

Institutional Review Board (IRB) Policies & Procedures Manual



Document: irbm-009-002-skin-biopsies.docx

Skin Biopsy Guidelines

Purpose

This policy provides IRB members with guidance on skin biopsy in research.

Policy

Boston Children's IRB may determine that research is minimal risk if the skin biopsy guidelines in this policy has been followed accordingly.

Procedure

Skin biopsies may be approved under the category of minimal risk in accordance with the following guidelines:

1. 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.
2. Biopsies must:
 - a. Be no greater than 2mm in diameter.
 - b. Require no sutures.
3. 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 needs to be applied.
4. The PI 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 they should not be included in the research if there is no potential for direct benefit.

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

Related Content

None Identified

Document Attributes

Title	Skin Biopsy Guidelines		
Author	Susan Kornetsky	Dates Reviewed/ Revised	4/23/2010 5/1/2015 11/15/2019
Reviewed/ Revised by	Susan Kornetsky	Last Modified	1/31/2020
Copyright	©Boston Children’s Hospital, 2020		
Approved	_____ Susan Kornetsky, MPH Director of Clinical Research Compliance _____ August Cervini, MBA Vice President for Research Administration		