



Extra Endoscopy Biopsies for Research Guidelines

Policy

This document provides IRB members and investigators guidance on whether extra research biopsies obtained during endoscopic procedures may be considered minimal risk. Research biopsy tissue obtained during endoscopic procedures are often used laboratory studies and there is no potential for direct benefit for the subject. For research that involves children the IRB must make specific regulatory determinations. These guidelines will be of assistance in making the required determinations in a consistent manner.

Obtaining extra research biopsies during a clinically indicated endoscopy procedure may be considered minimal risk if all of the following criteria can be met

1. The endoscopy is required for clinical care.
2. The subject must be greater than 10kg
3. 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 pinch biopsy. Such conditions may include: active transfusion dependent GI bleeding, coagulopathy, thrombocytopenia, or toxic megacolon.
4. 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 particular region (e.g. the terminal ileum, right colon, or duodenum).
5. If the protocol requires obtaining more than 10 research biopsies, an attending must obtain the additional research samples
6. 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).
7. Extra research biopsies should not be performed during a therapeutic endoscopy (e.g. dilation of a stricture, electrocautery of a vessel, or sphincterotomy).
8. Physicians performing repeat endoscopy may perform research biopsies no more frequently than every 30 days on the same patient.
9. Anesthesia and sedation must meet the criteria for minimal risk by following the attached guidelines [11.1 Additional Anesthesia and Sedation Guidelines](#)

If a protocol does not meet these criteria, it does not mean the protocol will not be approved, it means that the level of risk increases and the committee will consider that in accordance with the regulatory criteria for approval.

The Clinical Investigation Policy and Procedure Manual



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