Acute Phase Days 4 to Discharge Form

Section 1 - Participant Details

Trial Number	Initials *First, Middle, Last*	Site

Section 2 - Post-operative Care

Ward Locations - Please provide total number days participant was on each ward type from day 4 to discharge

	General Ward	Acute Ward	HDU Level 2	ITU Level 3
Number of days				

Please confirm all ward locations above have been considered and number of days patient stayed have been provided? ◯ No ◯ Yes

Was additional, unplanned involvement of the pain team required to address pain management? *In period from day 4 to discharge* ◯ No ◯ Yes

Date of discharge: *E.g. 31-Dec-2017* D D - M M M - Y Y Y Y

Section 3 - Post-operative Analgesia

Did the patient have any of the below analgesia from day 4 to discharge? ◯ No ◯ Yes

Please indicate analgesics given: *Tick if used*

◯ Gabapentin ◯ Pregabalin ◯ Ketamine ◯ PCA Opioid ◯ Oral opioid ◯ IV opioid ◯ Topical opioid

If oral/PCA/IV/topical opioid(s) used, please specify:

Please confirm all post-operative analgesia section data items were considered and all analgesia used has been ticked and recorded? ◯ No ◯ Yes

Section 4 - Post-operative Symptoms and Complications

Did the patient suffer any of the following complications in the period from day 4 to discharge? *Please tick all that apply and grade severity according to Thoracic Morbidity and Mortality Classi cation Format (refer to pages 4-8)*

◯ No ◯ Yes

Complications (consider if SAE)

	Yes	TMM Grade I-V e.g. IIIa, IVb
Nausea		
Vomiting		
Post-dural Headache		
Atelectasis		
Pneumonia		
ARDS		
Pulmonary Embolism		
Pulmonary Aspiration		
Atrial Arrythmia		
Ventricular Arrythmia		
Myocardial Infarction		

Please continue to next page

Trial Number	Initials *First, Middle, Last*

Complications Continued (consider if SAE)		
	Yes	TMM Grade I-V
DVT		
Renal Failure		
Urinary Retention		
Hypotension (systolic bp <90mmHg)		
Neurological Complication		

Please confirm all items in the complications section have been considered and only those ticked occurred? No Yes

Has the patient tested positive for an acute COVID19 infection in the period from day 4 to discharge? No Yes

Did the patient suffer an SAE as a result of a protocol defined expected event in the period from day 4 to discharge? *if yes indicate below* No Yes

If patient suffered an SAE that was not a protocol defined expected event an SAE form must be completed and sent to the trial office

Protocol defined expected event:

- ARDS
- Atelectasis
- Atrial arrhythmia
- Bronchpleural fistula
- DVT
- Failure of blockade
- Hypotension
- Inadequate pain relief
- Itching
- Myocardial infarct
- Nausea
- Neurological complication
- Pleural effusion
- Pleural puncture
- Pneumonia
- Pneumothorax
- Postdural puncture headache
- Post-surgical bleed
- Prolonged air leak
- Pulmonary aspiration
- Pulmonary embolism
- Renal failure
- Respiratory failure type 1
- Respiratory failure type 2
- Urinary retention
- Vascular puncture
- Ventricular arrhythmia
- Vomiting
- Surgical emphysema
- Chylothorax

Seriousness of Event (Each Yes/No question requires a response)		
	No	Yes
Death		
Life Threatening Event		
Prolongation of Existing Hospitalisation		
Persistent or Significant Disability/Incapacity		
Congenital Anomaly or Birth Defect		
Other Medical Reason For Reporting		

Specify other medical reason: _____

If death please complete trial exit/change of status form

Event severity: Mild Moderate Severe Life threatening Fatal

Date of onset: D D - M M M - Y Y Y Y

Date became serious: D D - M M M - Y Y Y Y

Date resolved: D D - M M M - Y Y Y Y

Please continue to next page.

Trial Number:	Initials: *First, Middle, Last*

Section 5 - Return To Theatre Day 4 to Discharge

Did the patient return to theatre? *If yes please complete below* ◯ No ◯ Yes

Bronchoscopy ◯ No ◯ Yes	Redo thoracotomy ◯ No ◯ Yes	Other ◯ No ◯ Yes

If other please specify:

Section 6 - Patient Completed Booklet

Did the patient complete booklet at discharge? ◯ No ◯ Yes

If no, please provide reason:

Section 7 - Willing to Continue

Has the patient confirmed their willingness to continue? *If no complete trial exit/change of status form* ◯ No ◯ Yes

Section 8 - Form Completion

Completed By (Name):	Signed:	Date: *E.g. 31-Jan-2017* D D - M M M - Y Y Y Y
PI Name:	PI Confirmation Signature:	Date: *E.g. 31-Jan-2017* D D - M M M - Y Y Y Y

Major cardiopulmonary complications as classified by the European Society of Thoracic Surgeons

ARDS: Adult respiratory distress syndrome defined according to the American---European consensus conference. All of the following criteria should be met:
1. Acute onset
2. Arterial hypoxemia with PaO2/FIO2 ratio lower than 200 (regardless PEEP level)
3. Bilateral infiltrates at chest radiograph or CT scan
4. No clinical evidence of left atrial hypertension or pulmonary artery occlusive pressure <18 mmHg
5. Compatible risk factors

Atrial Arrhythmia: new onset of atrial fibrillation/flutter (AF) requiring medical treatment or cardioversion. Does not include recurrence of AF which had been present preoperatively.

Ventricular Arrhythmia: sustained ventricular tachycardia or ventricular fibrillation that has been clinically documented and treated by ablation therapy, implantable cardioverter defibrillator, permanent pacemaker, pharmacologic treatment or cardioversion.

Bronchoscopy for atelectasis: postoperative atelectasis documented clinically or radiographically that needed bronchoscopy.

Pneumonia: defined according to the last CDC criteria. Two or more serial chest radiographs with at least **one** of the following:

- New or progressive and persistent infiltrate
- Consolidation
- Cavitation

And at least **one** of the following:

- Fever (>38°C or >100.4°F) with no other recognized cause
- Leukopenia (<4000 WBC/mm3) or leukocytosis (>12,000 WBC/mm3)
- For adults >70 years old, altered mental status with no other recognized cause

and at least **two** of the following:

- New onset of purulent sputum, or change in character of sputum, or increased respiratory secretions, or increased suctioning requirements
- New onset or worsening cough, or dyspnea, or tachypnea
- Rales or bronchial breath sounds Worsening gas exchange (e.g. O2 desaturations (e.g., PaO2/FiO2 < 240), increased oxygen requirements, or increased ventilator demand).

Pulmonary embolism: confirmed by V/Q scan, angiogram or CT scan.

DVT: deep venous thrombosis confirmed by Doppler study, contrast study or other study and that required treatment.

Myocardial infarct: evidenced by one of the following criteria:

1. Transmural infarction diagnosed by the appearance of a new Q wave in two or more contiguous leads on ECG.
2. Subendocardial infarction (non Q wave) evidenced by clinical, angiographic electrocardiographic signs.
3. Laboratory isoenzyme evidence of myocardial necrosis.

Renal failure: defined as the onset of new renal failure in the postoperative period according to one of the following criteria:

1. Increase of serum creatinine to greater than 2.0, and 2-fold the preoperative creatinine level.
2. A new requirement for dialysis postoperatively.

Neurological complication: occurrence of one of the following central neurologic postoperative events not present preoperatively:

1. A central neurologic deficit persisting postoperatively for more than 72 hours
2. A transient neurologic deficit (transient ischemic attack or reversible ischemic neurological deficit) with recovery within 72 hours
3. A new postoperative coma persisting at least 24 hours and caused by anoxic/ischemic and/or metabolic encephalopathy, thromboembolic event or cerebral bleed.

Seeley Systematic Classification of Morbidity and Mortality After Thoracic Surgery (TM &M) Classification of Severity

Complication: Any deviation from the normal postoperative course.

Minor	
Grade I	Any complication without need for pharmacologic treatment or other intervention.
Grade II	Any complication that requires pharmacologic treatment or minor intervention only.
Major	
Grade III	Any complication that requires surgical, radiologic, endoscopic intervention, or multi-therapy.
Grade IIIa	Intervention does not require general anaesthesia.
Grade IIIb	Intervention requires general anaesthesia.
Grade IV	Any complication requiring intensive care unit management and life support.
Grade IVa	Single organ dysfunction.
Grade IVb	Multi-organ dysfunction.
Mortality	
Grade V	Any complication leading to the death of the patient.

StEP Core Outcome Measures in Perioperative and Anaesthetic Care (COMPAQ) – Post-operative Pulmonary Complications

ARDS - Berlin definition

Timing: within 1 week of a known clinical insult or new or worsening respiratory symptoms **AND**…

Chest imaging: bilateral opacities not fully explained by effusions, lobar/lung collapse or nodules **AND**…

Origin of oedema: respiratory failure not fully explained by cardiac failure or fluid overload (requires objective assessment, e.g. echocardiography, to exclude hydrostatic oedema), **AND**…

Oxygenation: mild PaO_2:FiO_2 between 26.7 and 40.0 kPa (200-300 mm Hg) with PEEP or CPAP_5 cm H_2O; moderate PaO_2:FiO_2 between 13.3 and 26.6 kPa (100-200 mm Hg) with PEEP_5 cmH_2O; severe PaO_2:FiO_2_13.3 kPa (100 mm Hg) with PEEP_5 cm H_2O.

Mechanical ventilation
The need for need for tracheal re-intubation and mechanical ventilation after extubation, and within 30 days after surgery OR mechanical ventilation for more than 24 h after surgery. The inclusion of non-invasive ventilation may be considered on a study by study basis.

Post-operative Complications*

Composite of respiratory diagnoses that share common pathophysiological mechanisms including pulmonary collapse and airway contamination:

(i) atelectasis detected on computed tomography or chest radiograph,
(ii) pneumonia using US Centers for Disease Control criteria,
(iii) Acute Respiratory Distress Syndrome using Berlin consensus definition,
(iv) pulmonary aspiration (clear clinical history **AND** radiological evidence).

*Exclusions
Other diagnoses that do not share a common biological mechanism are best evaluated separately and only when clearly relevant to the treatment under investigation:

(i) pulmonary embolism,
(ii) pleural effusion,
(iii) cardiogenic pulmonary oedema,
(iv) pneumothorax,
(v) bronchospasm.

Post-operative Pneumonia

Two or more serial chest radiographs with at least one of the following (one radiograph is sufficient for patients with no underlying pulmonary or cardiac disease):
(i) New or progressive and persistent infiltrates, (ii) consolidation
(iii) cavitation; **AND** at least **one** of the following:

(a) fever (>38°C) with no other recognised cause,
(b) leucopaenia (white cell count <4_10^9 litre_1) or leucocytosis (white cell count >12_10^9 litre_1),
c) for adults >70 yr old, altered mental status with no other recognised cause;

AND at least **two** of the following:

(a) new onset of purulent sputum or change in character of sputum, or increased respiratory secretions, or increased suctioning requirements,
(b) new onset or worsening cough, or dyspnoea, or tachypnoea,
(c) rales or bronchial breath sounds,
(d) worsening gas exchange (hypoxaemia, increased oxygen requirement, increased ventilator demand).