; and
 - (E) Potential impact on the ability to obtain or afford health and life insurance.
- (g) The potential donor shall provide assurance and consent that the following areas have been addressed:
- (1) That there is no monetary profit to the potential donor. Coverage for expenses incurred as a result of the organ donation is not considered monetary profit;
 - (2) That family members or others did not coerce the potential donor into making his or her decision;
 - (3) That the potential donor has been provided with a general statement of unsuitability for donation if requested. Medical information regarding the potential donor shall not be falsified to provide the donor with an excuse to decline donation;
 - (4) That the potential donor is intellectually and emotionally capable of participation in a discussion of potential risks and benefits;
 - (5) That the potential donor has been provided adequate information to ensure his or her understanding regarding the risks of the donation;
 - (6) That the potential donor has been educated regarding the recipient's options for organs from deceased persons, including risks and outcomes; and
 - (7) That the potential donor understands that he or she may decline to donate at any time.
- (h) Documentation
- (1) A medical record, separate and distinct from the transplant recipient's record, shall be maintained to protect donor confidentiality; and
 - (2) The informed choice process and evaluation protocol shall be documented and placed in the potential donor's medical record.
- (i) Decision to Donate. Once the IDAT determines the suitability of the potential donor the IDAT shall discuss with the potential donor's surgical team and transplant team its decision prior to its presentation to the potential donor. If the potential donor wishes to donate, but the IDAT does not agree, the IDAT's opposition shall be so noted in a report to the donor surgeon, who shall document reasons for proceeding against the IDAT advice. The reason why the IDAT has objections shall be explained to the potential donor. For example, the potential donor may not have the ability to understand the information provided to him or her or the donor may be unable to integrate the degree of risk pertinent to his or her situation or there may be a lack of balance between the risks to the potential donor and potential benefits to the transplant recipient. Even if the potential donor is willing to donate his or her organ, the final review and decision whether or not to proceed with the donation rests with the donor surgical team and transplant team.
- (j) In cases involving living liver donation, prior to reaching a decision to donate the potential donor shall be provided in writing the U.S. Department of Health and Human Services Advisory Committee on Organ Transplantation (ACOT) recommendations entitled "Living Liver Donor Initial Consent for Evaluation" which is hereby incorporated by reference with all subsequent amendments. The ACOT recommendations can be obtained free of charge via the internet at: <http://www.organdonor.gov/acotrecs.html>. The items contained in the ACOT recommendations must be explained to the potential donor in language and terms which he or she can understand

and then be signed by the donor and the signature witnessed. Subsequent to this, if all the facts show that the potential donor is, in fact, in all respects a viable potential donor, then he or she shall execute the ACOT recommended form entitled "Living Liver Donor Informed Consent for Surgery" which is hereby incorporated by reference with all subsequent amendments. In addition, this form shall comply with G.S. 90-21.13 Informed Consent which is hereby incorporated by reference with all subsequent amendments.

*History Note: Authority G.S. 131E-75; 131E-79; 143B-165;
Eff. May 1, 2006;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 22, 2017.*