

**Title: Tools for screening of pulmonary function in children 1 to 8 years of age:
A formative study for the National Children's Study**

Research centers:

1. University of Miami
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2. Drexel University College of Medicine
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Introduction:

Lung development continues at a remarkable pace up to 6-7 years of age. Understanding the progression of normal lung function in young children would allow clinicians to identify early changes that may indicate an increased risk of pulmonary disorders. Young children cannot perform conventional spirometry; hence, alternative techniques such as airway resistance have recently gained popularity. Other techniques, such as exhaled nitric oxide (FeNO), measure airway inflammation.

Goa and objectives:

1. Recruit approximately 50 healthy children ages 1-8 years at each center to assess feasibility, reproducibility, reliability, and correlation of pulmonary function tests (PFTs) in young children.
2. Assess parental perceptions and likelihood to consent to the testing in the main NCS.
3. Identify technical and methodological issues.

Methods:

This will be a 2-center study. We will assess three tools for PFTs:

- Conventional spirometry (children ≥ 5 years)
- Airway resistance (Raw) (all participating children)
- Exhaled nitric oxide (FeNO) (all participating children)

Study visits will be as follows:

- Visit 1: Parents will fill a general health and respiratory questionnaire; PFTs will be assessed.
- Visit 2: PFTs only.
- Visit 2: PFTs; Survey regarding parental perception of the study and PFTs.
- Follow-up: Telephone calls at 6 and 12 months for development of respiratory symptoms.

Current status:

- Protocol development, approval and personnel training completed.
- First visit from UM to Drexel University done with cross training on protocol and procedure performance.
- Recruitment of allowed about 10 patients has started
- Currently awaiting OMB approval to proceed with further recruitment