



Extending Anesthesia and Sedation for Research Purposes

Policy

This document provides IRB members guidance on whether extending clinically indicated anesthesia or sedation for purposes of performing additional research assessments may be considered minimal risk. This guidance is limited to the risks associated with the extension of sedation and anesthesia only, not the additional research manipulations. The risks of the procedures to be performed during the extension time need to be considered separately and taken into consideration in the overall risk/benefit assessment. The document has been divided into two sections 1) anesthesia and 2) sedation/procedural sedation/analgesia

Anesthesia

The major of risks associated with administering anesthesia occur during induction and discontinuation of anesthesia. In general the Committee would consider the following minimal risk if all criteria are met;

- The extension of anesthesia time is limited to 10-15 minutes
- The appropriate level of anesthesia has been achieved and the patient is determined to be clinically stable by an anesthesiologist uninvolved in the research protocol.
- The method/mode of anesthesia to be used is determined not by the research protocol but is in accordance with current standard clinical practice.
- The same anesthetic agents are utilized for the extension of time required for research
- The same clinical care team responsible for administering and monitoring the anesthesia remain with the subject during the research procedure.
- The same level and frequency of monitoring will be maintained throughout the research procedures.

Sedation/procedural sedation/analgesia

Sedation, procedural sedation or sedation/analgesia is administered incrementally. It may be that one dose of a medication with a long enough duration of action is given and no additional doses are needed during a clinical procedure but often many small doses of sedatives/analgesics are used during the time needed to care for the patient. Sedation is performed all over the hospital by many different "providers" and the children sedated are monitored less stringently that those receiving anesthesia. For this reason if the research procedures can be accomplished without administration of any additional sedation medication other than what was planned for

Document5

the procedure, then the risk category of extending the time to perform procedures during sedation can be considered minimal as long as the patient is stable and appropriate monitoring continues. As mentioned above the risks of the procedure to be performed need to be considered separately and taken into consideration in the overall risk/benefit assessment

If the extension of anesthesia/ sedation/procedural sedation/analgesia does not meet the criteria listed above, it may or may not be considered minimal risk and should be reviewed carefully for final determination in accordance with the federal regulations.

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