



Skin Biopsy Guidelines

Policy

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. To be considered minimal risk the biopsies must be limited to:
 - a. 2mm in diameter (this should be explained in the consent in a measurement families are familiar with such as "The size of the biopsy that will be taken is 0.08 inches in diameter."
 - b. No sutures are required.
3. EMLA needs to be applied before the procedure.
4. The PI should ask about a subject's history of scar formation since some subjects may be subject to excess scar formation. If there is concern about a scar this may not be considered minimal risk for that individual; and they should not be included if there is no potential for direct benefit.
5. The consent needs to specify 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 keep the area clean and cover the site with a band-aid for a longer period of time than a blood draw.

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.

Related Content

Document Attributes

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