



RESPIRATORY RESEARCH, INC.

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Letter from IRB Attesting to Non-Significant Risk Nature of the RTube™ Collection System

School of Medicine

Dean's Office, Human Investigation Committee

August 10, 2000

██████████

██████████
Department of Pediatrics
Box 800386

RE: CONDENSED EXHALATE PH MEASUREMENT - HIC #7978

Dear Dr. ██████████:

At your request the Human Investigation Committee, at the meeting of August 8, 2000, discussed your request for a letter stating that your breath condensate collection apparatus is considered to be a non-significant risk device.

By a vote of 13-0, the committee agreed to such a letter, using 21CFR812.2(b)(3) as a criterion:

- 1) it is non-invasive
- 2) does not require an invasive sampling procedure that presents significant risk
- 3) does not by design or intention introduce energy into a subject, and
- 4) is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure

Sincerely,

██████████
Chair
Human Investigation Committee

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