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