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**Boston
Children's
Hospital**

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Department Research
Applicability Boston Children's
Hospital-
Guidelines

Skin Biopsy Guideline

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

Boston Children's Hospital Institutional Review Board (IRB) may determine that research is minimal risk if the skin biopsy guidance have been followed accordingly.

- Skin biopsies may be approved under the category of minimal risk in accordance of the following procedures.
- If a protocol **does not** meet criteria, it does not mean the protocol will be disapproved. It means that there is a level of risk and the IRB will consider that in accordance with the regulatory criteria for approval.

Process Steps

Skin biopsies are required to meet the aims of the research and there is no less traumatic alternative biological sample (such as blood) that could serve the same purpose.

1. Biopsies must:
 - a. Be no greater than 2mm in diameter.
 - b. Require no sutures.
2. Prior to the skin biopsy procedure:
 - a. Consent: The consent should specify:
 - i. The size in a measurement that families are familiar with. For example, "The size of the biopsy that will be taken is 0.08 inches in diameter."
 - ii. That obtaining skin biopsies may cause some discomfort but are similar to a blood drawing. However, it is important to note that subjects will need to keep the area clean and cover the site with a band-aid for a longer period of time than a blood draw.
 - b. EMLA Cream (topical anesthetic agent) needs to be applied.
3. The Principal Investigator should ask about a subject's history of scar formation, since some subjects may be subject to excess scar formation.
 - a. If there is concern about a scar, then this may not be considered minimal risk for that individual; and the potential subject should not be included in the research if there is no potential for direct benefit.

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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
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Applicability

Boston Children's Hospital- Guidelines