Correspondence

Same day consent for anaesthesia research

To the Editor:

In their 1993 April/May newsletter, the National Council on Bioethics in Human Research issued a strong statement against obtaining consent for research on the day of surgery.¹ The council argued that any attempt to obtain a research consent on the day of surgery may be intimidating, coercive and a breach of the principle of autonomy.

We evaluated our consent process in anaesthesia research at The Hospital for Sick Children, and have established standards for this process within our research group. It is our view that focusing on the consent process and adherence to these standards will maximize the adequacy of the consent process, preserve the rights of patients, and permit the consent process to take place on the day of surgery. These guidelines are not meant to be conclusive and we welcome input from other researchers.

- 1 With respect to ambulatory surgical patients: a mandatory clause is included in the parent information sheets as follows: "This study involves children having day surgery. Parents and their children are asked to participate in this study on the day of surgery. If you require more time to make this decision, feel free to decline involvement in this study. This decision will not affect your child's present or future medical care."
- 2 That parents be given time to read and consider the benefits and risks disclosed in the parent information sheet in the absence of the investigator or designate. The duration of this time period need not be stipulated.
- 3 Four mandatory questions are asked by the investigator/designate in the wake of a *positive* response to participation in the study and *prior* to having the parent sign the consent form. These are:
 - (i) Have you had enough time to make a decision?
 - (ii) Do you understand participation in this study is voluntary?
 - (iii) Do you understand you can withdraw from participating in this study at any time without affecting your child's health care now or in the future?
 - (iv) Do you have any further questions about this study/the risks and benefits?
- 4 In addition to these, each study should have "study-

specific sentences/questions" which highlight and reiterate unique considerations of that protocol.

For example:

- Do you understand I will be taking six blood samples from the *iv*?
- Do you understand this is an investigational drug?
- Do you understand your child may receive a placebo?

These "study-specific sentences" may be outlined in the study proposal and submitted with the information sheet as part of the overall research protocol submission to the research ethics board (REB). This committee could approve or amend these questions.

- 5 Investigators seeking informed consent should document in the health chart, the nature of their consent process for those patients who agree to participate in a research protocol.
- 6 Finally, that the recommendations of The Declaration of Helsinki be considered for same day consents and that is: where the subject may be felt to consent under duress that the informed consent be obtained by a doctor not engaged in the investigation and completely independent to this official role.²

Process is indeed a crucial element of informed consent which contributes to its validity. In contrast to timing, it is also the element which may be less difficult to standardize and of greater value in resolving the issue of the validity of same day consents. With careful attention to process, we believe that it is possible to obtain informed consent on the day of surgery while at the same time preserve the rights of patients.

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REFERENCES

- 1 Communiqué, Volume 4, Number 1, April/May 1993.
- 2 World Medical Association Declaration of Helsinki: Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects September 1989, Basic Principles: no. 10.