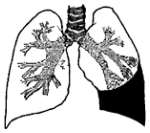
North Bristol NHS Trust

UKCRC Oxford
Respiratory Trials Unit
University of Oxford



Evaluating the efficacy of thoracoscopy and talc poudrage versus pleurodesis using talc slurry

TAPPS trial

CRF PACK

Trial Number:					**Patient's Initials**			

Please file the original CRFs at your site and send copies to:

Oxford Respiratory Trials Unit
University of Oxford
Oxford Centre for Respiratory Medicine
Churchill Hospital, Old Road
Oxford, OX3 7LE

If you need pre-paid envelopes for sending the CRFs, please contact ORTU on 01865 225205

Patient's trial number					Date of enrolment	DD	MM	YYYY	Patient's initials			

TAPPS TRIAL FORM 1 – **ENROLMENT**

Clinical data

1	**SEX**			MALE	FEMALE
2	**PATIENT'S DATE OF BIRTH**			DD MM YYYY	
3	**SMOKING STATUS**	CURRENT	EX-SMOKER	NEVER-SMOKER	
4	**WHO PERFORMANCE STATUS**	0	1	2	3

5 **UNDERLYING CANCER TYPE(S)**
1=lung 2=mesothelioma 3=breast 4=ovarian 5=lymphoma 6=upper GI 7=lower GI 8=renal 9=other 10=unknown

Cancer type(s) (use code above)	**Cell type** (write unknown if needed)	**TNM Staging at enrolment** (Write unknown if needed)			**Mode of diagnosis** (histological, cytological, radiological/clinical)	**Date of diagnosis** (Write unknown if needed)		
		T	N	M		DD	MM	YYYY
		T	N	M		DD	MM	YYYY
		T	N	M		DD	MM	YYYY

Effusion

6	**SIDE OF EFFUSION NEEDING INTERVENTION**	LEFT	RIGHT
7	**HAS THE PATIENT HAD ANY PLEURAL INTERVENTIONS ON THIS SIDE IN THE LAST 3 MONTHS?** If yes please enter details in the table below	YES	NO

1=Diagnostic tap
2=Therapeutic tap
3=Image-guided biopsy
4=Chest drain
5=Indwelling Pleural Catheter
6=Medical thoracoscopy
7=VATS
8=Other (Specify)

Procedure type (Use code on left)	**Date of procedure**			**Procedure type** (Use code on left)	**Date of procedure**		
	DD	MM	YYYY		DD	MM	YYYY
	DD	MM	YYYY		DD	MM	YYYY
	DD	MM	YYYY		DD	MM	YYYY

8	**HAVE THERE BEEN ANY ATTEMPTS AT PLEURODESIS ON THIS SIDE IN THE LAST MONTH?**	YES	NO

9	**WHAT IS THE MAXIMUM FLUID DEPTH ON THORACIC ULTRASOUND?**		Cm
	Date of scan (must be within the last 10 days)	DD MM YYYY	

Symptoms

10	**HOW LONG HAS THE PATIENT HAD SYMPTOMS FROM THIS EFFUSION?**	LESS THAN 1 WEEK	1 WEEK TO 3 WEEKS	MORE THAN 3 WEEKS

Patient's trial number					Patient's initials			

11 **PLEASE ASK THE PATIENT TO INDICATE HOW MUCH <u>CHEST PAIN</u> THEY HAVE AT THE MOMENT BY MAKING A SINGLE VERTICAL MARK ON THE LINE BELOW**

No pain at all ——————————— Worst possible pain

FOR OFFICE USE ONLY	Assessor 1 score	mm	Initials	Date	Assessor 2 score	mm	Initials	Date

12 **PLEASE ASK THE PATIENT TO INDICATE HOW MUCH <u>BREATHLESSNESS</u> THEY HAVE AT THE MOMENT BY MAKING A SINGLE VERTICAL MARK ON THE LINE BELOW**

No breathlessness at all ——————————— Worst possible breathlessness

FOR OFFICE USE ONLY	Assessor 1 score	mm	Initials	Date	Assessor 2 score	mm	Initials	Date

Treatment

13 **PLEASE GIVE DETAILS OF ALL THE <u>ORAL STEROIDS</u> THE PATIENT IS CURRENTLY TAKING.**
Tick 'none' if needed

NONE	

Type (Generic drug name in CAPITALS)	**Dose** (include units, e.g. 10 mg)	**Frequency** (Number of doses per day)

14 **PLEASE GIVE DETAILS OF ALL THE <u>NON-STEROIDAL ANTI-INFLAMMATORIES (NSAIDS)</u> THE PATIENT IS CURRENTLY TAKING.**
Tick 'none' if needed

NONE	

Type (Generic drug name in CAPITALS)	**Dose** (include units, e.g. 10 mg)	**Frequency** (Number of doses per day)	**Regular or PRN**	**Route** (oral / topical / rectal / other)

15 **PLEASE INDICATE IF THE PATIENT IS TAKING <u>ANY OTHER ANALGESICS</u> FROM THE FOLLOWING GROUPS**
Please tick all that apply and indicate whether they are taken regularly or on a PRN basis by circling

NONE		
PARACETAMOL		**Regular / PRN**
WEAK OPIATE (e.g. codeine / tramadol)		**Regular / PRN**
STRONG OPIATE (e.g. oramorph / fentanyl)		**Regular / PRN**
OTHER (Please specify, e.g. gabapentin).....		**Regular / PRN**
OTHER (Please specify, e.g. gabapentin).....		**Regular / PRN**

Patient's trial number					Patient's initials			

16	**HAS THE PATIENT EVER RECEIVED RADIOTHERAPY TO THE CHEST, ON THE SIDE OF THE PROPOSED INTERVENTION?**	YES			NO
17	**IS THE PATIENT <u>CURRENTLY</u> TAKING ANY CANCER-MODULATING HORMONE THERAPY?**	YES			NO
	If yes, what stage therapy is it?	1st LINE	2nd LINE	3rd LINE	OTHER
	When did this treatment start?	DD / MM / YYYY			UNKNOWN
18	**IS THE PATIENT <u>CURRENTLY</u> UNDERGOING ANY TREATMENT WITH ANTI-CANCER MONOCLONAL ANTIBODIES?**	YES			NO
	If yes, what stage therapy is it?	1st LINE	2nd LINE	3rd LINE	OTHER
	When did this treatment start?	DD / MM / YYYY			UNKNOWN
19	**IS THE PATIENT <u>CURRENTLY</u> RECEIVING ANY CHEMOTHERAPY?**	YES			NO
	If yes, what stage therapy is it?	1st line	2nd line	3rd LINE	OTHER
	When did this treatment start?	DD / MM / YYYY			UNKNOWN
20	**IS THE PATIENT <u>CURRENTLY</u> UNDERGOING ANY OTHER FORM OF ANTI-CANCER THERAPY?**	YES			NO
	If yes, please specify				
	When did this treatment start?	DD / MM / YYYY			UNKNOWN
21	**DOES THE PATIENT ROUTINELY TAKE TREATMENT-DOSE ANTICOAGULANT THERAPY?**	YES			NO

If yes, please tick all that apply from the list below. DO NOT INCLUDE ASPIRIN.

CLOPIDOGREL	
LOW MOLECULAR WEIGHT HEPARIN (e.g. Enoxaparin)	
WARFARIN	
OTHER (please specify).....	

Patient's trial number					Patient's initials			

Past medical history

22 **DOES THE PATIENT SUFFER FROM ANY OF THE FOLLOWING DISEASES?**

RESPIRATORY	COPD / ASTHMA	YES	NO
	INTERSTITIAL LUNG DISEASE	YES	NO
	BRONCHIECTASIS	YES	NO
	PULMONARY HYPERTENSION	YES	NO
	OTHER RESPIRATORY	YES	NO
	(Please specify)		
CARDIAC	ISCHAEMIC HEART DISEASE	YES	NO
	ATRIAL FIBRILLATION	YES	NO
	HEART FAILURE	YES	NO
	OTHER CARDIAC	YES	NO
	(Please specify)		

Blood test results

23 Date of tests (must be within the last 10 days) DD MM YYYY

Hb (g/dL)		**Sodium** (mmol/L)		**INR**	
WCC ($x10^9$/L)		**Potassium** (mmol/L)		**APTT** (seconds)	
Platelets ($x10^9$/L)		**Urea** (mmol/L)			
CRP (mg/L)		**Creatinine** (µmol/L)			

Checklist (Tick when done)

Complete form 2 and phone randomisation number to determine treatment arm and trial number	
Ensure every page of this CRF has the patient's trial number entered at the top	
Ensure the patient has completed the quality of life questionnaires (EQ-5D and SF-36)	
Ensure all trial samples have been taken as per protocol (if consent given)	

		DD	MM	YYYY
Name of researcher completing form	Signature	Date		

Recruiting centre		Date of randomisation	DD	MM	YYYY	Patient's initials			

TAPPS TRIAL FORM 2 – **RANDOMISATION**

INCLUSION CRITERIA

		TICK AS APPROPRIATE YES	NO
1	The patient has **one** of the following:		
	a. Pleural effusion with histocytologically proven pleural malignancy		
	b. Unexplained pleural effusion with histocytologically proven malignancy elsewhere		
	c. Pleural effusion and typical features of malignancy with pleural involvement on CT or MRI		
2	The patient is fit enough to undergo local anaesthetic thoracoscopy, as per BTS guidelines		
3	The patient's expected survival > 3 months		
4	The patient has signed the consent form		

EXCLUSION CRITERIA

		YES	NO
1	Local anaesthetic thoracoscopy is the only reasonable approach to making a diagnosis, and such a diagnosis would significantly affect further management		
2	The patient is < 18 years old		
3	The patient is pregnant or lactating		
4	There is evidence of extensive lung entrapment or fluid loculation which would normally exclude talc pleurodesis		
5	There is insufficient volume or positioning of fluid on ultrasound scan, performed in the lateral decubitus position, to allow local anaesthetic thoracoscopy without further intervention		
6	There has been a previously documented reaction to talc		
7	There is a clear contraindication to local anaesthetic thoracoscopy or chest drain insertion		

I CONFIRM THAT THE PATIENT IS ELIGIBLE FOR RANDOMISATION (circle one)	**YES**	**NO**

MINIMISATION INFORMATION

UNDERLYING MALIGNANCY (Tick one)	**Breast**		**WHO PERFORMANCE STATUS** (Tick one)	**0 or 1**	
	Lung				
	Mesothelioma			**2 or 3**	
	Other				

NAME OF DOCTOR ASSESSING ELIGIBILITY:	

IF THE PATIENT IS ELIGIBLE CALL THE RANDOMISATION LINE ON 07773 162 740. You will be given the following information:

				CONTROL Chest drain and slurry	**INTERVENTION** Thoracoscopy and poudrage
Patient's trial number				**Treatment allocation** (circle one)	

		DD	MM	YYYY
Name of researcher completing form	Signature	Date		

Patient's trial number					Date of insertion	DD	MM	YYYY	Patient's initials			

TAPPS TRIAL FORM 3a – **CHEST DRAIN INSERTION** (Control arm)

PLEASE COMPLETE THIS CRF AS SOON AS POSSIBLE AFTER DRAIN INSERTION

If drain was not attempted then please tick here □ and complete form 4

1	**WHERE WAS THE PROCEDURE PERFORMED?**	OPERATING THEATRE	'CLEAN ROOM'	BEDSIDE		
2	**TIMING OF PROCEDURE**	START hh mm	END hh mm			
3	**GRADE OF PRIMARY OPERATOR**	F1/F2	CT1/CT2	ST3+	CONSULTANT	OTHER
4	**WAS BEDSIDE ULTRASOUND USED TO GUIDE DRAIN INSERTION?**	YES	NO	UNKNOWN		

5 **DETAILS OF SEDATION GIVEN**
Write 'none' or 'unknown' if appropriate

Type (Generic drug name in CAPITALS)	**Dose** (include units, e.g. 10 mg)

6 **DETAILS OF PRE-MEDICATION GIVEN**
Write 'none' or 'unknown' if appropriate

Type (Generic drug name in CAPITALS)	**Dose** (include units, e.g. 10 mg)

		Type (generic drug name in CAPITALS) **and strength** (%)	**Dose or volume**
7	**DETAILS OF LOCAL ANAESTHETIC**		

8	**WHAT SIZE DRAIN WAS INSERTED?**	12 F	14 F

9	**WAS SELDINGER TECHNIQUE USED?**	YES	NO	UNKNOWN

10 **PLEASE CIRCLE WHICH COMPLICATIONS, IF ANY, OCCURRED <u>DURING THE PROCEDURE</u>** (circle all that apply individually)

NONE	BLEEDING	SIGNIFICANT COUGH	SYNCOPE
SIGNIFICANT PAIN	MULTIPLE PASSES	PLEURAL SPACE NOT ENTERED	NEW HYPOXIA
DYSRHYTHMIA	NEW HYPOTENSION	OTHER (Please specify).....	

If any circled event is considered to be an adverse event, complete a <u>separate adverse event form</u> and enter the number of forms used here

IF ANY COMPLICATION MIGHT MEET THE CRITERIA OF A SERIOUS ADVERSE EVENT, PLEASE COMPLETE AN SAE FORM AND FAX TO NORTH BRISTOL AND THE ORTU ASAP

		DD	MM	YYYY
Name of researcher completing form	Signature	Date		

Patient's trial number					Date of procedure	DD	MM	YYYY	Patient's initials			

TAPPS TRIAL FORM 3b – **THORACOSCOPY** (Intervention arm)

PLEASE COMPLETE THIS CRF AS SOON AS POSSIBLE AFTER THORACOSCOPY

If procedure was not attempted then please tick here □ and complete form 4

1	**WHERE WAS THE PROCEDURE PERFORMED?**	OPERATING THEATRE	'CLEAN ROOM'	OTHER
2	**TIMING OF PROCEDURE**	START hh mm	END hh mm	
3	**GRADE OF PRIMARY OPERATOR**	REGISTRAR (ST3+)	CONSULTANT	OTHER
4	**WAS ULTRASOUND GUIDANCE USED?**	YES	NO	UNKNOWN

5	**DETAILS OF SEDATION GIVEN** Write 'none' or 'unknown' if appropriate

Type (CAPITALS)	**Dose**

6	**DETAILS OF PRE-MEDICATION GIVEN** Write 'none' or 'unknown' if appropriate

Type (CAPITALS)	**Dose**

		Type (CAPITALS) **and strength** (%)	**Dose or volume**
7	**DETAILS OF LOCAL ANAESTHETIC**		

8	**HOW MUCH FLUID WAS DRAINED DURING THE PROCEDURE?**	mls

9	**WERE ANY ADHESIONS SEEN?**	YES – BROKEN DOWN	YES – NOT BROKEN	NO	UNKNOWN
10	**DID THE LUNG APPEAR TRAPPED?**	YES	NO	UNKNOWN	
11	**WAS TALC POUDRAGE UNDERTAKEN?** If no, tick reason(s) below	YES	NO	UNKNOWN	

TECHNICAL DIFFICULTIES	
SIGNIFICANT ADHESIONS OR LOCULATIONS	
PATIENT DISTRESS	
LUNG APPEARED TRAPPED	
OTHER (Please specify)	

Patient's trial number					Patient's initials			

12	**WERE ANY BIOPSIES TAKEN?**	YES	NO	UNKNOWN

13	**WHAT SIZE DRAIN WAS INSERTED?**	16 F	18 F	20 F	22 F	24 F

Please tick here if no drain was inserted ☐

14 **PLEASE CIRCLE CLEARLY WHICH COMPLICATIONS, IF ANY, OCCURRED <u>DURING THE PROCEDURE</u>**
(circle all that apply individually)

NONE	BLEEDING	SIGNIFICANT COUGH	SYNCOPE
SIGNIFICANT PAIN	VISCERAL DAMAGE	PLEURAL SPACE NOT ENTERED	NEW HYPOXIA
DYSRHYTHMIA	NEW HYPOTENSION	OTHER (Please specify).....	

15 **PLEASE CIRCLE CLEARLY WHICH COMPLICATIONS, IF ANY, OCCURRED <u>IN THE 2 HOURS POST PROCEDURE</u>**
(circle all that apply individually)

NONE	NAUSEA OR VOMITING	RESPIRATORY DEPRESSION NEEDING TREATMENT	GCS DROP > 2
UNCONTROLLED PAIN	NEW HYPOTENSION	SATURATIONS DROP NEEDING TREATMENT	ALLERGIC REACTION
NEW CONFUSION	BLEEDING	OTHER (Please specify).....	

If any circled event in questions 14 and 15 is considered to be an adverse event, complete a <u>separate adverse event form</u> and enter the number of forms used here ☐

IF ANY COMPLICATION MIGHT MEET THE CRITERIA OF A SERIOUS ADVERSE EVENT, PLEASE COMPLETE AN SAE FORM AND FAX TO NORTH BRISTOL AND THE ORTU ASAP

		DD	MM	YYYY
Name of researcher completing form	Signature	Date		

Patient's trial number					Date of discharge	DD	MM	YYYY	Patient's initials			

TAPPS TRIAL FORM 4 – **DISCHARGE**

PLEASE COMPLETE THIS CRF AS SOON AS POSSIBLE AFTER DISCHARGE

SECTION 1 – COMPLETE FOR ALL PATIENTS

1	**DID THE PATIENT DIE BEFORE DISCHARGE?** If no, skip to question 2	YES	NO

If yes, please enter details regarding death below and complete as much of the CRF as possible

Date of death		DD	MM	YYYY
Cause of death as per death certificate	**I a**			
	I b			
	I c			
	II			
Was a post-mortem performed?		YES		NO

Any other comments

2	**HAS THE PATIENT SUFFERED ANY ADVERSE EVENTS SINCE THE LAST CRF WAS COMPLETED?** If yes, please tick below as appropriate	YES	NO

ANAEMIA NEEDING TRANSFUSION	
POST-PROCEDURE FEVER	
WOUND INFECTION	
EMPYEMA	
BRONCHOPLEURAL FISTULA	
ATELECTASIS NEEDING BRONCHOSCOPY	
PNEUMONIA NEEDING ANTIBIOTICS	
RESPIRATORY FAILURE	
DYSRHYTHMIA	
MYOCARDIAL INFARCTION	
DEEP VEIN THROMBOSIS	
PULMONARY EMBOLUS	
SURGICAL EMPHYSEMA	
DRAIN DISLODGEMENT OR REPLACEMENT	
ANY OTHER RELEVANT ADVERSE EVENT(S)	

For each event ticked above, also complete a separate adverse event form and enter the number of forms used here

IF ANY COMPLICATION MIGHT MEET THE CRITERIA OF A SERIOUS ADVERSE EVENT, PLEASE COMPLETE AN SAE FORM AND FAX TO NORTH BRISTOL AND THE ORTU ASAP

Patient's trial number					Patient's initials			

3	**DID THE PATIENT USE ANY <u>NSAIDS</u> DURING THEIR ADMISSION?** If yes, complete below	YES	NO	UNKNOWN

Type (Generic drug name in CAPITALS)	**Dose** (include units, e.g. 10 mg)	**Frequency** (Doses / day)	**Route** (PO / IV / etc.)	**Date started**			**Date stopped**		
				DD	MM	YYYY	DD	MM	YYYY
				DD	MM	YYYY	DD	MM	YYYY
				DD	MM	YYYY	DD	MM	YYYY
				DD	MM	YYYY	DD	MM	YYYY

4	**DID THE PATIENT USE ANY <u>STEROIDS</u> DURING THEIR ADMISSION?** If yes, complete below	YES	NO	UNKNOWN

Type (Generic drug name in CAPITALS)	**Dose** (include units, e.g. 10 mg)	**Frequency** (Doses / day)	**Route** (PO / IV / etc.)	**Date started**			**Date stopped**		
				DD	MM	YYYY	DD	MM	YYYY
				DD	MM	YYYY	DD	MM	YYYY
				DD	MM	YYYY	DD	MM	YYYY

5	**WAS A CHEST X-RAY PERFORMED AT 18 – 24 HOURS POST DRAIN / THORACOSCOPY AS PER PROTOCOL?**	YES	NO

6	**INCLUDING THIS CHEST X-RAY, HOW MANY OF THE FOLLOWING DID THE PATIENT UNDERGO BETWEEN RANDOMISATION AND DISCHARGE?**	CHEST X-RAY		CT CHEST SCAN	

7 **PLEASE GIVE DETAILS OF ALL <u>ANALGESIC</u> MEDICATIONS THE PATIENT WAS TAKING <u>AT THE TIME OF DISCHARGE</u>**
(Write 'none' if needed)

Type (Generic drug name in CAPITALS)	**Dose** (include units, e.g. 10 mg)	**Frequency** (Number of doses per day)	**Regular or PRN**	**Route** (oral / topical / rectal / other)

8 **DAY 2 BLOOD TEST RESULTS**
To be taken on the second day post talc administration OR as close to discharge as possible if sooner

Date of tests	DD	MM	YYYY

Hb (g/dL)		**Sodium** (mmol/L)	
WCC ($x10^9$/L)		**Potassium** (mmol/L)	
Platelets ($x10^9$/L)		**Urea** (mmol/L)	
CRP (mg/L)		**Creatinine** (µmol/L)	

FOR CONTROL ARM PATIENTS COMPLETE SECTION 2

FOR INTERVENTION ARM PATIENTS COMPLETE SECTION 3

PLEASE REMEMBER TO COMPLETE SECTION 4 FOR ALL PATIENTS

Patient's trial number					Patient's initials			

SECTION 2 – CONTROL ARM ONLY (CHEST DRAIN AND TALC SLURRY)

9	**WAS A CHEST DRAIN ATTEMPTED?**	YES	NO

10	**WAS THIS ATTEMPT ABANDONED?** Only if yes, tick reasons below	YES	NO	N/A

TECHNICAL DIFFICULTIES	
SIGNIFICANT COMPLICATIONS	
PATIENT DISTRESS	
UNABLE TO ACCESS PLEURAL SPACE	
OTHER (Please specify)	
UNKNOWN	

11	**WAS TALC SLURRY GIVEN?**	YES	NO		
	When was this given**?** DD MM YYYY hh mm			N/A	UNKNOWN

If talc was not given, <u>or if it was given more than 48 hours after drain insertion</u>, tick reasons below

PLEURAL INFECTION	
PERSISTENT AIR LEAK	
POOR LUNG EXPANSION	
EXCESSIVE FLUID PRODUCTION	
OTHER (Please specify)	
UNKNOWN	

12	**GRADE OF PERSON ADMINISTERING TALC**	F1/F2	CT1/CT2	ST3+	CONS.	NURSE	N/A

13 **DETAILS OF SEDATION GIVEN PRE TALC**
Write 'none' or 'unknown' if appropriate

Type (CAPITALS)	**Dose**

14 **DETAILS OF PRE-MEDICATION GIVEN PRE TALC**
Write 'none' or 'unknown' if appropriate

Type (CAPITALS)	**Dose**

		Type (CAPITALS) **and strength** (%)	**Dose or volume**
15	**DETAILS OF LOCAL ANAESTHETIC PRE TALC**		

Patient's trial number					Patient's initials			

16 PLEASE CIRCLE WHICH COMPLICATIONS, IF ANY, OCCURRED IN THE 2 HOURS POST TALC ADMINISTRATION

NONE	NAUSEA OR VOMITING	RESPIRATORY DEPRESSION NEEDING TREATMENT	GCS DROP > 2
UNCONTROLLED PAIN	NEW HYPOTENSION	SATURATIONS DROP NEEDING TREATMENT	ALLERGIC REACTION
NEW CONFUSION	BLEEDING	OTHER (Please specify)……	

If any circled event is considered to be an adverse event, complete a separate adverse event form and enter the number of forms used here	

IF ANY COMPLICATION MIGHT MEET THE CRITERIA OF A SERIOUS ADVERSE EVENT, PLEASE COMPLETE AN SAE FORM AND FAX TO NORTH BRISTOL AND THE ORTU ASAP

17	**WAS THORACIC SUCTION APPLIED?**	YES	NO	N/A	
	If yes, when did this start?	**Start** DD MM YYYY		**Time** HH MM	
	If yes, when did this stop?	**Stop** DD MM YYYY		**Time** HH MM	
	If yes, what was the approximate total time spent OFF suction?			Hrs	
	If yes, what pressure was predominantly used?	5 – 10 cmH_2O	11 - 20 cmH_2O	21+ cmH_2O	
18	**DID THE DRAIN BUBBLE AFTER INSERTION?**	YES	NO	N/A	UNKNOWN
19	**DID THE DRAIN STOP BUBBLING?**	YES	NO	N/A	UNKNOWN
	If applicable, when did this stop?			DD MM YYYY	
20	**DID THE DRAIN SWING AFTER INSERTION?**	YES	NO	N/A	UNKNOWN
21	**DID THE DRAIN STOP SWINGING?**	YES	NO	N/A	UNKNOWN
	If applicable, when did this stop?			DD MM YYYY	
22	**WHAT WAS THE TOTAL VOLUME OF FLUID DRAINED?**	mls		N/A	UNKNOWN
23	**HOW MUCH FLUID DRAINED IN THE 24 HOURS BEFORE DRAIN REMOVAL?**	mls		N/A	UNKNOWN

Patient's trial number					Patient's initials			

24	WHEN DID THE DRAIN COME OUT?	DD	MM	YYYY	HH	MM	N/A	UNKNOWN

Did this occur when planned, or earlier or later? If not as planned tick reasons below	ON TIME	EARLIER	LATER
PLEURAL INFECTION			
PERSISTENT AIR LEAK			
POOR LUNG EXPANSION			
HIGH VOLUME FLUID PRODUCTION			
APPROPRIATELY QUALIFIED STAFF NOT AVAILABLE			
ACCIDENTAL DISLODGEMENT			
UNCONTROLLED PAIN			
BLOCKAGE			
OTHER (Please specify)			
UNKNOWN			

NOW GO TO SECTION 4

Patient's trial number					Patient's initials			

SECTION 3 – INTERVENTION ARM ONLY (THORACOSCOPY AND POUDRAGE)

25	**WAS A THORACOSCOPY ATTEMPTED?**	YES	NO

26	**WAS THIS ATTEMPT ABANDONED?** Only if yes, tick reasons below	YES	NO	N/A

TECHNICAL DIFFICULTIES	
SIGNIFICANT COMPLICATIONS	
PATIENT DISTRESS	
UNABLE TO ACCESS PLEURAL SPACE	
OTHER (Please specify)	
UNKNOWN	

27	**WAS A DRAIN INSERTED <u>AT ANY TIME?</u>** If yes, please tick below as appropriate	YES	NO

DRAIN INSERTED AT END OF PROCEDURE	
SMALL CALIBRE DRAIN (≤14 F) INSERTED SEPARATE TO THORACOSCOPY	
LARGE CALIBRE DRAIN (≥16 F) INSERTED SEPARATE TO THORACOSCOPY	
INDWELLING PLEURAL CATHETER INSERTED SEPARATE TO THORACOSCOPY	
OTHER (Please specify)	

28	**WAS THORACIC SUCTION APPLIED?**	YES	NO	N/A
	If yes, when did this start?	**Start** DD MM YYYY		**Time** HH MM
	If yes, when did this stop?	**Stop** DD MM YYYY		**Time** HH MM
	If yes, what was the approximate total time spent OFF suction?			Hrs
	If yes, what pressure was predominantly used?	5 – 10 cmH_2O	11 - 20 cmH_2O	21+ cmH_2O

29	**DID THE DRAIN BUBBLE AFTER INSERTION?**	YES	NO	N/A	UNKNOWN
30	**DID THE DRAIN STOP BUBBLING?**	YES	NO	N/A	UNKNOWN
	If applicable, when did this stop?			DD MM YYYY	
31	**DID THE DRAIN SWING AFTER INSERTION?**	YES	NO	N/A	UNKNOWN
32	**DID THE DRAIN STOP SWINGING?**	YES	NO	N/A	UNKNOWN
	If applicable, when did this stop?			DD MM YYYY	

Patient's trial number					Patient's initials			

33	**WHAT WAS THE TOTAL VOLUME OF FLUID DRAINED?** (Excluding fluid removed during thoracoscopy)	mls		N/A	UNKNOWN
34	**HOW MUCH FLUID DRAINED IN THE 24 HOURS BEFORE DRAIN REMOVAL?**	mls		N/A	UNKNOWN
35	**WHEN DID THE DRAIN COME OUT?**	DD / MM / YYYY	TIME	N/A	UNKNOWN

Did this occur when planned, or earlier or later? If not as planned tick reasons below	ON TIME	EARLIER	LATER
PLEURAL INFECTION			
PERSISTENT AIR LEAK			
POOR LUNG EXPANSION			
HIGH VOLUME FLUID PRODUCTION			
APPROPRIATELY QUALIFIED STAFF NOT AVAILABLE			
ACCIDENTAL DISLODGEMENT			
UNCONTROLLED PAIN			
BLOCKAGE			
OTHER (Please specify)			
UNKNOWN			

NOW GO TO SECTION 4

Patient's trial number					Patient's initials			

SECTION 4 – HEALTH RESOURCE USE

36 **TO WHICH WARDS / SPECIALTIES WAS THE PATIENT ADMITTED, AND / OR TRANSFERRED, DURING THEIR INITIAL ADMISSION?**

Ward / specialty type	Tick	Date of entry			Date of discharge		
ACCIDENT AND EMERGENCY (A+E)		DD	MM	YYYY	DD	MM	YYYY
ANAESTHETICS		DD	MM	YYYY	DD	MM	YYYY
CARDIOLOGY (EXCLUDING CCU)		DD	MM	YYYY	DD	MM	YYYY
CARDIOTHORACIC SURGERY		DD	MM	YYYY	DD	MM	YYYY
CARE OF THE ELDERLY MEDICINE		DD	MM	YYYY	DD	MM	YYYY
CLINICAL ONCOLOGY/RADIOTHERAPY		DD	MM	YYYY	DD	MM	YYYY
CLINICAL PHARMACOLOGY		DD	MM	YYYY	DD	MM	YYYY
CLINICAL PHYSIOLOGY		DD	MM	YYYY	DD	MM	YYYY
CORONARY CARE UNIT (CCU)		DD	MM	YYYY	DD	MM	YYYY
CRITICAL CARE MEDICINE (ITU/HDU)		DD	MM	YYYY	DD	MM	YYYY
DIABETES/ENDOCRINOLOGY		DD	MM	YYYY	DD	MM	YYYY
EAR, NOSE AND THROAT (ENT)		DD	MM	YYYY	DD	MM	YYYY
ENDOSCOPY UNIT		DD	MM	YYYY	DD	MM	YYYY
GASTROENTEROLOGY/HEPATOLOGY		DD	MM	YYYY	DD	MM	YYYY
GENERAL MEDICINE (INCLUDING MEDICAL ADMISSIONS)		DD	MM	YYYY	DD	MM	YYYY
GENERAL SURGERY		DD	MM	YYYY	DD	MM	YYYY
HAEMATOLOGY		DD	MM	YYYY	DD	MM	YYYY
INFECTIOUS DISEASES		DD	MM	YYYY	DD	MM	YYYY
MEDICAL ONCOLOGY		DD	MM	YYYY	DD	MM	YYYY
NEUROLOGY/NEUROSURGERY		DD	MM	YYYY	DD	MM	YYYY
NUCLEAR MEDICINE		DD	MM	YYYY	DD	MM	YYYY
ORTHOPAEDICS		DD	MM	YYYY	DD	MM	YYYY
PAIN MANAGEMENT		DD	MM	YYYY	DD	MM	YYYY
PALLIATIVE MEDICINE		DD	MM	YYYY	DD	MM	YYYY
PLASTIC SURGERY		DD	MM	YYYY	DD	MM	YYYY
PRE-OPERATIVE ASSESSMENT UNIT		DD	MM	YYYY	DD	MM	YYYY
RADIOLOGY		DD	MM	YYYY	DD	MM	YYYY
REHABILITATION		DD	MM	YYYY	DD	MM	YYYY
RENAL MEDICINE (INCLUDING DIALYSIS UNIT)		DD	MM	YYYY	DD	MM	YYYY
RESPIRATORY MEDICINE/THORACIC MEDICINE		DD	MM	YYYY	DD	MM	YYYY
RHEUMATOLOGY		DD	MM	YYYY	DD	MM	YYYY
TRANSPLANT MEDICINE		DD	MM	YYYY	DD	MM	YYYY
TROPICAL MEDICINE		DD	MM	YYYY	DD	MM	YYYY
OTHER (Please specify)		DD	MM	YYYY	DD	MM	YYYY

Patient's trial number					Patient's initials			

37 WHICH OPERATIONS OR PROCEDURES DID THE PATIENT UNDERGO DURING THEIR ADMISSION (EXCLUDING THE TRIAL PROCEDURE)

Procedure type	Date of procedure		
	DD	MM	YYYY
	DD	MM	YYYY
	DD	MM	YYYY
	DD	MM	YYYY
	DD	MM	YYYY
	DD	MM	YYYY

DISCHARGE CHECKLIST FOR ALL PATIENTS (Tick if when done, if applicable)

Ensure the patient has an appointment for their 1 month follow-up appointment	
Ensure every page of this CRF has the patient's trial number entered at the top	
Ensure the patient has been supplied with a resource use diary and a weekly VAS chart	
If time from randomisation to discharge is more than 7 days, ensure the patient has completed 7 days of VAS scores	
If time from randomisation to discharge is less than 7 days, ensure the completed scores have been copied, and that the patient has sufficient extra VAS sheets to complete at home and a pre-paid envelope to send them back in.	
Ensure the patient has an appointment to have any stitches removed	
Ensure the patient has had a standard clinical discharge summary sent, and that they have adequate analgesia to take home if needed.	

		DD	MM	YYYY
Name of researcher completing form	Signature	Date		

Patient's trial number					Date of Follow-up	DD	MM	YYYY	Patient's initials			

TAPPS TRIAL FORM 5 – **MONTH 1 FOLLOW-UP**

1	**DID THE PATIENT ATTEND THE FOLLOW-UP APPOINTMENT IN PERSON?** If no, go to question 2. If yes, skip to question 3.	YES	NO
2	**WAS A TELEPHONE CONSULATION UNDERTAKEN?** If no, give reason below by ticking in box. If yes, skip to question 4.	YES	NO

PATIENT HAS DIED (Complete section opposite)	
UNABLE TO CONTACT PATIENT	
PATIENT TOO UNWELL	
PATIENT DECLINED FOLLOW-UP	
OTHER (Please specify)	

Date of death		DD	MM	YYYY
Cause of death as per death certificate	**I a**			
	I b			
	I c			
	II			
Was a post-mortem performed?		YES		NO

Even if the patient has died, please complete as much of this CRF as possible.

3	**ARE THERE ANY ABNORMALITIES ON EXAMINING THE DRAIN SITE?** If yes, tick below as appropriate.	YES	NO	N/A

WOUND INFECTION	
WOUND BREAKDOWN OR MALUNION	
MALIGNANT INFILTRATION	
OTHER ABNORMALITY (Please specify)	

4	**CURRENT WHO PERFORMANCE STATUS**	0	1	2	3	4

5	**HAS THE PATIENT SUFFERED ANY <u>EXPECTED</u> ADVERSE EVENTS SINCE THE LAST CRF WAS COMPLETED?** If yes, tick below as appropriate	YES	NO	UNKNOWN

ANAEMIA NEEDING TRANSFUSION	
POST-PROCEDURE FEVER	
WOUND INFECTION	
EMPYEMA	
BRONCHOPLEURAL FISTULA	
ATELECTASIS NEEDING BRONCHOSCOPY	
PNEUMONIA NEEDING ANTIBIOTICS	
RESPIRATORY FAILURE	
DYSRHYTHMIA	
MYOCARDIAL INFARCTION	
DEEP VEIN THROMBOSIS	
PULMONARY EMBOLUS	
SURGICAL EMPHYSEMA	
DRAIN DISLODGEMENT OR REPLACEMENT	

Patient's trial number					Patient's initials			

		YES	NO	N/A
6	**HAS THE PATIENT SUFFERED ANY OTHER RELEVANT ADVERSE EVENTS SINCE THE LAST CRF WAS COMPLETED?**			

For each event above, also complete a separate adverse event form and enter the number of forms used here

IF ANY COMPLICATION MIGHT MEET THE CRITERIA OF A SERIOUS ADVERSE EVENT, PLEASE COMPLETE AN SAE FORM AND FAX TO NORTH BRISTOL AND THE ORTU ASAP

7 **PLEASE GIVE DETAILS OF ALL ANALGESIA THE PATIENT IS CURRENTLY TAKING** (Tick 'none' if needed)

NONE	

Type (Generic drug name in CAPITALS)	**Dose** (include units, e.g. 10 mg)	**Frequency** (Number of doses per day)	**Regular or PRN**	**Route** (oral / topical / rectal / other)

		YES	NO
8	**SINCE THE LAST TRIAL VISIT, HAS THE PATIENT UNDERGONE ANY OF THE FOLLOWING ON THE SAME SIDE AS THEIR TRIAL INTERVENTION?** If yes, complete below using code		

1 = Therapeutic aspiration of ≥100mls
2 = Insertion of an intercostal drain for fluid drainage
3 = Insertion of an indwelling pleural catheter
4 = Medical or surgical thoracoscopy

Event	**Date**			**IF ANY OF THESE DECISIONS WERE REGARDING AN EFFUSION OCCUPYING <1/3 OF THE HEMITHORAX, WAS A DISCUSSION HELD WITH A BLINDED COLLEAGUE BEFORE A TREATMENT DECISION WAS MADE?**		
	DD	MM	YYYY	YES	NO	N/A
	DD	MM	YYYY	YES	NO	N/A
	DD	MM	YYYY	YES	NO	N/A
	DD	MM	YYYY	YES	NO	N/A
	DD	MM	YYYY	YES	NO	N/A
	DD	MM	YYYY	YES	NO	N/A
	DD	MM	YYYY	YES	NO	N/A
	DD	MM	YYYY	YES	NO	N/A

		YES	NO	UNKNOWN
9	**WERE ANY OF THE PROCEDURES IN Q8 FELT TO BE NECESSARY, BUT NOT CARRIED OUT, OR ATTEMPTED BUT NOT COMPLETED?**			

If yes, please give details

DD	MM	YYYY	
DD	MM	YYYY	

Patient's trial number					Patient's initials			

10	**HAS THE PATIENT RECEIVED RADIOTHERAPY TO THE CHEST ON THE SIDE OF THEIR PROCEDURE SINCE THE LAST CRF WAS COMPLETED?**	YES			NO		
11	**HAS THE PATIENT RECEIVED ANY CANCER-MODULATING HORMONE THERAPY SINCE THE LAST CRF WAS COMPLETED?**	YES			NO		
	If yes, what stage therapy was it?	1st LINE	2nd LINE	3rd LINE	OTHER		
	When did this treatment start?	DD	MM	YYYY	UNKNOWN		
	When did this treatment end?	DD	MM	YYYY	ONGOING	UNKNOWN	
12	**HAS THE PATIENT UNDERGONE ANY TREATMENT WITH ANTI-CANCER MONOCLONAL ANTIBODIES SINCE THE LAST CRF WAS COMPLETED?**	YES			NO		
	If yes, what stage therapy was it?	1st LINE	2nd LINE	3rd LINE	OTHER		
	When did this treatment start?	DD	MM	YYYY	UNKNOWN		
	When did this treatment end?	DD	MM	YYYY	ONGOING	UNKNOWN	
13	**HAS THE PATIENT RECEIVED ANY CHEMOTHERAPY SINCE THE LAST CRF WAS COMPLETED?**	YES			NO		
	If yes, what stage therapy was it?	1st LINE	2nd LINE	3rd LINE	OTHER		
	When did this treatment start?	DD	MM	YYYY	UNKNOWN		
	When did this treatment end?	DD	MM	YYYY	ONGOING	UNKNOWN	
14	**HAS THE PATIENT UNDERGONE ANY OTHER FORM OF ANTI-CANCER THERAPY SINCE THE LAST CRF WAS COMPLETED?**	YES			NO		
	If yes, please specify and state what stage therapy it was						
	When did this treatment start?	DD	MM	YYYY	UNKNOWN		
	When did this treatment end?	DD	MM	YYYY	ONGOING	UNKNOWN	

15	**HAS THE PATIENT HAD A STAGING SCAN SINCE THEIR LAST TRIAL VISIT?**	YES	NO	UNKNOWN
	If yes, when was the most recent scan and what did it show compared to the previous one?	DD	MM	YYYY

DISEASE PROGRESSION	
STABLE DISEASE	
PARTIAL DISEASE REMISSION	
COMPLETE REMISSION	

Patient's trial number					Patient's initials			

16 **PLEASE ASK THE PATIENT TO INDICATE HOW MUCH <u>CHEST PAIN</u> THEY HAVE AT THE MOMENT BY MAKING A SINGLE VERTICAL MARK ON THE LINE BELOW**

No pain at all ——————————— Worst possible pain

FOR OFFICE USE ONLY	Assessor 1 score mm	Initials	Date	Assessor 2 score mm	Initials	Date

17 **PLEASE ASK THE PATIENT TO INDICATE HOW MUCH <u>BREATHLESSNESS</u> THEY HAVE AT THE MOMENT BY MAKING A SINGLE VERTICAL MARK ON THE LINE BELOW**

No breathlessness at all ——————————— Worst possible breathlessness

FOR OFFICE USE ONLY	Assessor 1 score mm	Initials	Date	Assessor 2 score mm	Initials	Date

CHECKLIST (Tick if when done, if applicable)

Ensure patient has had a chest x-ray today	
Ensure every page of this CRF has the patient's trial number entered at the top	
Ensure the patient has completed the quality of life questionnaires (EQ-5D and SF-36)	
Ensure the patient has completed the health resource use questionnaire	
Ensure the patient has enough space in their health resource use diary	
Ensure the patient has sufficient VAS booklet space, and that their previous charts are handed in	
Ensure the patient has been given a date for their next trial follow-up	

		DD	MM	YYYY
Name of researcher completing form	Signature	Date		

Patient's trial number					Date of Follow-up	DD	MM	YYYY	Patient's initials			

TAPPS TRIAL FORM 6 (**MONTH 1** FOLLOW-UP)
HEATLH SERVICE UTILISATION QUESTIONNAIRE

THIS DOCUMENT SHOULD BE COMPLETED WITH THE PATIENT USING THEIR DIARY AS A REFERENCE DOCUMENT. IF EXACT ANSWERS ARE UNAVAILABLE, PLEASE ENTER THE BEST ESTIMATE.

IF THE PATIENT HAS DIED THEN PLEASE TICK HERE □ AND COMPLETE AS MUCH AS POSSIBLE FROM AVAILABLE HOSPITAL RECORDS.

SECTION 1 – GP APPOINTMENTS

1	**SINCE THE LAST CRF WAS COMPLETED, HAS THE PATIENT HAD ANY APPOINTMENTS WITH A GENERAL PRACTITIONER?**	YES	NO
	If yes, complete below, if no skip to question 2		
	HOW MANY TIMES HAS THE PATIENT VISITED A GP?		
	HOW MANY TIMES HAS A GP VISITED THE PATIENT AT HOME?		
	HOW MANY TIMES HAS THE PATIENT HAD A TELEPHONE CONULTATION WITH A GP?		

SECTION 2 – OUTPATIENT ATTENDANCES

2	**SINCE THE LAST CRF WAS COMPLETED, HAS THE PATIENT HAD ANY HOSPITAL OUTPATIENT APPOINTMENTS?**	YES	NO
	If yes, complete below, if no skip to question 3		
	HOW MANY TIMES HAS THE PATIENT ATTENDED A HOSPITAL OUTPATIENT APPOINTMENT?		
	HOW MANY OF THESE APPOINTMENTS REQUIRED HOSPITAL TRANSPORT?		

SECTION 3 – A+E ATTENDANCES

3	**SINCE THE LAST CRF WAS COMPLETED, HAS THE PATIENT HAD ANY ATTENDANCES AT ACCIDENT AND EMERGENCY?**	YES	NO
	If yes, complete below, if no skip to question 4		
	HOW MANY TIMES HAS THE PATIENT ATTENDED A+E FOR A CONSULTATION?		
	HOW MANY TIMES DID THE PATIENT USE THE AMBULANCE SERVICE TO ATTEND A+E?		

Patient's trial number					Patient's initials			

SECTION 4 – ADMISSIONS TO ACUTE HOSPITAL

4	SINCE THE LAST CRF WAS COMPLETED, HAS THE PATIENT HAD ANY ADMISSIONS TO AN ACUTE HOSPITAL?	YES	NO

If yes, complete below, if no skip to question 5

HOW MANY TIMES HAS THE PATIENT BEEN ADMITTED? Please give details below

	Reason for admission	Did the patient have surgery? Tick if yes	Type(s) of surgery Write 'not applicable' if needed	Number of days in ITU or HDU	Number of days in hospital
1					
2					
3					
4					
5					

SECTION 5 – ADMISSIONS TO REHABILITATION HOSPITAL

5	SINCE THE LAST CRF WAS COMPLETED, HAS THE PATIENT HAD ANY ADMISSIONS TO A REHABILITATION HOSPITAL?	YES	NO

If yes, complete below, if no skip to question 6

HOW MANY TIMES HAS THE PATIENT BEEN ADMITTED? Please give details below

	Reason for admission	Number of days in hospital
1		
2		
3		
4		
5		

Patient's trial number					Patient's initials			

SECTION 6 – PALLIATIVE AND HOSPICE CARE

6	**SINCE THE LAST CRF WAS COMPLETED, HAS THE PATIENT HAD ANY CONTACT WITH PALLIATIVE CARE OR HOSPICE SERVICES?**	YES	NO

If yes, complete below, if no skip to question 7

HOW MANY TIMES HAS THE PATIENT ATTENDED A HOSPICE (WITHOUT ADMISSION)?	
HOW MANY NIGHTS HAS THE PATIENT SPENT AS AN INPATIENT AT A HOSPICE?	
HOW MANY TIMES HAS THE PATIENT SEEN A HOSPICE OR PALLIATIVE CARE NURSE AT HOME?	
HOW MANY TIMES HAS THE PATIENT SPOKEN TO A HOSPICE OR PALLIATIVE CARE SPECIALIST OVER THE PHONE?	

SECTION 7 – OTHER HEALTHCARE CONTACT

SINCE THE LAST CRF WAS COMPLETED…

7	**HOW MANY TIMES HAS THE PATIENT SEEN A NURSE IN A HOSPITAL CLINIC SETTING?**	
8	**HOW MANY TIMES HAS THE PATIENT SEEN A NURSE IN THEIR OWN HOME?**	
9	**HOW MANY TIMES HAS THE PATIENT SEEN AN NHS PHYSIOTHERAPIST?**	
10	**HOW MANY TIMES HAS THE PATIENT SEEN AN OCCUPATIONAL THERAPIST?**	
11	**HOW MANY TIMES HAS THE PATIENT SEEN A PSYCHOLOGIST?**	
12	**HOW MANY TIMES HAS THE PATIENT SEEN A COUNSELLOR?**	
13	**HOW MANY TIMES HAS THE PATIENT ATTENDED A DAY HOSPITAL?**	

Patient's trial number					Patient's initials			

14	HAS THERE BEEN ANY OTHER CONTACT WITH HEALTHCARE SERVICES?	YES	NO

If yes, give details below, if no, please check document and sign at the end

	Type of healthcare contact	Number of contacts
1		
2		
3		
4		

		DD	MM	YYYY
Name of researcher completing form	Signature	Date		

Patient's trial number					Date of Follow-up	DD	MM	YYYY	Patient's initials			

TAPPS TRIAL FORM 7 – **MONTH 3 FOLLOW-UP**

1	**DID THE PATIENT ATTEND THE FOLLOW-UP APPOINTMENT IN PERSON?** If no, go to question 2. If yes, skip to question 3.	YES	NO
2	**WAS A TELEPHONE CONSULATION UNDERTAKEN?** If no, give reason below by ticking in box. If yes, skip to question 4.	YES	NO

PATIENT HAS DIED (Complete section opposite)	
UNABLE TO CONTACT PATIENT	
PATIENT TOO UNWELL	
PATIENT DECLINED FOLLOW-UP	
OTHER (Please specify)	

Date of death		DD	MM	YYYY
Cause of death as per death certificate	**I a**			
	I b			
	I c			
	II			
Was a post-mortem performed?		YES		NO

Even if the patient has died, please complete as much of this CRF as possible.

3	**ARE THERE ANY ABNORMALITIES ON EXAMINING THE DRAIN SITE?** If yes, tick below as appropriate.	YES	NO	N/A

WOUND INFECTION	
WOUND BREAKDOWN OR MALUNION	
MALIGNANT INFILTRATION	
OTHER ABNORMALITY (Please specify)	

4	**CURRENT WHO PERFORMANCE STATUS**	0	1	2	3	4

5	**HAS THE PATIENT SUFFERED ANY <u>EXPECTED</u> ADVERSE EVENTS SINCE THE LAST CRF WAS COMPLETED?** If yes, tick below as appropriate	YES	NO	UNKNOWN

ANAEMIA NEEDING TRANSFUSION	
POST-PROCEDURE FEVER	
WOUND INFECTION	
EMPYEMA	
BRONCHOPLEURAL FISTULA	
ATELECTASIS NEEDING BRONCHOSCOPY	
PNEUMONIA NEEDING ANTIBIOTICS	
RESPIRATORY FAILURE	
DYSRHYTHMIA	
MYOCARDIAL INFARCTION	
DEEP VEIN THROMBOSIS	
PULMONARY EMBOLUS	
SURGICAL EMPHYSEMA	
DRAIN DISLODGEMENT OR REPLACEMENT	

Patient's trial number					Patient's initials			

6	**HAS THE PATIENT SUFFERED ANY OTHER RELEVANT ADVERSE EVENTS SINCE THE LAST CRF WAS COMPLETED?**	YES	NO	N/A

For each event above, also complete a separate adverse event form and enter the number of forms used here

IF ANY COMPLICATION MIGHT MEET THE CRITERIA OF A SERIOUS ADVERSE EVENT, PLEASE COMPLETE AN SAE FORM AND FAX TO NORTH BRISTOL AND THE ORTU ASAP

7	**SINCE THE LAST TRIAL VISIT, HAS THE PATIENT UNDERGONE ANY OF THE FOLLOWING ON THE SAME SIDE AS THEIR TRIAL INTERVENTION?** If yes, complete below using code	YES	NO

1 = Therapeutic aspiration of ≥100mls
2 = Insertion of an intercostal drain for fluid drainage
3 = Insertion of an indwelling pleural catheter
4 = Medical or surgical thoracoscopy

Event	Date			IF ANY OF THESE DECISIONS WERE REGARDING AN EFFUSION OCCUPYING <1/3 OF THE HEMITHORAX, WAS A DISCUSSION HELD WITH A BLINDED COLLEAGUE BEFORE A TREATMENT DECISION WAS MADE?		
	DD	MM	YYYY	YES	NO	N/A
	DD	MM	YYYY	YES	NO	N/A
	DD	MM	YYYY	YES	NO	N/A
	DD	MM	YYYY	YES	NO	N/A
	DD	MM	YYYY	YES	NO	N/A
	DD	MM	YYYY	YES	NO	N/A
	DD	MM	YYYY	YES	NO	N/A
	DD	MM	YYYY	YES	NO	N/A

8	**WERE ANY OF THE PROCEDURES IN Q7 FELT TO BE NECESSARY, BUT NOT CARRIED OUT, OR ATTEMPTED BUT NOT COMPLETED?**	YES	NO	UNKNOWN

If yes, please give details

DD	MM	YYYY	
DD	MM	YYYY	

9	**HAS THE PATIENT RECEIVED RADIOTHERAPY TO THE CHEST ON THE SIDE OF THEIR PROCEDURE SINCE THE LAST CRF WAS COMPLETED?**	YES	NO

10	**HAS THE PATIENT RECEIVED ANY CANCER-MODULATING HORMONE THERAPY SINCE THE LAST CRF WAS COMPLETED?**	YES	NO

If yes, what stage therapy was it?	1st LINE	2nd LINE	3rd LINE	OTHER
When did this treatment start?	DD MM YYYY		UNKNOWN	
When did this treatment end?	DD MM YYYY		ONGOING	UNKNOWN

Patient's trial number					Patient's initials			

11	**HAS THE PATIENT UNDERGONE ANY TREATMENT WITH <u>ANTI-CANCER MONOCLONAL ANTIBODIES</u> SINCE THE LAST CRF WAS COMPLETED?**	YES		NO	
	If yes, what stage therapy was it?	1st LINE	2nd LINE	3rd LINE	OTHER
	When did this treatment start?	DD / MM / YYYY		UNKNOWN	
	When did this treatment end?	DD / MM / YYYY		ONGOING	UNKNOWN
12	**HAS THE PATIENT RECEIVED ANY <u>CHEMOTHERAPY</u> SINCE THE LAST CRF WAS COMPLETED?**	YES		NO	
	If yes, what stage therapy was it?	1st LINE	2nd LINE	3rd LINE	OTHER
	When did this treatment start?	DD / MM / YYYY		UNKNOWN	
	When did this treatment end?	DD / MM / YYYY		ONGOING	UNKNOWN
13	**HAS THE PATIENT UNDERGONE ANY <u>OTHER FORM OF ANTI-CANCER THERAPY</u> SINCE THE LAST CRF WAS COMPLETED?**	YES		NO	
	If yes, please specify and state what stage therapy it was				
	When did this treatment start?	DD / MM / YYYY		UNKNOWN	
	When did this treatment end?	DD / MM / YYYY		ONGOING	UNKNOWN

14	**HAS THE PATIENT HAD A STAGING SCAN SINCE THEIR LAST TRIAL VISIT?**	YES	NO	UNKNOWN
	If yes, when was the most recent scan and what did it show compared to the previous one?	DD / MM / YYYY		

DISEASE PROGRESSION	
STABLE DISEASE	
PARTIAL DISEASE REMISSION	
COMPLETE REMISSION	

15 **PLEASE ASK THE PATIENT TO INDICATE HOW MUCH <u>CHEST PAIN</u> THEY HAVE AT THE MOMENT BY MAKING A SINGLE VERTICAL MARK ON THE LINE BELOW**

No pain at all ——————————— Worst possible pain

FOR OFFICE USE ONLY	Assessor 1 score mm	Initials	Date	Assessor 2 score mm	Initials	Date

16 **PLEASE ASK THE PATIENT TO INDICATE HOW MUCH <u>BREATHLESSNESS</u> THEY HAVE AT THE MOMENT BY MAKING A SINGLE VERTICAL MARK ON THE LINE BELOW**

No breathlessness at all ——————————— Worst possible breathlessness

FOR OFFICE USE ONLY	Assessor 1 score mm	Initials	Date	Assessor 2 score mm	Initials	Date

Patient's trial number					Patient's initials			

CHECKLIST (Tick if when done, if applicable)

Ensure patient has had a chest x-ray today	
Ensure every page of this CRF has the patient's trial number entered at the top	
Ensure the patient has completed the quality of life questionnaires (EQ-5D and SF-36)	
Ensure the patient has completed the health resource use questionnaire	
Ensure the patient has enough space in their health resource use diary	
Ensure the patient has sufficient VAS booklet space, and that their previous charts are handed in	
Ensure the patient has been given a date for their next trial follow-up	

		DD	MM	YYYY
Name of researcher completing form	Signature	Date		

Patient's trial number					Date of Follow-up	DD	MM	YYYY	Patient's initials			

TAPPS TRIAL FORM 8 (**MONTH 3** FOLLOW-UP)
HEATLH SERVICE UTILISATION QUESTIONNAIRE

THIS DOCUMENT SHOULD BE COMPLETED WITH THE PATIENT USING THEIR DIARY AS A REFERENCE DOCUMENT. IF EXACT ANSWERS ARE UNAVAILABLE, PLEASE ENTER THE BEST ESTIMATE.

IF THE PATIENT HAS DIED THEN PLEASE TICK HERE □ AND COMPLETE AS MUCH AS POSSIBLE FROM AVAILABLE HOSPITAL RECORDS.

SECTION 1 – GP APPOINTMENTS

1	**SINCE THE LAST CRF WAS COMPLETED, HAS THE PATIENT HAD ANY APPOINTMENTS WITH A GENERAL PRACTITIONER?**	YES	NO
	If yes, complete below, if no skip to question 2		
	HOW MANY TIMES HAS THE PATIENT VISITED A GP?		
	HOW MANY TIMES HAS A GP VISITED THE PATIENT AT HOME?		
	HOW MANY TIMES HAS THE PATIENT HAD A TELEPHONE CONULTATION WITH A GP?		

SECTION 2 – OUTPATIENT ATTENDANCES

2	**SINCE THE LAST CRF WAS COMPLETED, HAS THE PATIENT HAD ANY HOSPITAL OUTPATIENT APPOINTMENTS?**	YES	NO
	If yes, complete below, if no skip to question 3		
	HOW MANY TIMES HAS THE PATIENT ATTENDED A HOSPITAL OUTPATIENT APPOINTMENT?		
	HOW MANY OF THESE APPOINTMENTS REQUIRED HOSPITAL TRANSPORT?		

SECTION 3 – A+E ATTENDANCES

3	**SINCE THE LAST CRF WAS COMPLETED, HAS THE PATIENT HAD ANY ATTENDANCES AT ACCIDENT AND EMERGENCY?**	YES	NO
	If yes, complete below, if no skip to question 4		
	HOW MANY TIMES HAS THE PATIENT ATTENDED A+E FOR A CONSULTATION?		
	HOW MANY TIMES DID THE PATIENT USE THE AMBULANCE SERVICE TO ATTEND A+E?		

Patient's trial number					Patient's initials			

SECTION 4 – ADMISSIONS TO ACUTE HOSPITAL

4	**SINCE THE LAST CRF WAS COMPLETED, HAS THE PATIENT HAD ANY ADMISSIONS TO AN ACUTE HOSPITAL?**	YES	NO

If yes, complete below, if no skip to question 5

HOW MANY TIMES HAS THE PATIENT BEEN ADMITTED? Please give details below

	Reason for admission	**Did the patient have surgery?** Tick if yes	**Type(s) of surgery** Write 'not applicable' if needed	**Number of days in ITU or HDU**	**Number of days in hospital**
1					
2					
3					
4					
5					

SECTION 5 – ADMISSIONS TO REHABILITATION HOSPITAL

5	**SINCE THE LAST CRF WAS COMPLETED, HAS THE PATIENT HAD ANY ADMISSIONS TO A REHABILITATION HOSPITAL?**	YES	NO

If yes, complete below, if no skip to question 6

HOW MANY TIMES HAS THE PATIENT BEEN ADMITTED? Please give details below

	Reason for admission	**Number of days in hospital**
1		
2		
3		
4		
5		

Patient's trial number					Patient's initials			

SECTION 6 – PALLIATIVE AND HOSPICE CARE

6	**SINCE THE LAST CRF WAS COMPLETED, HAS THE PATIENT HAD ANY CONTACT WITH PALLIATIVE CARE OR HOSPICE SERVICES?**	YES	NO

If yes, complete below, if no skip to question 7

	HOW MANY TIMES HAS THE PATIENT ATTENDED A HOSPICE (WITHOUT ADMISSION)?	
	HOW MANY NIGHTS HAS THE PATIENT SPENT AS AN INPATIENT AT A HOSPICE?	
	HOW MANY TIMES HAS THE PATIENT SEEN A HOSPICE OR PALLIATIVE CARE NURSE AT HOME?	
	HOW MANY TIMES HAS THE PATIENT SPOKEN TO A HOSPICE OR PALLIATIVE CARE SPECIALIST OVER THE PHONE?	

SECTION 7 – OTHER HEALTHCARE CONTACT

SINCE THE LAST CRF WAS COMPLETED…

7	**HOW MANY TIMES HAS THE PATIENT SEEN A NURSE IN A HOSPITAL CLINIC SETTING?**	
8	**HOW MANY TIMES HAS THE PATIENT SEEN A NURSE IN THEIR OWN HOME?**	
9	**HOW MANY TIMES HAS THE PATIENT SEEN AN NHS PHYSIOTHERAPIST?**	
10	**HOW MANY TIMES HAS THE PATIENT SEEN AN OCCUPATIONAL THERAPIST?**	
11	**HOW MANY TIMES HAS THE PATIENT SEEN A PSYCHOLOGIST?**	
12	**HOW MANY TIMES HAS THE PATIENT SEEN A COUNSELLOR?**	
13	**HOW MANY TIMES HAS THE PATIENT ATTENDED A DAY HOSPITAL?**	

Patient's trial number					Patient's initials			

14	HAS THERE BEEN ANY OTHER CONTACT WITH HEALTHCARE SERVICES?	YES	NO

If yes, give details below, if no, please check document and sign at the end

	Type of healthcare contact	Number of contacts
1		
2		
3		
4		

		DD	MM	YYYY
Name of researcher completing form	Signature	Date		

Patient's trial number					Date of Follow-up	DD	MM	YYYY	Patient's initials			

TAPPS TRIAL FORM 9 – **MONTH 6 FOLLOW-UP**

1	**DID THE PATIENT ATTEND THE FOLLOW-UP APPOINTMENT IN PERSON?** If no, go to question 2. If yes, skip to question 3.	YES	NO
2	**WAS A TELEPHONE CONSULATION UNDERTAKEN?** If no, give reason below by ticking in box. If yes, skip to question 4.	YES	NO

PATIENT HAS DIED (Complete section opposite)	
UNABLE TO CONTACT PATIENT	
PATIENT TOO UNWELL	
PATIENT DECLINED FOLLOW-UP	
OTHER (Please specify)	

Date of death		DD	MM	YYYY
Cause of death as per death certificate	**I a**			
	I b			
	I c			
	II			
Was a post-mortem performed?		YES		NO

Even if the patient has died, please complete as much of this CRF as possible.

3	**ARE THERE ANY ABNORMALITIES ON EXAMINING THE DRAIN SITE?** If yes, tick below as appropriate.	YES	NO	N/A

WOUND INFECTION	
WOUND BREAKDOWN OR MALUNION	
MALIGNANT INFILTRATION	
OTHER ABNORMALITY (Please specify)	

4	**CURRENT WHO PERFORMANCE STATUS**	0	1	2	3	4

5	**HAS THE PATIENT SUFFERED ANY <u>EXPECTED</u> ADVERSE EVENTS SINCE THE LAST CRF WAS COMPLETED?** If yes, tick below as appropriate	YES	NO	UNKNOWN

ANAEMIA NEEDING TRANSFUSION	
POST-PROCEDURE FEVER	
WOUND INFECTION	
EMPYEMA	
BRONCHOPLEURAL FISTULA	
ATELECTASIS NEEDING BRONCHOSCOPY	
PNEUMONIA NEEDING ANTIBIOTICS	
RESPIRATORY FAILURE	
DYSRHYTHMIA	
MYOCARDIAL INFARCTION	
DEEP VEIN THROMBOSIS	
PULMONARY EMBOLUS	
SURGICAL EMPHYSEMA	
DRAIN DISLODGEMENT OR REPLACEMENT	

Patient's trial number					Patient's initials			

6	**HAS THE PATIENT SUFFERED ANY OTHER <u>RELEVANT</u> ADVERSE EVENTS SINCE THE LAST CRF WAS COMPLETED?**	YES	NO	N/A

For each event above, also complete a <u>separate adverse event form</u> and enter the number of forms used here

IF ANY COMPLICATION MIGHT MEET THE CRITERIA OF A SERIOUS ADVERSE EVENT, PLEASE COMPLETE AN SAE FORM AND FAX TO NORTH BRISTOL AND THE ORTU ASAP

7	**SINCE THE LAST TRIAL VISIT, HAS THE PATIENT UNDERGONE ANY OF THE FOLLOWING ON THE SAME SIDE AS THEIR TRIAL INTERVENTION?** If yes, complete below using code	YES	NO

1 = Therapeutic aspiration of ≥100mls
2 = Insertion of an intercostal drain for fluid drainage
3 = Insertion of an indwelling pleural catheter
4 = Medical or surgical thoracoscopy

Event	Date			IF ANY OF THESE DECISIONS WERE REGARDING AN EFFUSION OCCUPYING <1/3 OF THE HEMITHORAX, WAS A DISCUSSION HELD WITH A BLINDED COLLEAGUE BEFORE A TREATMENT DECISION WAS MADE?		
	DD	MM	YYYY	YES	NO	N/A
	DD	MM	YYYY	YES	NO	N/A
	DD	MM	YYYY	YES	NO	N/A
	DD	MM	YYYY	YES	NO	N/A
	DD	MM	YYYY	YES	NO	N/A
	DD	MM	YYYY	YES	NO	N/A
	DD	MM	YYYY	YES	NO	N/A
	DD	MM	YYYY	YES	NO	N/A

8	**WERE ANY OF THE PROCEDURES IN Q7 FELT TO BE NECESSARY, BUT NOT CARRIED OUT, OR ATTEMPTED BUT NOT COMPLETED?**	YES	NO	UNKNOWN

If yes, please give details

DD	MM	YYYY	
DD	MM	YYYY	

9	**HAS THE PATIENT RECEIVED RADIOTHERAPY TO THE CHEST <u>ON THE SIDE OF THEIR PROCEDURE</u> SINCE THE LAST CRF WAS COMPLETED?**	YES	NO	
10	**HAS THE PATIENT RECEIVED ANY <u>CANCER-MODULATING HORMONE THERAPY</u> SINCE THE LAST CRF WAS COMPLETED?**	YES	NO	
	If yes, what stage therapy was it?	1st LINE	2nd LINE	3rd LINE	OTHER
	When did this treatment start?	DD MM YYYY	UNKNOWN		
	When did this treatment end?	DD MM YYYY	ONGOING	UNKNOWN	

Patient's trial number					Patient's initials			

11	**HAS THE PATIENT UNDERGONE ANY TREATMENT WITH <u>ANTI-CANCER MONOCLONAL ANTIBODIES</u> SINCE THE LAST CRF WAS COMPLETED?**	YES		NO	
	If yes, what stage therapy was it?	1st LINE	2nd LINE	3rd LINE	OTHER
	When did this treatment start?	DD / MM / YYYY		UNKNOWN	
	When did this treatment end?	DD / MM / YYYY		ONGOING	UNKNOWN
12	**HAS THE PATIENT RECEIVED ANY <u>CHEMOTHERAPY</u> SINCE THE LAST CRF WAS COMPLETED?**	YES		NO	
	If yes, what stage therapy was it?	1st LINE	2nd LINE	3rd LINE	OTHER
	When did this treatment start?	DD / MM / YYYY		UNKNOWN	
	When did this treatment end?	DD / MM / YYYY		ONGOING	UNKNOWN
13	**HAS THE PATIENT UNDERGONE ANY <u>OTHER FORM OF ANTI-CANCER THERAPY</u> SINCE THE LAST CRF WAS COMPLETED?**	YES		NO	
	If yes, please specify and state what stage therapy it was				
	When did this treatment start?	DD / MM / YYYY		UNKNOWN	
	When did this treatment end?	DD / MM / YYYY		ONGOING	UNKNOWN

14	**HAS THE PATIENT HAD A STAGING SCAN SINCE THEIR LAST TRIAL VISIT?**	YES	NO	UNKNOWN
	If yes, when was the most recent scan and what did it show compared to the previous one?	DD / MM / YYYY		

DISEASE PROGRESSION	
STABLE DISEASE	
PARTIAL DISEASE REMISSION	
COMPLETE REMISSION	

15 **PLEASE ASK THE PATIENT TO INDICATE HOW MUCH <u>CHEST PAIN</u> THEY HAVE AT THE MOMENT BY MAKING A SINGLE VERTICAL MARK ON THE LINE BELOW**

No pain at all ——————————— Worst possible pain

FOR OFFICE USE ONLY	Assessor 1 score mm	Initials	Date	Assessor 2 score mm	Initials	Date

16 **PLEASE ASK THE PATIENT TO INDICATE HOW MUCH <u>BREATHLESSNESS</u> THEY HAVE AT THE MOMENT BY MAKING A SINGLE VERTICAL MARK ON THE LINE BELOW**

No breathlessness at all ——————————— Worst possible breathlessness

FOR OFFICE USE ONLY	Assessor 1 score mm	Initials	Date	Assessor 2 score mm	Initials	Date

Patient's trial number					Patient's initials			

CHECKLIST (Tick if when done, if applicable)

Ensure patient has had a chest x-ray today	
Ensure every page of this CRF has the patient's trial number entered at the top	
Ensure the patient has completed the quality of life questionnaires (EQ-5D and SF-36)	
Ensure the patient has completed the health resource use questionnaire	
Ensure the patient has handed in their VAS booklets	
Ensure all images have been transferred to the trial co-ordinating centre	

		DD	MM	YYYY
Name of researcher completing form	Signature	Date		

Patient's trial number					Date of Follow-up	DD	MM	YYYY	Patient's initials			

TAPPS TRIAL FORM 10 (**MONTH 6** FOLLOW-UP)
HEATLH SERVICE UTILISATION QUESTIONNAIRE

THIS DOCUMENT SHOULD BE COMPLETED WITH THE PATIENT USING THEIR DIARY AS A REFERENCE DOCUMENT. IF EXACT ANSWERS ARE UNAVAILABLE, PLEASE ENTER THE BEST ESTIMATE.

IF THE PATIENT HAS DIED THEN PLEASE TICK HERE □ AND COMPLETE AS MUCH AS POSSIBLE FROM AVAILABLE HOSPITAL RECORDS.

SECTION 1 – GP APPOINTMENTS

1	**SINCE THE LAST CRF WAS COMPLETED, HAS THE PATIENT HAD ANY APPOINTMENTS WITH A GENERAL PRACTITIONER?**	YES	NO
	If yes, complete below, if no skip to question 2		
	HOW MANY TIMES HAS THE PATIENT VISITED A GP?		
	HOW MANY TIMES HAS A GP VISITED THE PATIENT AT HOME?		
	HOW MANY TIMES HAS THE PATIENT HAD A TELEPHONE CONULTATION WITH A GP?		

SECTION 2 – OUTPATIENT ATTENDANCES

2	**SINCE THE LAST CRF WAS COMPLETED, HAS THE PATIENT HAD ANY HOSPITAL OUTPATIENT APPOINTMENTS?**	YES	NO
	If yes, complete below, if no skip to question 3		
	HOW MANY TIMES HAS THE PATIENT ATTENDED A HOSPITAL OUTPATIENT APPOINTMENT?		
	HOW MANY OF THESE APPOINTMENTS REQUIRED HOSPITAL TRANSPORT?		

SECTION 3 – A+E ATTENDANCES

3	**SINCE THE LAST CRF WAS COMPLETED, HAS THE PATIENT HAD ANY ATTENDANCES AT ACCIDENT AND EMERGENCY?**	YES	NO
	If yes, complete below, if no skip to question 4		
	HOW MANY TIMES HAS THE PATIENT ATTENDED A+E FOR A CONSULTATION?		
	HOW MANY TIMES DID THE PATIENT USE THE AMBULANCE SERVICE TO ATTEND A+E?		

Patient's trial number					Patient's initials			

SECTION 4 – ADMISSIONS TO ACUTE HOSPITAL

4	**SINCE THE LAST CRF WAS COMPLETED, HAS THE PATIENT HAD ANY ADMISSIONS TO AN ACUTE HOSPITAL?**	YES	NO

If yes, complete below, if no skip to question 5

HOW MANY TIMES HAS THE PATIENT BEEN ADMITTED? Please give details below

	Reason for admission	**Did the patient have surgery?** Tick if yes	**Type(s) of surgery** Write 'not applicable' if needed	**Number of days in ITU or HDU**	**Number of days in hospital**
1					
2					
3					
4					
5					

SECTION 5 – ADMISSIONS TO REHABILITATION HOSPITAL

5	**SINCE THE LAST CRF WAS COMPLETED, HAS THE PATIENT HAD ANY ADMISSIONS TO A REHABILITATION HOSPITAL?**	YES	NO

If yes, complete below, if no skip to question 6

HOW MANY TIMES HAS THE PATIENT BEEN ADMITTED? Please give details below

	Reason for admission	**Number of days in hospital**
1		
2		
3		
4		
5		

Patient's trial number					Patient's initials			

SECTION 6 – PALLIATIVE AND HOSPICE CARE

6	**SINCE THE LAST CRF WAS COMPLETED, HAS THE PATIENT HAD ANY CONTACT WITH PALLIATIVE CARE OR HOSPICE SERVICES?**	YES	NO

If yes, complete below, if no skip to question 7

HOW MANY TIMES HAS THE PATIENT ATTENDED A HOSPICE (WITHOUT ADMISSION)?	
HOW MANY NIGHTS HAS THE PATIENT SPENT AS AN INPATIENT AT A HOSPICE?	
HOW MANY TIMES HAS THE PATIENT SEEN A HOSPICE OR PALLIATIVE CARE NURSE AT HOME?	
HOW MANY TIMES HAS THE PATIENT SPOKEN TO A HOSPICE OR PALLIATIVE CARE SPECIALIST OVER THE PHONE?	

SECTION 7 – OTHER HEALTHCARE CONTACT

SINCE THE LAST CRF WAS COMPLETED…

7	**HOW MANY TIMES HAS THE PATIENT SEEN A NURSE IN A HOSPITAL CLINIC SETTING?**	
8	**HOW MANY TIMES HAS THE PATIENT SEEN A NURSE IN THEIR OWN HOME?**	
9	**HOW MANY TIMES HAS THE PATIENT SEEN AN NHS PHYSIOTHERAPIST?**	
10	**HOW MANY TIMES HAS THE PATIENT SEEN AN OCCUPATIONAL THERAPIST?**	
11	**HOW MANY TIMES HAS THE PATIENT SEEN A PSYCHOLOGIST?**	
12	**HOW MANY TIMES HAS THE PATIENT SEEN A COUNSELLOR?**	
13	**HOW MANY TIMES HAS THE PATIENT ATTENDED A DAY HOSPITAL?**	

Patient's trial number					Patient's initials			

14	HAS THERE BEEN ANY OTHER CONTACT WITH HEALTHCARE SERVICES?	YES	NO

If yes, give details below, if no, please check document and sign at the end

	Type of healthcare contact	Number of contacts
1		
2		
3		
4		

		DD	MM	YYYY
Name of researcher completing form	Signature	Date		

Patient's trial number					Patient's initials			

Only complete this form if there is no further patient involvement in the trial (i.e. visits, telephone, follow-up through medical notes, etc.)

TAPPS TRIAL FORM 11

LOSS TO FOLLOW- UP/ WITHDRAWAL FORM

1	**THE PATIENT HAS BEEN:** (CIRCLE ONE ANSWER)	**WITHDRAWN**	**YES**	**LOST TO FOLLOW-UP**	**YES**

2	**DATE OF PATIENT'S WITHDRAWAL OR LOSS TO FOLLOW-UP?**	DD	MM	YYYY

3	**IS THE PATIENT HAPPY FOR THE RESEARCH TEAM TO USE ALL THE DATA COLLECTED PRIOR TO WITHDRAWAL?**	**YES**	**NO**	**N/A**
4	**IS THE PATIENT HAPPY FOR THE RESEARCH TEAM TO USE ALL THE BLOOD AND PLEURAL FLUID SAMPLES COLLECTED PRIOR TO WITHDRAWAL?**	**YES**	**NO**	**N/A**
5	**IS THE PATIENT HAPPY FOR THE RESEARCH TEAM TO USE THE BLOOD SAMPLES COLLECTED <u>FOR GENETIC ANALYSIS</u> PRIOR TO WITHDRAWAL?**	**YES**	**NO**	**N/A**

6	**REASON FOR WITHDRAWAL/LOSS TO FOLLOW-UP** (PLEASE TICK ONE BOX)		PATIENT WITHDREW CONSENT
			INELIGIBILITY
			OTHER (please specify):

		DD	MM	YYYY
Name of researcher completing form	Signature	Date		