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

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

[ ]  Maximum Expiratory Pressure (MEP)

[ ]  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 for the measurements, etc.

MIP Results [ ]  N/A

Table 1 MIP Results

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

MEP Results **[ ]**  N/A

**Table 2 MEP Results**

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

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

**\*\*Table 3 FEV1 Results**

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

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

\*\*Table 4 FVC Results

| Trial | \*\*Results (liters) | Flow volume crossed X-axis? | % Predicted Normal |
| --- | --- | --- | --- |
| 1 | L | [ ]  Yes [ ]  No | TBD |
| 2 | L | [ ]  Yes [ ]  No | TBD |
| 3 | L | [ ]  Yes [ ]  No | TBD |

Recorder Signature: Date:

## General Instructions

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

For mitochondrial disease studies, the position for the assessment is sitting and a tube mouthpiece is used.

The ratio of FEV1/FVC allows distinction between restrictive and obstructive ventilatory defects.

Important note: None of the data elements included on this CRF Module are classified as Core (i.e., strongly recommended for all mitochondrial disease clinical studies to collect). Some of the data elements are classified as Supplemental – Highly Recommended (i.e., essential information for specified conditions, study types, or designs), as indicated by the asterisks below.

\*\* Element is classified as Supplemental – Highly Recommended.

The remaining 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.

* Date of Pulmonary Function Testing (PFT) – Date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in an unambiguous format acceptable to the study database like DD-MMM-YYYY. When date/time data are prepared for aggregation or sharing, they should be converted to the format specified by [ISO 8601](https://www.iso.org/iso-8601-date-and-time-format.html);  YYYY-MM-DD T:hh:mm:ss.