Extending Anesthesia and Sedation for Research Purposes

Purpose

This policy provides IRB members with guidance on whether extending clinically indicated anesthesia or sedation for purposes of performing additional research assessments may be considered minimal risk.

Policy

Boston Children's IRB may determine that research may be minimal risk when there is an extension of clinically indicated anesthesia or sedation for purposes of performing additional research assessments.

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: Anesthesia and Sedation/procedural or sedation/analgesia.

Procedure

Anesthesia

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

1. The extension of anesthesia time is limited to 10-15 minutes.
2. 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.
3. The method/mode of anesthesia to be used is determined not by the research protocol but is in accordance with current standard clinical practice.
4. The same anesthetic agents are utilized for the extension of time required for research.
5. The same clinical care team responsible for administering and monitoring the anesthesia remain with the subject during the research procedure.
6. The same level and frequency of monitoring will be maintained throughout the research procedures.

Sedation/procedural or 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. However, 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 the procedure, then the risk category of extending the time to perform procedures during sedation can be considered minimal, if:

- 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 sedation/procedural or 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.

Related Content

None Identified

Document Attributes

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