

Consent and Randomisation Form

To randomise a patient please go to <https://www.trials.bham.ac.uk/TOPIC2> or call 0800 953 0274 between 9am-5pm, Monday to Friday

Section 1 - Participant Details

Initials: <i>First, Middle, Last</i> <input type="text"/> <input type="text"/> <input type="text"/>	Site: _____
Date of birth: <i>E.g. 31-Dec-2017</i> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Patient Gender: <i>Please tick one</i> <input type="radio"/> Male <input type="radio"/> Female

Section 2 - Eligibility Checklist

Inclusion checklist:

Aged 18 or over? <i>Tick one</i>	<input type="radio"/> No <input type="radio"/> Yes
Having an elective open thoracotomy? <i>Tick one</i>	<input type="radio"/> No <input type="radio"/> Yes
Able to understand the study information and provide written informed consent? <i>Tick one</i>	<input type="radio"/> No <input type="radio"/> Yes
State version of informed consent form signed by patient: <i>e.g. 1.0, 2.0 etc</i> <input type="text"/> <input type="text"/>	
Willing and able to comply with completion of questionnaires out to 12 months post-randomisation? <i>Tick one</i>	<input type="radio"/> No <input type="radio"/> Yes

Exclusion checklist:

Contraindication to TEB or PVB e.g. known allergy to local anaesthetics; infection near the proposed puncture site; coagulation disorders, thoracic spine disorders <i>Tick one</i>	<input type="radio"/> No <input type="radio"/> Yes
Will be having a rib/chest wall resection or planned pleurectomy? <i>Tick one</i>	<input type="radio"/> No <input type="radio"/> Yes
Undergoing emergency thoracic surgery? <i>Tick one</i>	<input type="radio"/> No <input type="radio"/> Yes
Has had a previous thoracotomy on the same side? <i>Tick one</i>	<input type="radio"/> No <input type="radio"/> Yes
Has had a median sternotomy in the last 90 days? <i>Tick one</i>	<input type="radio"/> No <input type="radio"/> Yes

Please note: if any of the **shaded boxes** above are ticked then the patient is **ineligible** to take part in TOPIC2

Section 3 - Co-enrolment

Has the patient, or is the patient intending to co-enrol into another trial/study? <i>Tick one</i>	<input type="radio"/> No <input type="radio"/> Yes
If Yes , specify: _____	

Section 4 - Randomisation

Please note: if patient is having thoracotomy for suspected lung cancer they should be randomised to lung cancer resection

Reason for lung thoracotomy? <i>Tick one</i> <input type="radio"/> Lung cancer resection <input type="radio"/> Other indication	Age <input type="radio"/> <65 years <input type="radio"/> ≥65 years
Patient Trial Number: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Date randomised: <i>e.g. 31-JAN-2017</i> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
	Time randomised: 24hr <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Intervention Allocation: <i>Tick one</i>	<input type="radio"/> Paravertebral Blockade (PVB) <input type="radio"/> Thoracic Epidural Blockade (TEB)

Section 5 - Form Completion Details

Form completed by: _____	Signature: _____	Date: <i>e.g. 31-JAN-2017</i> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Principal Investigator Name: _____	Principal Investigator Signature: _____	Date: <i>e.g. 31-JAN-2017</i> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>