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Owner	Susan Kornetsky: Manager
Department	Research
Applicability	Boston Children's Hospital- Guidelines

Extending Anesthesia and Sedation for Research Purposes Guideline

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Internal Approval

SVP, Research Administration

EVP, Chief Scientific Officer

Scope

This guideline applies to all Boston Children's Hospital (BCH) licensed locations, BCH operational and clinical departments, and staff (inclusive of W-2 employees, contracted staff, and members of the medical staff irrespective of their appointment category or employer). As applicable, the guideline also applies to foundation practices leasing space at hospital-licensed locations.

Guideline Statements

This guidance provides Institutional Review Board (IRB) members with guidance on whether extending clinically indicated anesthesia or sedation for purposes of performing additional research assessments that may be considered minimal risk.

Boston Children's Institutional Review Board (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 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.

Process Steps

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.

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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:

1. The patient is stable and
2. Appropriate monitoring continues

As mentioned above, the risks of the procedure to be performed should 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.

Approval Signatures

Step Description	Approver	Date
Co-chair Approval	David Davis	3/1/2025
Site Administrator: Education/ Training Requirement	Dwight Mayfield	2/26/2025
Steering Committee	Dwight Mayfield	2/26/2025
Required Departmental Review/Approval	August Cervini	1/17/2025
Committee Chair(s)	Susan Kornetsky: Manager	1/17/2025
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Applicability

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