March 15, 2022

COLUMBIA UNIVERSITY INSTITUTIONAL REVIEW BOARD

GUIDANCE ON RISK TO SUBJECTS FROM SKIN BIOPSIES

I. Background

The federal Common Rule (46 CFR 46 and 21 CFR 56) provides that the Institutional Review Board (**IRB**) of an institution conducting human subjects research is responsible for evaluating the potential risks of research procedures and the magnitude of the harm that may result in relation to the potential benefit of the research, if any.

As Punch Biopsies (as such term and certain other terms used herein are defined in Section IV below) are used in research, it is important that the IRBs at Columbia University have clear guidance on how to evaluate the potential risks to subjects from research procedures involving Punch Biopsies.

II. Effective Date.

The effective date of this Guidance is March 15, 2022.

III. Scope

This Guidance applies to all research with human subjects (adult and pediatric) that involves collection of skin specimens from Punch Biopsies.

IV. Definitions

As used in this Guidance, certain terms are defined as follows:

Child: Any person under the age of 18 who is not married or a parent.

Greater Than Minimal Risk: The probability and magnitude of harm or discomfort anticipated are greater than those associated with Minimal Risk.

Incapacitated Adult: Any adult who lacks the capacity to provide informed consent, either because of mental impairment or the nature of an illness.

Minimal Risk: The probability and magnitude of harm or discomfort anticipated in the research procedure 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.

Punch Biopsy: A Skin Biopsy using a circular tool to remove a small core of skin tissue.

Skin Biopsy: the removal of skin cells or tissue for testing.

V. Guidance

A. Review by Convened IRB

All research studies involving Punch Biopsies must be reviewed at a convened meeting of the IRB, regardless of the level of risk.

B. Risk Assessment

1. Minimal Risk.

A Punch Biopsy shall typically be considered to be Minimal Risk if (1) it is a single Punch Biopsy, (2) the skin to be removed is three millimeters or less in diameter and (3) the research subject is able to provide informed consent, or with respect to Children or Incapacitated Adults, assent, for him/herself.

2. Greater Than Minimal Risk

A Punch Biopsy shall typically be considered to be Greater Than Minimal Risk if one or more of the elements is present:

- The skin to be removed is more than three millimeters in diameter; or
- The skin to be removed is less than three millimeters in diameter and
    - There are more than one Punch Biopsies scheduled to be performed during the research study; or
    - The Punch Biopsy requires sutures; or
    - Sedation is required to administer the Punch Biopsy; or
    - The subject's underlying health condition is such that a Punch Biopsy may be of greater risk than for a healthy subject; or
- The subject is a Child or an Incapacitated Adult who is (a) unable to provide assent to the procedure or (b) must be involuntarily restrained to administer the Punch Biopsy AND the Punch Biopsy involves no prospect of direct benefit to the subject.