1. \*Date of Pulmonary Function Testing: (mm/dd/yyyy)

Attempted, but failed. Indicate reason\*: [ ]  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 scoliosis, contractures, cannot move to bed (for supine only)

[ ]  Other, specify:

1. What type of pulmonary 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

[ ]  MVV

[ ]  Maximum Expiratory Pressure

[ ]  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)
2. 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
2. Type of Pulmonary Function Testing Equipment used:

Table Pulmonary Function Testing Equipment

| Manufacturer: | Model:  | Software Program: |
| --- | --- | --- |
| Data to be entered by site | Data to be entered by site | Data to be entered by site |

## Additional Pediatric-specific Elements

These elements are recommended for pediatric studies

1. Ulna length: [pre-populated field] cm
2. Ulna length measured with: [ ]  Harpenden Anthropomenter [ ]  Segmomenter, type:
3. Was patient taking brochodulator at time of testing? [ ]  Yes [ ]  No

Table Index of Lung Function

| Index of Lung Function | Trial 1 | Trial 2 | Trial 3 |
| --- | --- | --- | --- |
| Complete Exhalation: | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |
| FVC\*(liters) | \*(liters)[ ]  Check if Best Trial | \*(liters)[ ]  Check if Best Trial | \*(liters)[ ]  Check if Best Trial |
| FEV1 (liters) | Data to be entered by site | Data to be entered by site | Data to be entered by site |
| FEV1/FVC(ratio/ no units) | Data to be entered by site | Data to be entered by site | Data to be entered by site |
| FEV0.5 (liters) | Data to be entered by site | Data to be entered by site | Data to be entered by site |
| FEV0.5/FVC (ratio/ no units) | Data to be entered by site | Data to be entered by site | Data to be entered by site |
| FEF25-75 (liters/ second) | Data to be entered by site | Data to be entered by site | Data to be entered by site |
| FEFmax(liters/ second) | Data to be entered by site | Data to be entered by site | Data to be entered by site |
| PCF (liters/ second) | Data to be entered by site | Data to be entered by site | Data to be entered by site |
| SNIP (cmH20) | Data to be entered by site | Data to be entered by site | Data to be entered by site |
| TLC (liters) | Data to be entered by site | Data to be entered by site | Data to be entered by site |
| SVC (liters) | Data to be entered by site | Data to be entered by site | Data to be entered by site |
| IC (liters) | Data to be entered by site | Data to be entered by site | Data to be entered by site |
| FRC (liters) | Data to be entered by site | Data to be entered by site | Data to be entered by site |
| RV (liters) | Data to be entered by site | Data to be entered by site | Data to be entered by site |
| FRC/TLC (ratio/ no unit) | Data to be entered by site | Data to be entered by site | Data to be entered by site |
| RV/TLC(ratio/ no unit) | Data to be entered by site | Data to be entered by site | Data to be entered by site |
| MEP (cm of water) | Data to be entered by site | Data to be entered by site | Data to be entered by site |
| MIP (cm of water) | Data to be entered by site | Data to be entered by site | Data to be entered by site |

## Additional questions for MIP/MEP

1. Was there a difference of greater than 3 cm of H2O 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
2. Was there a leak during exhalation? [ ]  Yes [ ]  No
3. Are the 2 largest values for FVC within 10% of each other? [ ]  Yes [ ]  No
4. Was there early termination with steep cut off? [ ]  Yes [ ]  No
5. Was there a clearly defined peak flow? [ ]  Yes [ ]  No

## GENERAL INSTRUCTIONS

This CRF is used to capture data on Pulmonary Function Testing the participant/ subject is undergoing during the course of the study.

## 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 those whose standing height or recumbent height is unable to be measured, then ulna length should be recorded. Arm span length can be used (instead of ulna length), however, arm span length is not a surrogate for height.