



BIOPSIES FOR RESEARCH PURPOSES

Description

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45 CFR 46.102(i)).

The IRB is responsible for determining if research-only biopsies are considered to be minimal risk or greater than minimal risk. The following is a guideline to assist in making risk determinations for biopsies.

These guidelines can be applied to both adults and children, though extra consideration for children and other vulnerable populations should be given whenever applicable. The participant's underlying condition might make a biopsy greater than minimal risk (e.g. hemophilia, etc.). Depending on subject's underlying condition, these may be a minor increase over minimal, or more than a minor increase over minimal. The IRB may choose to apply different guidelines on a case-by-case basis in order to protect subjects.

Research biopsies should only be obtained *after* any clinical biopsies have been obtained and the physician has determined the patient remains stable and the additional research biopsies will not increase the risk of harm to the patient.

Biopsy Site	Minimal Risk	Greater than Minimal Risk
Skin	<p>For affected participants and healthy controls, a single biopsy \leq 2mm can be minimal risk.</p> <p>Skin biopsies limited to a few mm and do not [routinely] require sutures are minimal risk.</p>	<p>Biopsies requiring sutures are considered a minor increase over minimal.</p> <p>Punch biopsies are usually a minor increase over minimal risk.</p> <p>Skin biopsies of any size done on the face are greater than minimal risk due to the motor nerves and arteries close to the skin in this region.</p>
GI Tract (Upper and Lower), Transbronchial	<p>Biopsies, when done during a clinically indicated procedure, can be considered minimal risk, if:</p> <ul style="list-style-type: none">The endoscopy is required for clinical care.	<p>Any research biopsies obtained beyond those described in the minimal risk criteria.</p>

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.



Lung, Brochial Wall Biopsies	<ul style="list-style-type: none">• The subject must be greater than 10kg (~22 lbs.)• 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 biopsy.• 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, left colon or duodenum).• 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).• Extra research biopsies should not be performed during a therapeutic endoscopy (e.g. dilation of a stricture, electrocautery of a vessel, or sphincterotomy).• Physicians performing repeat endoscopy may perform research biopsies no more frequently than every 30 days on the same patient.	
Liver/Kidney		Liver and kidney biopsies are greater than minimal risk.

References & Links

“Extra Endoscopy Biopsies for Research Guidelines” from Children’s Hospital Boston

http://www.childrenshospital.org/~media/Research%20and%20Innovation/Office%20of%20Clinical%20Investigation/cipp_014_004_ExtraGI_Reseach_Biopsy_Risk_Guidance.ashx

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“Risk of Common Procedures” from The Children’s Hospital of Philadelphia

<https://irb.research.chop.edu/risk-common-procedures>

“Skin Biopsies in Children for the Purpose of Research” from USCF

<http://www.research.ucsf.edu/chr/Guide/Biopsy.asp>

“Tip Sheet: Minimal Risk” from UCLA

http://ora.research.ucla.edu/OHRPP/Documents/Policy/4/Minimal_Risk.pdf

American Society of Anesthesiologists (ASA) Physical Status Classification System

<https://www.asahq.org/resources/clinical-information/asa-physical-status-classification-system>

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