WEAN SAFE

Data Collection Forms
FORM 0: - ORGANIZATIONAL DATA OF THE PARTICIPATING ICU
TO BE FILLED ONLY ONCE FOR THE STUDY

0.1 Name of the INSTITUTION: ________________________________

0.2 Mailing Address: _______________________________________

0.3 Phone _______________________

0.4 Contact person #1: __________________________

0.5 Email: _____________________________________________

0.6 Contact person #2: __________________________

0.7 Email: _____________________________________________

0.8 ICU Medical Director: ____________________________

0.9 □ Open ICU □ Closed ICU [ONE SELECTION ONLY]

0.10 Type of hospital: □ University/Academic □ Non-University [ONE SELECTION ONLY]

Type of ICU (check all that apply):

0.11 □ Medical

0.12 □ Respiratory ICU

0.13 □ Surgical

0.14 □ Cardiothoracic

0.15 □ Neurosurgical

0.16 □ Other specialty

0.17 Total number of beds in the hospital: _________

0.18 Number of beds in use in the ICU at commencement of study: _________

0.19 Total number of admissions to the ICU in last calendar year: _________

0.20 Total number of ICU beds in the hospital (including all ICUs, also not involved in this study, excluding intermediate care): _________

0.21 Was this ICU involved in research activities (other than surveys) in the last 5 years?

□ YES □ NO [ONE SELECTION ONLY]

0.22 Is there a step-down/intermediate care unit in your hospital?

□ YES □ NO [ONE SELECTION ONLY]

0.23 Does this hospital have a dedicated weaning facility within the hospital?

□ YES □ NO [ONE SELECTION ONLY]
Average number of Health Professionals present in the ICU:

<table>
<thead>
<tr>
<th>Staff Physicians</th>
<th>Daytime</th>
<th>Night time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doctors in training/Non-staff</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurses/Nurse practitioners</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physician assistants</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Occupational Therapists</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physiotherapists</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacists</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Respiratory Therapists</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Which UNITS are used for the following:

0.40 Noradrenaline/norepinephrine: □ mcg/min □ mcg/kg/min □ mg/hour [ONE SELECTION ONLY]

0.41 Adrenaline/epinephrine: □ mcg/min □ mcg/kg/min □ mg/hour [ONE SELECTION ONLY]

0.42 Dopamine: □ mcg/min □ mcg/kg/min □ mg/hour [ONE SELECTION ONLY]

0.43 Dobutamine: □ mcg/min □ mcg/kg/min □ mg/hour [ONE SELECTION ONLY]

0.44 Blood gases?: □ mmHg □ kPa [ONE SELECTION ONLY]

0.45 Platelets: □ 10^3/mm3 □ 10^9/L [ONE SELECTION ONLY]

0.46 Hemoglobin: □ g/100 ml □ g/L □ mmol/L [ONE SELECTION ONLY]

0.47 Height: □ inch □ cm [ONE SELECTION ONLY]

0.48 Weight: □ lbs □ kg [ONE SELECTION ONLY]

0.49 Do you use written/electronic sedation protocols? □ YES □ NO [ONE SELECTION ONLY]

0.50 Do you use a sedation scale? □ YES □ NO [ONE SELECTION ONLY]

0.51 (IF YES): □ SAS □ RASS □ Ramsay □ Other ______________

0.52 Does your ICU have weaning protocols for patients ventilated > 24 hours? □ YES □ NO [ONE SELECTION ONLY]

0.53 If yes: □ Physician driven □ Nurses driven □ RT driven [ONE SELECTION ONLY]

0.54 Please upload your protocol.

0.55 Do you use automated weaning system?
□ YES □ NO [ONE SELECTION ONLY]

0.56 If yes, please indicate which one: ______________

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¹ This number may be less than 1.0, particularly for allied health professionals such as physiotherapists. If so, please estimate amount of time as a proportion of a full working day spent by these personnel in the ICU.
Study ID: _______  Date of Data collection: ________________

DAILY SCREENING FORM

Patient’s initials: ______
Gender: M □  F □  Year of Birth:______________

First day of ventilation in the present ICU [FIRST DAY OF VENTILATION] ________________

Are there any exclusion Criteria present? Yes □  No □

<table>
<thead>
<tr>
<th>Date</th>
<th>Is this patient in ICU today?</th>
<th>Is this patient receiving Invasive Mechanical Ventilation today</th>
</tr>
</thead>
<tbody>
<tr>
<td>[FIRST DAY OF VENTILATION] +1</td>
<td>Yes □  No □</td>
<td>Yes □  No □</td>
</tr>
<tr>
<td>[FIRST DAY OF VENTILATION] +2</td>
<td>Yes □  No □</td>
<td>Yes □  No □</td>
</tr>
</tbody>
</table>

If Yes PATIENT ENROLLED!

ICU Outcome (non-enrolled Patients)

Alive at ICU Discharge: Yes □  No □
FORM 1: - TO BE COMPLETED FOR ALL INVASIVELY VENTILATED PATIENTS ON
STUDY DAY 1

Sub Form “GENERAL”

1.1 Date of enrollment (between 7AM and 10AM on study day 1): __/__/____ [FILLED AUTOMATICALLY FROM THE FORM BEFORE]

1.2 Date and hour of commencement of IMV: __/__/_____ (DD/MM/Year)

1.3 at _______ (24 hour clock)

1.4 Date of ICU admission in the current episode: _ _ / _ _ /201 _ (DD/MM/Year)

1.5 Gender: M   F [ONE SELECTION ONLY]

1.6 Age: __________

What was the main category of ICU admission? (SELECT ONLY ONE OPTION)

1.7 □ Medical

1.8 □ Scheduled Surgery

1.9 □ Emergency surgery (excluding Trauma)

1.10 □ Trauma [with □ or without □ surgery]

1.11 □ Monitoring (e.g. in situ thrombolysis, desensitization), or post non-surgical procedure (including PCI, bronchoscopy)

Hospital Admission

1.12 Date of presentation in current Hospital: _ _ / _ _ /201 _ (DD/MM/Year)

1.13 Height (first documented at ICU admission): __________

1.14 Weight (first documented at ICU admission): __________

1.15 Residence Status prior to hospital admission [ONE SELECTION ONLY]

□ Home   □ Other healthcare facility   □ Nursing home   □ Unknown   □ Homeless

1.16 Admission Source: [ONE SELECTION ONLY]

□ Other ICU  □ Ward  □ ER  □ OR/Recovery  □ Other, please specify

1.17 Was the patient previously intubated for greater than 24 hours during this hospital admission prior to enrollment? □ YES   □ NO [ONE SELECTION ONLY]

1.18 Was the patient previously enrolled in this study? □ YES   □ NO [ONE SELECTION ONLY]

1.19 (If yes, indicate the patient’s previous study number____________________)

Co-morbidities present before ICU admission (check all that apply):

1.20 □ COPD (If known, GOLD: □ I □ II □ III □ IV)  1.21 □ Interstitial Lung Disease  1.22 □ Other chronic lung disease
1.23 □ Asthma requiring home inhaled or oral medications
1.24 □ Active solid organ Neoplasm
1.25 □ Hematologic neoplasm
1.26 □ Bone marrow transplant
1.27 □ Diabetes Mellitus requiring insulin or oral hypoglycaemic therapy therapy
1.28 □ Heart failure: NYHA classes III-IV
1.29 □ Chronic Renal Failure (if selected: 1.29a □ Requiring dialysis)
1.3 □ Immunosuppression
1.31 □ Chronic liver failure (1.32 □ Child-Pugh Class C)
1.33 □ Congenital/Acquired Myopathies/Neuropathies
1.34 □ alcohol abuse
1.35 □ active smoker
1.36 □ pulmonary hypertension
1.37 □ kyphoscoliosis
with respiratory dysfunction
1.38 Pregnancy [ONE SELECTION ONLY] □ Yes □ No □ Unknown
1.39 Known or suspected diagnosis of dementia? [ONE SELECTION ONLY]
□ None □ Mild □ Moderate/severe
1.40 Clinical Frailty Scale Score (in the 2 months prior to first ICU admission) [ONE SELECTION ONLY]
1. Very fit — robust, active, energetic, well motivated and fit; exercise regularly; most fit group for their age
2. Well — without active disease, but less fit than people in category 1
3. Managing Well, with treated comorbid disease — disease symptoms are well controlled
4. Apparently Vulnerable — not frankly dependent, patients “slowed up” or have disease symptoms
5. Mildly Frail — with limited dependence on others for instrumental activities of daily living
6. Moderately Frail — help is needed with all outside activities and with keeping house, i.e. in both instrumental and non-instrumental activities of daily living
7. Severely frail — completely dependent on others for personal care, from whatever cause (physical or cognitive).
8. Very Severely Frail – Completely dependent, approaching the end of life. Terminally Ill – life expectancy < 6 months, whether or not evidently frail.

What is/are the cause(s) of the patient’s ICU admission (check all that apply)?
1.41 □ Hypercapnic Respiratory Failure
1.42 □ Hypoxaemic Respiratory Failure
1.43 □ Sepsis/septic shock
1.44 □ Cardiogenic pulmonary edema
1.45 □ Cardiac arrest
1.46 □ Emergency surgery
1.47 □ Elective surgery (1.48 □ CARDIAC)
1.49 □ ABDOMINAL
1.50 □ THORACIC
1.51 □ NEUROSURGICAL
1.52 □ Other (___________)
1.53 □ Shock (other than septic)
1.54 □ Trauma
1.55 □ Neurologic impairment
1.56 □ Drug overdose
1.57 □ Airway protection
1.58 □ Other (___________)
1.59 □ Metabolic/electrolyte

2 Excluding non-melanoma skin cancer
3 Includes drugs such as cyclosporine, azathioprine, rituximab or cancer chemotherapy, steroids (except for adrenal insufficiency replacement)
**FORM 2: - DAILY DATA COLLECTION FORM**

*THIS FORM HAS TO BE FILLED EVERY DAY, REPORTING DATA COLLECTED BETWEEN 7-10 am*

2.1a Was this patient in the ICU in the last 24 hours?  
☐ YES  ☐ NO (Go to form 4)  [ONE SELECTION ONLY]

2.1b Was patient invasively ventilated in the last 24 hours?  
☐ YES  ☐ NO (Go to form 3)  [ONE SELECTION ONLY]

2.2 Patient’s interface:  ☐ ETT  ☐ Tracheostomy  ☐ Not invasively ventilated anymore  [ONE SELECTION ONLY]

2.3 Sedation level (before sedation interruption):  [ONE SELECTION ONLY]

☐ RASS  ☐ SASS  ☐ RAMSAY  ☐ Not measured

2.4 Was there a sedation interruption in the last 24 hours:  [ONE SELECTION ONLY]

☐ Yes  ☐ No

What is the current (at the time of evaluation) level of ventilator assistance received (if on separation attempt, please give prior level of assistance)?

Full support:  ☐ Volume A/C  ☐ PC/BIPAP/APRV  ☐ SIMV  ☐ PRVG
Partial support:  ☐ PSV  ☐ NAVA
Minimal support:  ☐ CPAP  ☐ T-Tube  ☐ Other (specify)

*Please record ventilator settings:*

2.14 Peak___________  
2.15 Plateau (if different)___________

2.16 RR (set)___________  
2.17 RR (total)___________  
2.18 PEEP (cmH2O)___________

2.21 FiO2___________  
2.22 Actual Tidal volume___________  
2.23 p0.1___________(if measured)

Arterial Blood Gas (as close as possible to above vent settings, if measured):

2.24 pH: __ . __ __  
2.25 PaO2: __ __ __  
2.26 PaCO2: __ __ __  
2.27 Lactate __ . __ __

2.28 If no Arterial Blood Gas Analysis: Pulse Oximeter SpO2: __ __ __ %

2.29 What is the lowest level of assistance received in the last 24 hours? IF DIFFERENT FROM ABOVE  
[ONE SELECTION ONLY]

☐ Assistance level not different from above

Full support:  ☐ Volume A/C  ☐ PC/BIPAP/APRV  ☐ SIMV  ☐ PRVG
Partial support:  ☐ PSV  ☐ NAVA
Minimal support:  ☐ CPAP  ☐ T-Tube  ☐ Other (specify)
Extubation:  ☐ Accidental Extubation  ☐ Planned Extubation

2.30 Peak___________  
2.31 Plateau (if different)___________[if cmv]

2.31 Pressure support level___________[if PSV]

2.32 RR (set)___________  
2.33 RR (total)___________  
2.34 PEEP (cmH2O)___________

2.35 FiO2___________  
2.36 Actual Tidal volume___________  
2.37 p0.1___________(if measured)

2.38 How long was this level maintained for? ____________ hours  
Start time_________
2.39 What was the reason for termination of lower level of support?

☐ Pre-planned termination ☐ Patient deterioration ☐ Other (Specify)____________

Arterial Blood Gas (if measured during reduced support):

2.40 pH: __ . __ __
2.41 PaO$_2$: __ __ __
2.42 PaCO$_2$: __ __ __
2.43 Lactate __ . __ __

2.44 If no Arterial Blood Gas Analysis: Pulse Oximeter SpO$_2$: ____ ____ %

2.45 Was this a spontaneous breathing trial (SBT), to predict success in separating the patient from the ventilator?

☐ YES ☐ NO [ONE SELECTION ONLY]
### SOFA Score (every third day from day 1, 4, etc.)

<table>
<thead>
<tr>
<th>Values</th>
<th>NOT AVAILABLE</th>
</tr>
</thead>
</table>

(Please give worst value in the last 24 hours)

**Glasgow Coma Scale (3-15)**

- **2.46 motor**
- **2.47 eye**
- **2.48 verbal**
  - 1
- **2.49 Platelet Count (UNITS)**
- **2.50 Total Bilirubin (if measured)**
- **2.51 Creatinine (if measured)**
- **2.52 OR Urine Output (mL/day)**
- **2.53 Mean Arterial Pressure (mmHg)**
- **2.54 Dopamine infusion**
- **2.55 Dobutamine infusion**
- **2.56 Noradrenaline infusion**
- **2.57 Adrenaline infusion**
- **2.58 Others vasopressors? (Yes/No) or dosage?**
- **2.59 PDE inhibitors (Yes/No) or dosage?**

In the last 24 hours, did the patient receive any of the following drugs:

- **2.60 Sedatives [ONE SELECTION ONLY]:** Continuous □ Intermittent □ None □
- **2.61 Opioids [ONE SELECTION ONLY]:** Continuous □ Intermittent □ None □
- **2.62 NM blockers [ONE SELECTION ONLY]:** Continuous □ Intermittent □ None □
- **2.63 Steroids [ONE SELECTION ONLY]:** High dose □ Low dose □ None □
- **2.64 Diuretics [ONE SELECTION ONLY]:** High dose □ Low dose □ None □

- **2.65 Renal replacement therapy [ONE SELECTION ONLY] □ YES □ NO**
- **2.66 Is the patient receiving ECMO/ECCO2R □ YES □ NO Blood flow________ l/min**
PART B: - TO BE FILLED FOR PATIENTS WITH PEEP < 10 cm H2O, and FiO2 < 50%, if they are not receiving neuromuscular blockers or high doses of vasopressors (> 0.2 mcg/kg/min of noradrenaline or equivalent)

What are the reasons for not separating the patient from the ventilator according to the attending physician (check all that apply)?

2.67 □ Unresolved surgical condition
2.68 □ Unresolved respiratory failure
2.69 □ Upper airway protection
2.70 □ Decreased level of consciousness
2.71 □ Agitation/ delirium
2.72 □ Cardiac failure / Fluid Overload
2.73 □ Hemodynamic instability
2.74 □ Muscle weakness
2.75 □ Planned intervention requiring airway protection
2.76 □ Failed spontaneous breathing trial
2.77 □ Recent [< 24 hours] re-intubation
2.78 □ Excessive secretion
2.79 □ Weak cough

2.80 Maximum Inspiratory Pressure (if measured in the last 24 hours) _______________ cmH2O

2.81 Is this patient considered in weaning phase according to the attending physician?  
☐ Yes  ☐ No  ☐ Uncertain  ☐ Unknown  [ONE SELECTION ONLY]

2.82 Amount of secretions:  ☐ none/mild  ☐ moderate  ☐ abundant [ONE SELECTION ONLY]

2.83 Cough strength:  ☐ weak  ☐ intermediate  ☐ normal/strong  ☐ NOT RECORDED  [ONE SELECTION ONLY]

2.84 Was the patient out of the bed last 24 hours?  ☐ Yes  ☐ No  [ONE SELECTION ONLY]

2.85 Did the patient do mobility exercise last 24 hours?  
☐ Yes, active  ☐ Yes, passive  ☐ No  [ONE SELECTION ONLY]

2.86 Current heart rate _______________
2.87 Current systolic blood pressure _______________
2.88 Current diastolic blood pressure _______________
2.89 Fluid balance in last 24 hours _______________
FORM 3: - DAILY DATA COLLECTION FORM FOR PATIENTS NOT CONNECTED TO THE VENTILATOR IN THE LAST 24 HOURS

IN THE LAST 24 HOURS DID THE PATIENT RECEIVE ANY OF THE FOLLOWING? (Check all that apply)

3.1 □ Face mask/Nasal cannula low flow oxygen (<15)
3.2 □ NIV/CPAP via Helmet interface
3.3 □ NIV/CPAP via Face/Nose Mask interface
3.4 □ High Flow nasal cannula
3.5 □ None of the above

IF YES, WHAT WAS THE REASON? (Check all that apply)

3.6 □ Hypoxia
3.7 □ Hypercapnia
3.8 □ Respiratory distress
3.9 □ Prophylaxis
3.10 □ Restoration of home ventilatory support (including Sleep Apnea Syndrome)
Study ID: __________ Date of Data collection: ______________

FORM 4: - OUTCOMES – ICU DISCHARGE/DEATH

ICU Outcome
4.1 □ Alive □ Dead [ONE SELECTION ONLY]
4.2 Date of ICU discharge/Death: _ _ / _ _ / _ _ _ _ (DD/MM/Year)

For pts discharged alive
4.3 Discharged to: [ONE SELECTION ONLY]
This Hospital: □ Other ICU □ Intermediate Care Unit □ Weaning unit □ Hospital Ward
Other Hospital: □ ICU □ Intermediate Care Unit □ Weaning unit □ Hospital Ward
Other Location: □ Home □ Rehabilitation facility □ Other (Specify)____________

Respiratory status at ICU Discharge (check all that apply):
4.4 □ Intubated 4.5 □ Tracheostomy 4.6 □ Non-invasive ventilation
4.7 □ Oxygen therapy 4.8 □ No oxygen therapy

4.9 Level of physical Dependence (at discharge) [ONE SELECTION ONLY]
□ Independent □ Partially Dependent □ Completely Dependent

Changes in Goals of Care
4.10 Was there a pre-existing order limiting life-sustaining measures prior to ICU admission? (E.g. no CPR/withdraw/withhold)
□ Yes □ No □ Not legally available [ONE SELECTION ONLY]

If answer to 4.11= “yes”
What was the life sustaining measure limited? [CHECK ALL THAT APPLY]
4.12 □ No CPR
4.13 □ No re-intubation
4.14 □ No re-admission to ICU
4.15 □ ICU trial
4.16 □ Full comfort care [i.e. no organ support]
4.17 □ Extubation with full comfort and/or palliative care.

4.18 Did a difficulty in weaning influence the decision to limit life-sustaining measures? [ONE SELECTION ONLY]
□ No
□ Yes – Sole/major reason
□ Yes – One of a number of reasons

4.19 Date of decision for ‘No CPR’ measures in event of cardiac arrest: _ _ / _ _ / _ _ _ _
4.20 Date of decision to withhold/withdraw other life sustaining measures: _ _ / _ _ / _ _ _ _

Co-Enrollment in another Study
4.21 Was this patient co-enrolled in another study □ Yes □ No [ONE SELECTION ONLY]
4.22 If patient was co-enrolled, was there a protocol for weaning from mechanical ventilation □ Yes □ No [ONE SELECTION ONLY]
If ICU outcome = “alive”
Hospital (or 90 day) Outcome (whichever event occurs first)

4.23 □ Alive □ Dead [ONE SELECTION ONLY]

4.24 Date of hospital discharge: _ _ / _ _ / _ _ _ _