1. \*Date of Pulmonary Function Testing (m m/d d/y y y y):

Not Done

\*Reason not done:

Fatigue

URI/LRI/ severe coughing

Behavioral issues

Equipment failure

Unable to follow directions

Low oral motor tone/unable to hold mouthpiece

Unable to get subject into supine position due to scloiosis, contractures, cannot move to bed (for supine only)

Other, specify:

1. What type of pulmonary function testing is being performed? (Check all that apply. Record results in appropriate tables below):

Slow Vital Capacity (sVC)

Maximum Inspiratory Pressure (MIP)

Helium lung volumes

Sniff Nasal Inspiratory Pressure (SNIP)

Maximal Voluntary Ventilation (MVV)

Maximum Expiratory Pressure (MEP)

Unassisted Peak Cough Flow (PCF)

Forced Vital Capacity (FVC)

Inspiratory Capacity (IC)

Other, specify

Note: Position should remain consistent for all trials.

1. Position for the assessment\*:

Sitting

Supine (FVC only)

Both (sitting and supine)

1. \*If assessment performed sitting, what was the subject’s seated position?

Semi-erect

Erect

Leaning forward

N/A – assessment done supine

1. \*What type of mouthpiece was used?:

Scuba

Cardboard

Mask

1. \*Type of Pulmonary Function Testing Equipment Used:

Manufacturer

Model

Software program

## Additional Pediatric-specific Elements

These elements are recommended for pediatric studies.

1. \*Ulna length: [pre-populated field] cm

\*Ulna length measured with:

Harpenden Anthropomenter

Rosscraft segmometer

1. Was patient taking brochodulator at time of testing?

Yes

No

Index of Lung Function Table

| Index of Lung Function\* | \*Trial 1  \*Complete Exhalation  Yes No | \*Trial 2  \*Complete Exhalation  Yes No | \*Trial 3  \*Complete Exhalation  Yes No | BEST TRIAL |
| --- | --- | --- | --- | --- |
| FVC (liters) | Yes No | Yes No | Yes No | Yes No |
| FEV1 (liters) | Yes No | Yes No | Yes No | Yes No |
| FEV1/FVC  (ratio/ no units) | Yes No | Yes No | Yes No | Yes No |
| FEV0.5 (liters) | Yes No | Yes No | Yes No | Yes No |
| FEV0.5/FVC  (ratio/ no units) | Yes No | Yes No | Yes No | Yes No |
| FEF25-75  (liters/ second) | Yes No | Yes No | Yes No | Yes No |
| FEFmax  (liters/ second) | Yes No | Yes No | Yes No | Yes No |
| PCF  (liters/ second) | Yes No | Yes No | Yes No | Yes No |
| BEST TRIAL | Yes No | Yes No | Yes No | Yes No |
| TLC (liters) | Yes No | Yes No | Yes No | Yes No |
| SVC (liters) | Yes No | Yes No | Yes No | Yes No |
| IC (liters) | Yes No | Yes No | Yes No | Yes No |
| FRC (liters) | Yes No | Yes No | Yes No | Yes No |
| RV (liters) | Yes No | Yes No | Yes No | Yes No |
| FRC/TLC  (ratio/ no unit) | Yes No | Yes No | Yes No | Yes No |
| RV/TLC  (ratio/ no unit) | Yes No | Yes No | Yes No | Yes No |

## Additional questions for MIP/MEP

1. \*Was there a difference of greater than 3cm of H20 between trial efforts?

Yes

No

## Additional questions for Forced Vital Capacity (FVC)

1. \*Was there a cough during the first second of exhalation?

Yes

No

\*Was there a leak during exhalation?

Yes

No

1. \*Are the 2 largest values for FVC within 10% of each other?

Yes

No

1. \*Was there early termination with steep cut off?

Yes

No

1. \*Was there a clearly defined peak flow?

Yes

No

## General Instructions

This CRF contains data that would be collected when a pulmonary study is performed studying lung function.

Please note that the questions on Page 2 are for specific pulmonary function tests.

Important note: None of the data elements included on this CRF Module are classified as Core (i.e., strongly recommended for all adult NMD clinical studies to collect). All data elements are classified as supplemental (i.e., non Core) and should only be collected if the research team considers them appropriate for their study. Please see the Data Dictionary for element classifications.

## Specific Instructions

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

* Position for the Assessment – Please note that “Supine” is for FVC only.
* Ulna length –If the Date performed on this form is the same as the Date performed on the Vital Signs form, then this field will be pre-populated from the value recorded on the Vital Signs form. For adults whose height cannot be measured or is unknown, arm span length can be used (instead of ulna length), however, arm span length is not a surrogate for height.

\*Element is classified as Core