LEADS Study Checklist – For Respiratory Therapists Intervention Group (+Extubation Advisor):

1. Bedside Setup *(ref: EA Monitor Connections)*

2. Perform SBT *(ref: 7-Step Guide)*

SBT Criteria:

- T-piece or CPAP / PSV **≤8** cmH_2O
- PEEP / FiO_2 at discretion of RT/MD
- Duration: aim **30 - 120** mins
- Required: inline capnography

3. Generate SBT Report: Print/Review with MD *prior to extubation decision making*

→ Attach MD Usefulness Scale Questionnaire to EA report for completion

4. Complete **Form 6: Intervention (EA) Daily Data Form** (one per day)

5. In the event of an ***adverse device event (related to EA use)***, complete **Form 11: Extubation Advisor-Related Adverse Event Form**

This may be:

- Related to capnography monitor
- Related to capnography tubing
- Related to tablet / laptop use
- Related to use of extubation readiness checklist

A serious adverse device event *may* include:

- Death
- Prolonged ICU stay/hospitalization
- Need for medical or surgical intervention
- Life-threatening event
- Persistent or significant disability/ incapacity

6. In the event of a ***protocol violation***, complete **Form 8: Protocol Violation Form** *this may* include:

- SBT not initiated after randomization
- EA software not initiated for SBT
- Prediction not generated successfully
- EA report not shown to physician
- SBT initiated, but incomplete prior to extubation
- Capnography not performed successfully
- EA report not generated

7. In the event of an ***adverse device event (related to SBT conduct)***, complete **Form 9: Adverse/Serious Adverse Event Form** *this may be:*

Dysrhythmia
Cardiac ischemia/myocardial infarction
Cardiac or respiratory arrest
Pulmonary edema
Mucous plugging
*Extreme Fatigue (sustained, as opposed to intermittent, or exacerbated by an SBT &/or cumulative)
*Barotrauma (pneumothorax, pneumomediastinum, pneumatocoele on imaging etc)
*Extreme Anxiety (sustained, as opposed to intermittent, or exacerbated by an SBT &/or cumulative)

*NOTE: To distinguish adverse events from failure criteria: an adverse event must require intervention (pharmacologic, procedure, or other) + return to pre-screening ventilator settings or higher) except for responses indicated by a * which may not require a specific intervention but are either closely followed clinically (pneumatocoele, pneumomediastinum) or considered extreme by virtue of being sustained or cumulative.*

Study forms are available in the LEADS bedside folder.

Contact the Research Coordinator if additional study forms are required.

LEADS Study Checklist – For Respiratory Therapists
Control Group (Standard-of-care):

1. Perform SBT <u>without</u> Extubation Advisor

SBT Criteria:

- T-piece or CPAP / PSV **≤8** cmH_2O
- PEEP / FiO_2 at discretion of RT/MD
- Duration: aim **30 – 120** mins
- Optional: inline capnography

2. Complete **Form 6: Standard-of-care Daily Data Form** (one per day)

3. In the event of a ***protocol violation***, complete **Form 8: Protocol Violation Form** *this may include:*

- SBT not initiated after randomization
- SBT initiated, but not completed prior to extubation
- EA used on standard-of-care patient

4. In the event of an ***adverse device event (related to SBT conduct)***, complete **Form 9: Adverse/Serious Adverse Event Form** *this may be:*

Dysrhythmia
Cardiac ischemia/myocardial infarction
Cardiac or respiratory arrest
Pulmonary edema
Mucous plugging
*Extreme Fatigue (sustained, as opposed to intermittent, or exacerbated by an SBT &/or cumulative)
*Barotrauma (pneumothorax, pneumomediastinum, pneumatocoele on imaging etc)
*Extreme Anxiety (sustained, as opposed to intermittent, or exacerbated by an SBT &/or cumulative)

*NOTE: To distinguish adverse events from failure criteria: an adverse event must require intervention (pharmacologic, procedure, or other) + return to pre-screening ventilator settings or higher) except for responses indicated by a * which may not require a specific intervention but are either closely followed clinically (pneumatocoele, pneumomediastinum) or considered extreme by virtue of being sustained or cumulative.*

5. In the event a "control" patient is placed on EA and an ***adverse device event (related to EA use)*** *occurs*, complete ❶ **Form 11: Extubation Advisor-Related Adverse Event Form**

This may be:

- Related to capnography monitor
- Related to capnography tubing
- Related to tablet / laptop use
- Related to use of extubation readiness checklist

A serious adverse device event *may* include:

- Death
- Prolonged ICU stay/hospitalization
- Need for medical or surgical intervention
- Life-threatening event
- Persistent or significant disability/ incapacity

Study forms are available in the LEADS bedside folder.
Contact the Research Coordinator if additional study forms are required.