

Status **Active** PolicyStat ID **13321887**



**Boston
Children's
Hospital**

Where the world comes for answers

Effective 1/1/2023
Next Review 1/1/2026

Owner Susan Kornetsky:
Manager
Department Research
Applicability Boston Children's
Hospital- Policies
& Procedures

Extra Endoscopy Biopsies for Research Policy/Procedure

Internal Approval

SVP, Research

EVP & Chief Scientific Officer, Research

Scope

This policy 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 policy also applies to foundation practices leasing space at hospital-licensed locations.

Policy Statements

For research that involves children, the Institutional Review Board (IRB) must make specific regulatory determinations. This guidance provides IRB members and investigators guidance on determining whether extra research biopsies obtained during endoscopic procedures may be considered minimal risk in a consistent manner.

- Research biopsy tissue obtained during endoscopic procedures is often used in laboratory studies and there is no potential for direct benefit for the subject.

Procedures

1. The IRB will review the protocol to assess if the criteria is met.
2. Obtaining extra research biopsies during a clinically indicated endoscopy procedure may be considered minimal risk if all the following criteria are met:
 - a. The endoscopy is required for clinical care.

- b. The subject must be greater than 10kg.
 - c. The subject must be ASA category I, II, or III and must not have any medical conditions that would increase the risk of bleeding or perforation from a gastrointestinal punch biopsy. Such conditions may include active transfusion dependent GI bleeding, coagulopathy, thrombocytopenia, or toxic megacolon.
 - d. No more than 20 additional research biopsies may be obtained during any single endoscopy. In addition, the investigator may only take 6 extra biopsies from any one region (e.g. the terminal ileum, right colon, or duodenum).
 - e. If the protocol requires obtaining more than 10 research biopsies, an attending must obtain the additional research samples.
 - f. No research biopsies may be obtained if in the judgment of the physician, prolonging anesthesia may cause a medical deterioration (e.g. in an ASA III patient with severe chronic lung disease).
 - g. Extra research biopsies should not be performed during a therapeutic endoscopy (e.g. dilation of a stricture, electrocautery of a vessel, or sphincterotomy).
 - h. Physicians performing repeat endoscopy may perform research biopsies no more frequently than every 30 days on the same patient.
 - i. Anesthesia and sedation should meet the criteria for minimal risk by following the IRB guidance: ***Extending Anesthesia and Sedation for Research Purposes.***
3. If a protocol does not meet the criteria, it does **not** mean the protocol will be disapproved. It means that the level of risk has increased, and the IRB will take that in consideration in accordance with the regulatory criteria for approval.

Related Content

- IRB Guidance: Extending Anesthesia and Sedation for Research Purposes

Approval Signatures

Step Description

Approver

Date

Applicability

Boston Children's Hospital- Policies & Procedures