1. Date of Pulmonary Function Testing (PFT)\* (yyyy-mm-dd):
2. What type of pulmonary function testing is being performed?\* (Check all that apply. Record results in appropriate tables on next page):

[ ]  Slow Vital Capacity (sVC)

[ ]  Maximum Inspiratory Pressure (MIP) – specify type below:

[ ]  Sniff Nasal Inspiratory Pressure (SNIP)

[ ]  Maximal Voluntary Ventilation (MVV)

[ ]  Maximum Expiratory Pressure (MEP)

[ ]  Peak Expiratory Flow (PEF)

[ ]  Forced Vital Capacity (FVC)

[ ]  Forced Expiratory Volume in 1 second (FEV1)

Note: A study should write detailed standard operating procedures (SOPs) for the PFT to help ensure consistent measurements. The SOP should cover details like the equipment used, the position of the participant/subject for the measurements, etc.

1. Position for the assessment:

[ ]  Sitting [ ]  Supine (FVC only) [ ]  Sitting and Supine

1. What type of mouthpiece was used (if applicable)?

[ ]  Scuba [ ]  Tube [ ]  Mask [ ]  Other

sVC Results\* [ ]  N/A MIP Results [ ]  N/A

Table 1 sVC Results

| Trial | Results\* (liters) | % of Predicted |
| --- | --- | --- |
| 1 | L  | % |
| 2 | L | % |
| 3 | L | % |

Table 2 MIP Results

| Trial | Results (cm H20) |
| --- | --- |
| 1 | cm H20ata to be entered by site |
| 2 | cm H20ta to be entered by site |
| 3 | cm H20a to be entered by site |

MEP Results **[ ]**  N/A PEF Results **[ ]**  N/A

Table 3 MEP Results

| Trail | Results (cm H20) |
| --- | --- |
| 1 | cm H20 |
| 2 | cm H20 |
| 3 | cm H20 |

Table 4 PEF Results

| Trial | Results (liters/min) |
| --- | --- |
| 1 | L/min |
| 2 | L/min |
| 3 | L/min |

FEV1 Results\* **[ ]**  N/A FVC Results\* **[ ]**  N/A

Table 5 FEV1 Results\*

| Trial | Results (liters) |
| --- | --- |
| 1 | L |
| 2 | L  |
| 3 | L |

Table 6 FVC Results\*

| Trial | Results\* (liters) | Flow volume crossed X-axis? | % Predicted Normal |
| --- | --- | --- | --- |
| 1 | Data to be entered by site | [ ]  Yes [ ]  No | TBD |
| 2 | Data to be entered by site | [ ]  Yes [ ]  No | TBD |
| 3 | Data to be entered by site | [ ]  Yes [ ]  No | TBD |

SNIP Results **[ ]**  N/A MVV Results **[ ]**  N/A

Table 7 SNIP Results

| Trial | Results (cm H20) |
| --- | --- |
| 1 | cm H20 |
| 2 | cm H20a to be e |
| 3 | cm H20  |
| Peak Pressure Value: cm H2O |

Table 8 MVV Results

| Trial | Results(liters/min) |
| --- | --- |
| 1 | L/min |
| 2 | L/min |
| 3 | L/min |

Nare: **[ ]**  Left **[ ]**  Right

Nasal Congestion: **[ ]**  Yes **[ ]**  No

## General Instructions

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

Important note: The data elements noted with an asterisk on this CRF Module are classified as Core (i.e., strongly recommended for all ALS studies). 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.

* Nare – This question is answered for SNIP
* Nasal Congestion – This question is answered for SNIP

\* Element is classified as Core for ALS