

Skin Biopsy Risk Level- IRB Guidance



Summary

To standardize minimal risk determinations for specific skin biopsies in research.

Guideline:

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 or about the thickness of a nickel"
 - b. No sutures are required
3. LMX4 needs to be applied before the procedure
4. The PI should ask about a subjects' history of scar formation since some subjects may be at risk for excess scar formation. If there is concern about a scar, this procedure 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 draw. 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.

Questions

Contact the [IRB](#) at irb@choa.org