



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

TAPPS trial

CRF PACK

Trial			Patient's		
Number:			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	DD	MM	YYYY
enrolment			

Patient's		
initials		

TAPPS TRIAL FORM 1 – **ENROLMENT**

Clinical data

1 SEX		MA	ALE	FEM	1ALE
2 PATIENT'S DATE OF BIRTH				DD MM	YYYY
3 SMOKING STATUS	CURRENT	EX-SN	10KER	NEVER-	SMOKER
4 WHO PERFORMANCE STATUS		0	1	2	3
LINDERLYING CANCER TYPE(S)					

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)			diagnosis own if needed)
		Т	Ν	M		DD	MM	YYYY
		Т	N	M		DD	MM	YYYY
		Т	N	M		DD	MM	YYYY

1=lung 2=mesothelioma 3=breast 4=ovarian 5=lymphoma 6=upper GI 7=lower GI 8=renal 9=other 10=unknown

Effusion

6 SIDE OF EFFUSION NE	6 SIDE OF EFFUSION NEEDING INTERVENTION							IGHT
7 HAS THE PATIENT HAI IN THE LAST 3 MONTH	YES			NO				
1=Diagnostic tap 2=Therapeutic tap 3=Image-guided biopsy	Procedure type (Use code on left)	Date of procedure		f procedure				
4=Chest drain 5=Indwelling Pleural Catheter		DD	MM	YYYY		DD	MM	YYYY
6=Medical thoracoscopy 7=VATS		DD	MM	YYYY		DD	MM	YYYY
8=Other (Specify)		DD	MM	YYYY		DD	MM	YYYY
8 HAVE THERE BEEN AN PLEURODESIS ON THIS	IY ATTEMPTS AT S SIDE IN THE LAST MON	NTH?			YES			NO
9 WHAT IS THE MAXIM				Cm				
Date of scan (must be		DD	MM	YYYY				
Symptoms								

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

	<u> </u>								
	Patient's trial number						Patien initi		
11	PLEASE ASK THE P VERTICAL MARK (UCH <u>CHEST PA</u>	<u>IIN</u> THEY HA	VE AT THE I	MOMENT BY MA	KING A SINGI	.E
	No pain at	all					v	Vorst possible	e pain
FOI	R OFFICE USE ONLY		Assessor 1 score	mm	Initials		ssessor score m	m Initials	Date
12	PLEASE ASK THE P VERTICAL MARK O			UCH <u>BREATHL</u>	ESSNESS TH	EY HAVE AT	THE MOMENT B	SY MAKING A	SINGLE
N	o breathlessness at	all						Vorst possible reathlessness	
FOI	R OFFICE USE ONLY		Assessor 1 score	mm	Initials	Date 2 s	sessor score m	m Initials	Date
T	reatment								
13	PLEASE GIVE DETA Tick 'none' if need		ORAL STEROIL	OS THE PATIEN	IT IS CURREI	NTLY TAKIN	G.		
NO	NE								
	(Generic dr	Type ug name in CAPITA	LS)			ose ts, e.g. 10 mg)		Freque (Number of dos	
14	PLEASE GIVE DETA		NON-STEROID	AL ANTI-INFL	AMMATORII	ES (NSAIDS)	THE PATIENT IS	CURRENTLY T	TAKING.
NO	NE								
	Type (Generic drug name in CAPITALS)		Dose nits, e.g. 10 mg)	Freque (Number of do	•	Regu	lar or PRN	Rout (oral / topical / re	
15	PLEASE INDICATE Please tick all that							S	
NO	NE								
PAI	RACETAMOL							Regular /	PRN

OTHER (Please specify, e.g. gabapentin).....

OTHER (Please specify, e.g. gabapentin)

WEAK OPIATE (e.g. codeine / tramadol)

STRONG OPIATE (e.g. oramorph / fentanyl)

Regular / PRN

Regular / PRN

Regular / PRN

Regular / PRN

Patient's trial number		ent's itials
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?	1 st LINE 2 nd LINE	3 rd LINE OTHER
When did this treatment start?	DD MM YYYY	UNKNOWN
IS THE PATIENT <u>CURRENTLY</u> UNDERGOING ANY TREATMENT WITH ANTI-CANCER MONOCLONAL ANTIBODIES?	YES	NO
If yes, what stage therapy is it?	1 st LINE 2 nd LINE	3 rd 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?	1 st line 2 nd line	3 rd 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
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 ASPIR	IIN.	
CLOPIDOGREL		
LOW MOLECULAR WEIGHT HEPARIN (e.g. Enoxaparin)		
WARFARIN		
OTHER (please specify)		

Patient's trial number			Patient's initials		
namber			illians.		

Past medical history

22 DOES THE PATIENT	SUFFER FROM ANY OF THE FOLLOWING DISEASES?		
	COPD / ASTHMA	YES	NO
	INTERSTITIAL LUNG DISEASE	YES	NO
	BRONCHIECTASIS	YES	NO
RESPIRATORY	PULMONARY HYPERTENSION	YES	NO
	OTHER RESPIRATORY	YES	NO
	(Please specify)		
	ISCHAEMIC HEART DISEASE	YES	NO
	ATRIAL FIBRILLATION	YES	NO
CARDIAC	HEART FAILURE	YES	NO
3.115176	OTHER CARDIAC	YES	NO
	(Please specify)		

Blood test results

Date of tests (must be within the last 10 days)						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		Da	ate

	Recruiting		Date of DD	MM YYYY	Patient's		
	centre	ran	ndomisation		initials		
	TAPP:	S TRIAL FC	PRM 2	– RANDON	/IISATIC	N	
181	CLUSION CRITE) I A			TICK AS	APPROI	
IIN 1	CLUSION CRITEF The patient has one of				163		NO
	· -	with histocytologically pro	oven nleural mal	ignancy			
		ural effusion with histocy	•				
	1	_		eural involvement on CT or	MADI		
2				copy, as per BTS guidelines	IVIIXI		
3	The patient's expecte			copy, as per bro guidennes			
4	The patient has signed						
	CLUSION CRITEI				YES		NO
							110
1		ficantly affect further mar	• •	n to making a diagnosis, and	such a		
2	The patient is < 18 ye	ars old					
3	The patient is pregnar	nt or lactating					
4	There is evidence of e talc pleurodesis	extensive lung entrapment	t or fluid loculati	on which would normally ex	clude		
5		olume or positioning of fluor allow local anaesthetic the		d scan, performed in the late hout further intervention	eral		
6	There has been a prev	viously documented react	ion to talc				
7	There is a clear contra	aindication to local anaest	hetic thoracosco	ppy or chest drain insertion			
I C	ONFIRM THAT THE PAT	FIENT IS ELIGIBLE FOR RAI	NDOMISATION (circle one)	YES		NO
MI	NIMISATION INF	ORMATION					
		Breast			0 or 1		
	UNDERLYING Lung WHO PERFORMANCE STATUS				0 01 1		
	(Tick one) Mesothelioma (Tick one)						
		Other					
NA	ME OF DOCTOR ASSES	SSING ELIGIBILITY:					
	IF THE PATIENT IS ELIG	SIBLE CALL THE RANDOMI	ISATION LINE ON	N 07773 162 740. You will be	given the followin	g inform	nation:

				CONTROL INTERVEN Chest drain and slurry Thoracoscopy and						
Patient's trial number			Treatment allocation (circle one)							
						DD		MM	YYYY	
Name of	f researcher	completin	ng form	Sig	gnature			D	ate	
			.6		,					

Patient's trial		
number		

Date of	DD	MM	YYYY
insertion			

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 PRO	OCEDURE PERFORMED?	OPERATIN	IG THEATRE	'CLEAN	ROOM'	BEDS	SIDE
2	TIMING OF PROCEDU	RE			START	hh mm	END	hh mm
3	GRADE OF PRIMARY	OPERATOR	F1/F2	CT1/CT2	ST3+	CONSU	JLTANT	OTHER
4	WAS BEDSIDE ULTRA DRAIN INSERTION?	SOUND USED TO GUIDE	١	'ES	N	0	UNKNOWN	
5	DETAILS OF SEDATION Write 'none' or 'unknown	_		6	AILS OF PRE-I te 'none' or 'u			
	Type (Generic drug name in CAP	Dose (include units, e.g	. 10 mg)	(Gen	Type eric drug name i	n CAPITALS)		ose s, e.g. 10 mg)
7	DETAILS OF LOCAL AN	NAFCTHETIC	Type (gene	eric drug name in	CAPITALS) and s	trength (%)	Dose or	volume
7	DETAILS OF LOCAL AN	NAESTHETIC						
8	WHAT SIZE DRAIN WA	AS INSERTED?			12	2 F	14	F
9	WAS SELDINGER TECI	HNIQUE USED?	١	'ES	N	0	UNKN	OWN
10	PLEASE CIRCLE WHICH	H COMPLICATIONS, IF ANY	, OCCURRED	DURING THE	PROCEDURE	circle all tha	t apply individ	ually)
NO	NE	BLEEDING	SIGNIFICAN	r cough			SYNCOPE	
SIG	NIFICANT PAIN	MULTIPLE PASSES	PLEURAL SPACE NOT ENTERED NEW HYPOXIA			А		
DYS	SRHYTHMIA	NEW HYPOTENSION	OTHER (Ple	ase 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		L Da	ite

Patient's trial		
number		

Date of	DD	MM	YYYY
procedure			

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	ОТН	HER
4 WAS ULTRASOUND GUIDANCE USED?	YES	NO	UNKNOWN	
DETAILS OF SEDATION GIVEN Write 'none' or 'unknown' if appropriate	6	TAILS OF PRE-MEDICATION te 'none' or 'unknown' if a	_	
Type (CAPITALS) Dose		Type (CAPITALS)	De	ose
	Type (CAPITALS)	and strength (%)	Dose or	volume
7 DETAILS OF LOCAL ANAESTHETIC	Next s,			
8 HOW MUCH FLUID WAS DRAINED DURING THE	PROCEDURE?			mls
9 WERE ANY ADHESIONS SEEN?	YES – BROKEN DOWN	YES – NOT BROKEN	NO	UNKNOWN
DID THE LUNG APPEAR TRAPPED?	YES	NO	UNKN	IOWN
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						Patie init	nt's ials	
12 WERE ANY BIOPSIES	TAKEN?	YES			NO		UNKNOWN	
13 WHAT SIZE DRAIN W	AS INSERTED?	16 F 18 F 20 F				22 F	24 F	
Please tick here if no	drain was inserted							
PLEASE CIRCLE CLEARLY WHICH COMPLICATIONS, IF ANY, OCCURRED DURING THE PROCEDURE (circle all that apply individually)								
NONE BLEEDING SIGNIFICANT COUGH SYNC					SYNCOPE			
SIGNIFICANT PAIN	VISCERAL DAMAGE	PLEURAL SPACE NOT ENTERED					NEW HYPOXIA	
DYSRHYTHMIA	NEW HYPOTENSION	OTHER (Please specify)						
PLEASE CIRCLE CLEAR (circle all that apply in	RLY WHICH COMPLICATION ndividually)	NS, IF ANY, OCCU	JRRED <u>IN T</u>	HE 2	HOURS POST PR	ROCED	<u>OURE</u>	
NONE	NAUSEA OR VOMITING	RESPIRATORY D)EPRESSIOI	N NEE	DING TREATME	NT	GCS DROP	> 2
UNCONTROLLED PAIN	NEW HYPOTENSION	SATURATIONS (OROP NEEL	DING 1	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</u> 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								

		DD	MM	YYYY
Name of researcher completing form	Signature		Da	ate

			1			1	1
Patient's trial			Date of	DD	MM	YYYY	Patient's
number			discharge				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 PATIEN	1 DID THE PATIENT DIE BEFORE DISCHARGE? If no, skip to question 2			YES	N	0		
If yes, please en	ter details reg	garding	death	below and cor	mplete as much o	f the CRF as possible		
Date of death		DD	MM	YYYY	Any oth	ner comments		
	l a			•				
Cause of death as	l b							
per death certificate	l c							
	II							
Was a post-mortem	performed?	YE	S	NO				
2 HAS THE PATIENT WAS COMPLETE					CE THE LAST CRF	YES	N	0
ANAEMIA NEEDING	TRANSFUSION	١						
POST-PROCEDURE F	EVER							
WOUND INFECTION								
ЕМРҮЕМА								
BRONCHOPLEURAL	FISTULA							
ATELECTASIS NEEDII	NG BRONCHO	SCOPY						
PNEUMONIA NEEDI	NG ANTIBIOTI	CS						
RESPIRATORY FAILU	RE							
DYSRHYTHMIA								
MYOCARDIAL INFAR	RCTION							
DEEP VEIN THROMB								
PULMONARY EMBO	LUS							
SURGICAL EMPHYSE	MA							
DRAIN DISLODGEME	ENT OR REPLA	CEMEN	Т					
ANY OTHER RELEVA	<u>nt</u> adverse e	VENT(S	5)					
For each event ticke	ed above, also	comple	te a <u>se</u>	eparate advers	se event form and	l enter the number of forms	s 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

	number								Patient's initials			
3		USE ANY <u>NSAIDS</u> DU N? If yes, complete be		Y	ES	NO				UNKI	NOWN	
	Type (Generic drug name in CAPITALS)	Dose (include units, e.g	. 10 mg)	Frequency (Doses / day)	Route (PO / IV / etc.)	Date started Date st			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		USE ANY <u>STEROIDS</u> DE N? If yes, complete be		Y	ES		N	10		UNKI	NOWN	
	Type (Generic drug name in CAPITALS)	Dose (include units, e.g	. 10 mg)	Frequency (Doses / day)	Route (PO / IV / etc.)		Date	started		Date s	stopped	
						DD	MM	YYYY	DD	MM	YYYY	
						DD	MM	YYYY	DD	MM	YYYY	
						DD	MM	YYYY	DD	MM	YYYY	
5	HOURS POST DRA	RAY PERFORMED AT 1 AIN / THORACOSCOPY CHEST X-RAY, HOW M DERGO BETWEEN RAI	AS PER	THE FOLLOW		_	EST X-	ES		CHEST CAN	10	
7	PLEASE GIVE DET (Write 'none' if no	AILS OF ALL <u>ANALGES</u> eeded)	SIC MEDIO	CATIONS THE	PATIENT WA	S TAK	ING <u>AT</u>	THE TIM	E OF DISCH	HARGE		
	Type (Generic drug name in CAPITALS)	Dose (include units, e.g	. 10 mg)		Jency Joses per day)		Regular or PRN			Route (oral / topical / rectal / other)		
8	DAY 2 BLOOD TEST	ST RESULTS ne second day post talo	c adminis	tration OR as	close to disch	narge	as poss	ible if soc	oner			
D	ate of tests								DD	MM	YYYY	
	Hb (g/dL)		Sodi	um (mmol/L)								
	WCC (x10 ⁹ /L)			um (mmol/L)								
	Platelets (x10 ⁹ /L)			rea (mmol/L)								
	CRP (mg/L)		Creatin	nine (µmol/L)								

Patient's trial		
number		

Patient's		
initials		

FOR <u>CONTROL ARM</u> PATIENTS COMPLETE SECTION 2

FOR <u>INTERVENTION ARM</u> 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 ATTEMP	WAS A CHEST DRAIN ATTEMPTED?					NO		
10 WAS THIS ATTEMPT ABANDO	NED? Only if yes,	tick reason	s below	Y	ES	NO	N/A	
TECHNICAL DIFFICULTIES								
SIGNIFICANT COMPLICATIONS								
PATIENT DISTRESS								
UNABLE TO ACCESS PLEURAL SPAC	E							
OTHER (Please specify)								
UNKNOWN								
11 WAS TALC SLURRY GIVEN?				Y	ES	N	10	
When was this given?		DD MM	YYYY	hh	mm	N/A	UNKNOWN	
If talc was not given, or if it was given more than 48 hours after drain insertion, tick reasons below								
PLEURAL INFECTION								
PERSISTENT AIR LEAK								
POOR LUNG EXPANSION								
EXCESSIVE FLUID PRODUCTION								
OTHER (Please specify)								
UNKNOWN								
12 GRADE OF PERSON ADMINIST	ERING TALC	F1/F2	CT1/CT2	ST3+	CONS.	NURSE	N/A	
DETAILS OF SEDATION GIVEN Write 'none' or 'unknown' if ap			1/1		MEDICATION unknown' if a _l		ALC	
Type (CAPITALS)	Dose			Type (CAPIT	ALS)	D	ose	
			Type (CAPITALS)	and strength (%	 5)	Dose or	volume	
15 DETAILS OF LOCAL ANAESTHE	TIC PRE TALC							

Patient's trial number						
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 <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

17 WAS T	HORACIC SUCTION APPLIED?	YES		YES NO			N/	′A
If yes,	when did this start?	Start) MM YYY	Υ			Time	нн мм
If yes,	when did this stop?	Stop DE) MM YYY	Υ		-	Time	нн мм
If yes,	what was the approximate total time spe	nt OFF sucti	on?					Hrs
If yes,	what pressure was predominantly used?	5 – 1	0 cmH ₂ O	11 - 20 c	mH ₂ O		21 + cr	mH₂O
18 DID TH	IE DRAIN BUBBLE AFTER INSERTION?	YES		NO		N/A	A	UNKNOWN
19 DID TH	IE DRAIN STOP BUBBLING?	YES		NC	NO		A	UNKNOWN
If app	icable, when did this stop?					DD I	MM	YYYY
20 DID TH	IE DRAIN SWING AFTER INSERTION?		YES	NC)	N/A	A	UNKNOWN
21 DID TH	IE DRAIN STOP SWINGING?	YES		YES NO		N/A	Ą	UNKNOWN
If app	icable, when did this stop?					DD I	MM	YYYY
22 WHAT	WAS THE TOTAL VOLUME OF FLUID DRA	INED?		ml	5	N/A	A	UNKNOWN
731	MUCH FLUID DRAINED IN THE 24 HOURS E DRAIN REMOVAL?			ml	5	N//	A	UNKNOWN

Patient's trial number		ient's nitials				
	DD MM YYYY HH MM		_			
24 WHEN DID THI	DRAIN COME OUT?	N/A	UNKNOWN			
Did this occur when planned, or earlier or later? If not as planned tick reasons below ON TIME EARLIER						
PLEURAL INFECTIO	V					
PERSISTENT AIR LEAK						
POOR LUNG EXPANSION						
HIGH VOLUME FLUID PRODUCTION						
APPROPRIATELY QUALIFIED STAFF NOT AVAILABLE						
ACCIDENTAL DISLODGEMENT						
UNCONTROLLED PAIN						
BLOCKAGE						
OTHER (Please spec	ify)					
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	N	0
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				
WAS A DRAIN INSERTED AT ANY TIME? If yes, please tick below as appropriate		YES	N	0
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 SEPARA	TE 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	нн мм
If yes, when did this stop?	Stop DD MM YYYY		Time	нн мм
If yes, what was the approximate total time spen	nt OFF suction?			Hrs
If yes, what pressure was predominantly used?	5 – 10 cmH ₂ O	11 - 20 cmH ₂ O	21+ c	mH ₂ O
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	Patie ini	ent's tials		
WHAT WAS THE TOTAL VOLUME OF FLUID DRAINED? (Excluding fluid removed during thoracoscopy)	3	N/A	UNKNOWN	
HOW MUCH FLUID DRAINED IN THE 24 HOURS BEFORE DRAIN REMOVAL?	3	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				
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	
number	initials	

SECTION 4 – HEALTH RESOURCE USE

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

Ward / specialty type	Tick		Date o	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

WHICH OPERATIONS OR PROCEDURES DID THE PATIENT UNDERGO DURING THEIR ADMISSION (EXCLUDING THE TRIAL PROCEDURE)					
	Procedure type		C	Date of _I	orocedure
			DD	MM	YYYY
			DD	MM	YYYY
			DD	MM	YYYY
			DD	MM	YYYY
			DD	MM	YYYY
			DD	MM	YYYY
DISCHARGE CHECKLIST FO	OR ALL PATIENTS (Tick if when don	e, if applica	able)		
Ensure the patient has an appointment for t	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		Da	te	

Patient's

initials

Patient's trial

number

Patient's trial		
number		

Date of	DD	MM	YYYY
Follow-up			

Patient's		
initials		

TAPPS TRIAL FORM 5 – MONTH 1 FOLLOW-UP

1	DID THE PATIENT ATTEND THE FOLLOW-UP APPLIF no, go to question 2. If yes, skip to question 3.		PERSON?		YES	NO			
2	WAS A TELEPHONE CONSULATION UNDERTAKE If no, give reason below by ticking in box. If yes,		ո 4.		YES		NO		
PA	TIENT HAS DIED (Complete section opposite)		Date of	death		DD MM	YYYY		
UN	ABLE TO CONTACT PATIENT				l a				
PATIENT TOO UNWELL Cause of death									
PA	TIENT DECLINED FOLLOW-UP		as per d		l c				
ОТ	HER (Please specify)		Ceremee		II				
		L	Was a p	ost-mort	em performed?	YES	NO		
Even if the patient has died, please complete as much of this CRF as possible.									
3	ARE THERE ANY ABNORMALITIES ON EXAMINIT If yes, tick below as appropriate.	NG THE DRAIN S	SITE?		YES	NO	N/A		
WOUND INFECTION									
WC	DUND BREAKDOWN OR MALUNION								
MA	ALIGNANT INFILTRATION								
ОТ	HER ABNORMALITY (Please specify)								
4	CURRENT WHO PERFORMANCE STATUS		0	1	2	3	4		
5	HAS THE PATIENT SUFFERED ANY EXPECTED AD THE LAST CRF WAS COMPLETED? If yes, tick below				YES	NO	UNKNOWN		
AN	AEMIA NEEDING TRANSFUSION								
PO	ST-PROCEDURE FEVER								
WC	DUND INFECTION								
EM	PYEMA								
BR	ONCHOPLEURAL FISTULA								
ATI	ELECTASIS NEEDING BRONCHOSCOPY								
PN	EUMONIA NEEDING ANTIBIOTICS								
RES	SPIRATORY FAILURE								
DYS	SRHYTHMIA								
MY	OCARDIAL INFARCTION								
DEI	EP VEIN THROMBOSIS								
PU	LMONARY EMBOLUS								
SUI	SURGICAL EMPHYSEMA								
DR	AIN DISLODGEMENT OR REPLACEMENT								

	Patient's trial number									Patie init	nt's ials			
6	HAS THE PATIENT SUFF SINCE THE LAST CRF W			EVAN	<u>IT</u> ADVE	RSE EVEN	TS	Y	YES NO			0	N/A	
For	each event above, also	complete a <u>s</u>	eparate ac	lverse	e event f	orm and	enter	the number of	of forn	ns used h	nere			
	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	7 PLEASE GIVE DETAILS OF ALL ANALGESIA THE PATIENT IS CURRENTLY TAKING (Tick 'none' if needed)													
NO	NE													
	Type (Generic drug name in CAPITALS)	Dos (include units,		Frequency O mg) (Number of doses per day)			Regula	Regular or PRN		Route (oral / topical / rectal / other)		er)		
8	SINCE THE LAST TRIAL IN THE FOLLOWING ON THE IT IS IN THE IT.	HE SAME SID						Υ	ES			N	0	
	Therapeutic aspiration of Insertion of an intercost		Event		Da	te		IF ANY OF THESE DECISIONS WERE REGARDING AN EFFUSI OCCUPYING <1/3 OF THE HEMITHORAX, WAS A DISCUSSION HELD WITH A BLINDED COLLEAGUE BEFORE A TREATMENT DECISION WAS MADE?				DISCUSSION	I	
for	fluid drainage			DD	MM	YYYY		YES		NC)		N/A	
	Insertion of an indwellin heter	ig pleural		DD	MM	YYYY		YES		NC)		N/A	
4 =	Medical or surgical thora	acoscopy		DD	MM	YYYY		YES		NC			N/A	
				DD	MM	YYYY		YES		NC			N/A	
		-		DD	MM	YYYY		YES		NC NC			N/A N/A	
		-		DD	MM	YYYY		YES		NC			N/A	
				DD	MM	YYYY		YES		NC			N/A	
9	WERE ANY OF THE PRO OUT, OR ATTEMPTED B				NECESS	ARY, BUT	NOT	CARRIED	Y	ËS	N	0	UNKNOW	VN
If y	es, please give details	DD M	M YYYY	/										
		DD M	M YYYY	/										

Patient's trial number			Patie ini	ent's tials		
HAS THE PATIENT RECEIVED RADIOTHERAPY TO THE CHEST ON THE SIDE OF THEIR PROCEDURE SINCE THE LAST CRF WAS COMPLETED?		Υ	'ES	N	0	
HAS THE PATIENT RECEIVED ANY <u>CANCER-MODULATING</u> HORMONE THERAPY SINCE THE LAST CRF WAS COMPLETED?		Υ	'ES	NO		
If yes, what stage therapy was it?	1 st	LINE	2 nd LINE	3 rd LINE	OTHER	
When did this treatment start?	DD	MM	YYYY	UNKN	IOWN	
When did this treatment end?	DD	MM	YYYY	ONGOING	UNKNOWN	
HAS THE PATIENT UNDERGONE_ANY TREATMENT WITH ANTI-CANCER MONOCLONAL ANTIBODIES SINCE THE LAST CRF WAS COMPLETED?		Υ	'ES	NO		
If yes, what stage therapy was it?	1 st	LINE	2 nd LINE	3 rd LINE	OTHER	
When did this treatment start?	DD MM YYYY			UNKNOWN		
When did this treatment end?	DD	MM	YYYY	ONGOING	UNKNOWN	
HAS THE PATIENT RECEIVED ANY <u>CHEMOTHERAPY</u> SINCE THE LAST CRF WAS COMPLETED?	YES			NO		
If yes, what stage therapy was it?	1 st	LINE	2 nd LINE	3 rd LINE	OTHER	
When did this treatment start?	DD	MM	YYYY	UNKNOWN		
When did this treatment end?	DD	MM	YYYY	ONGOING	UNKNOWN	
HAS THE PATIENT UNDERGONE ANY <u>OTHER FORM OF ANTI-CANCER</u> THERAPY SINCE THE LAST CRF WAS COMPLETED?		Υ	'ES	N	0	
If yes, please specify and state what stage therapy it was						
When did this treatment start?	DD	MM	YYYY	UNKN	IOWN	
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 t	the pre	evious	one?	DD MM	YYYY	
DISEASE PROGRESSION						
STABLE DISEASE						
PARTIAL DISEASE REMISSION						
COMPLETE REMISSION						

Patient's trial number						Patient's initials		
PLEASE ASK THE PATIENT VERTICAL MARK ON THE		E HOW MUCH	I <u>CHEST PA</u>	<u>IN</u> THEY HAV	/E AT THE MOMEI	NT BY MAKING	G A SINGLE	
No pain at all	<u> </u>					H Wors	t possible pa	nin
FOR OFFICE USE ONLY		Assessor 1 score	mm	Initials	Assessor Date 2 score	mm	Initials	Date
PLEASE ASK THE PATIENT VERTICAL MARK ON THE		E HOW MUCH	I <u>BREATHLI</u>	<u>ESSNESS</u> THE	Y HAVE AT THE M	IOMENT BY M	AKING A SIN	IGLE
No breathlessness at all	<u> </u>						t possible hlessness	
FOR OFFICE USE ONLY		Assessor 1 score	mm	Initials	Assessor Date 2 score	mm	Initials	Date
Ensure patient has had a chest Ensure every page of this CRF Ensure the patient has complete Ensure the patient has complete Ensure the patient has enough	thas the patie eted the quali	ity of life ques	stionnaires se question	(EQ-5D and	SF-36)			
Ensure the patient has sufficion	ent VAS bookl	et space, and	that their	previous cha	rts are handed in			
Ensure the patient has been g	given a date fo	or their next ti	rial follow-ા	nb				
					DD	MM	YYYY	

Signature

Name of researcher completing form

Date

Patient's trial number					Date of Follow-up	DD	MM	YYYY	Patient's initials			
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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		
9	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 OUTPATIEN	IT APPOINTMENT?	
	HOW MANY OF THESE APPOINTMENTS REQUIRED HOSPITAL TRANSPORT	7?	
	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 CONSULTATI	ON?	
	HOW MANY TIMES DID THE PATIENT USE THE AMBULANCE SERVICE TO A	ATTEND A+E?	

	ent's trial number	ACUTE HO	OSPITAL	ini	ent's itials		
	CE THE LAST CRF WAS COMPLETED, HAS TH MISSIONS TO AN ACUTE HOSPITAL?	E PATIENT HA	D ANY	YES	NO		
If ye	es, complete below, if no skip to question 5						
НΟ\	W MANY TIMES HAS THE PATIENT BEEN AD	MITTED? Plea	se give detail	s below			
	Reason for admission	Did the patient have surgery?		pe(s) of surgery ot applicable' if needed	Number of days in ITU or HDU	Number of days in hospital	
1							
2							
3							
4							
5							
SEC	TION 5 – ADMISSIONS TO F	REHABILI	TATION	HOSPITAL			
	CE THE LAST CRF WAS COMPLETED, HAS TH MISSIONS TO A REHABILITATION HOSPITAL		D ANY	YES	N	0	
If ye	es, complete below, if no skip to question 6						
НΟ\	W MANY TIMES HAS THE PATIENT BEEN AD	MITTED? Plea	se give detail	s below			
	Reaso	n for admissic	on	_		of days in pital	
1							
2							

Patient's trial number					Patient's initials		
SECTION (6 – P	ΔΙΙΙ	ΔΤΙ\/	FΔN	ID 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 A		
	HOW MANY NIGHTS HAS THE PATIENT SPENT AS AN INPATIENT AT A HOS		
	HOW MANY TIMES HAS THE PATIENT SEEN A HOSPICE OR PALLIATIVE CA		
	HOW MANY TIMES HAS THE PATIENT SPOKEN TO A HOSPICE OR PALLIATION OVER THE PHONE?	VE CARE SPECIALIST	

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?	

Patie	nt's trial number	Patie ini	nt's tials							
14 HAS	THERE BEEN ANY OTHER CONTACT WITH HEALTHCARE SERVICES?	NO								
If ye	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							

Signature

Name of researcher completing form

Date

Patient's trial		
number		

Date of	DD	MM	YYYY
Follow-up			

Patient's		
initials		

TAPPS TRIAL FORM 7 - MONTH 3 FOLLOW-UP

	17 (1 1 5 11 (1) (2 1 5 (1) 1 7			0.01		•.
1	DID THE PATIENT ATTEND THE FOLLOW-UP APPOINTMENT If no, go to question 2. If yes, skip to question 3.	IN PERSON?		YES	N	10
2	WAS A TELEPHONE CONSULATION UNDERTAKEN? If no, give reason below by ticking in box. If yes, skip to quest	ion 4.		YES	N	10
PAT	FIENT HAS DIED (Complete section opposite)	Date of	death		DD MM	YYYY
UN	ABLE TO CONTACT PATIENT			l a		
PAT	FIENT TOO UNWELL	Cause o		l b		
PAT	FIENT DECLINED FOLLOW-UP	as per d certifica		I c		
ОТІ	HER (Please specify)			II		
	·	Was a p	ost-mort	em performed?	YES	NO
	Even if the patient has died, please co	mplete as n	nuch of	this CRF as po	ssible.	
3	ARE THERE ANY ABNORMALITIES ON EXAMINING THE DRAI If yes, tick below as appropriate.	YES		NO	N/A	
WOUND INFECTION						
WC	OUND BREAKDOWN OR MALUNION					
MA	LIGNANT INFILTRATION					
ОТІ	HER ABNORMALITY (Please specify)					
4	CURRENT WILL REPEORMANCE STATUS	0	1	2	2	4
4	CURRENT WHO PERFORMANCE STATUS	0	1 2		3	4
5	HAS THE PATIENT SUFFERED ANY EXPECTED ADVERSE EVEN THE LAST CRF WAS COMPLETED? If yes, tick below as appropriate the complete of the complete			YES	NO	UNKNOWN
AN	AEMIA NEEDING TRANSFUSION					
POS	ST-PROCEDURE FEVER					
WC	OUND INFECTION					
EM	PYEMA					
BRO	ONCHOPLEURAL FISTULA					
ATE	ELECTASIS NEEDING BRONCHOSCOPY					
PNI	EUMONIA NEEDING ANTIBIOTICS					
RESPIRATORY FAILURE						
DYS	SRHYTHMIA					
MY	OCARDIAL INFARCTION					
DE	EP VEIN THROMBOSIS					

PULMONARY EMBOLUS
SURGICAL EMPHYSEMA

DRAIN DISLODGEMENT OR REPLACEMENT

	Patient's trial number								Patie ini	ent's tials		
6	HAS THE PATIENT SUFFE SINCE THE LAST CRF WA		OTHER RELEVANT ADVERSE EVENTS ETED? YES				ES	NO	N/A			
For	each event above, also co	omplete a s	separate a	dverse	event 1	form and ente	r the nu	ımber o	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							Y	ES	NO		
	Therapeutic aspiration of Insertion of an intercosta		Event Date O			OCCUP HELD V	YING <1,	E DECISIONS WEI /3 OF THE HEMIT LINDED COLLEAG MADE?	HORAX, WAS A	DISCUSSION		
for	fluid drainage			DD	MM	YYYY		YES	NO)	N/A	
	Insertion of an indwelling heter	pleural		DD	MM	YYYY		YES	NO	ס	N/A	
4 =	Medical or surgical thorac	coscopy		DD	MM	YYYY		YES	NO)	N/A	
				DD	MM	YYYY		YES	NO)	N/A	
		-		DD DD	MM	YYYY		YES	NO		N/A	
		-		DD	MM	YYYY		YES	NO		N/A	
		-		DD	MM	YYYY		YES	NO NO		N/A	
								YES	NO.)	N/A	
8	WERE ANY OF THE PROC OUT, OR ATTEMPTED BU			_	NECESS	SARY, BUT NO	CARR	ED	YES	NO	UNKNOWN	
If y	es, please give details	DD N	1M YY	YY								
		DD N	1M YY	YY								
9	HAS THE PATIENT RECEITHE SIDE OF THEIR PROC							Y	ES	N	10	
10	HAS THE PATIENT RECEITHERAPY SINCE THE LAS				ATING F	HORMONE		Y	ES	NO		
	If yes, what stage therap	y was it?					1 st	LINE	2 nd LINE	3 rd LINE	OTHER	
	When did this treatment	start?					DD	MM	YYYY	UNKI	NOWN	
	When did this treatment	end?					DD	MM	YYYY	ONGOING	UNKNOWN	

Patient's trial number						Patient's initials					
HAS THE PATIENT UNDER MONOCLONAL ANTIBOD						Y	ES		N	10	
If yes, what stage therapy	was it?				1 st	LINE	2 nd LINE	3 rd	LINE	ОТ	HER
When did this treatment	start?				DD	MM	YYYY		UNKI	NOWN	
When did this treatment	end?				DD	MM	YYYY	ONG	GOING	UNKI	NOWN
HAS THE PATIENT RECEIVE WAS COMPLETED?	ED ANY <u>CHEM</u>	1OTHERAPY	SINCE THE	LAST CRF		Y	ES		N	10	
If yes, what stage therapy	was it?				1 st	LINE	2 nd LINE	3 rd	LINE	ОТ	HER
When did this treatment	start?				DD	MM	YYYY		UNKI	NOWN	
When did this treatment	end?				DD	MM	YYYY	ONG	GOING	UNKI	NOWN
HAS THE PATIENT UNDER THERAPY SINCE THE LAST			OF ANTI-C	CANCER	YES N				10		
If yes, please specify and	state what stag	ge therapy it	was								
When did this treatment	start?				DD MM YYYY			UNKNOWN			
When did this treatment	end?				DD	MM	YYYY	ONG	OING	UNKN	NOWN
14 HAS THE PATIENT HAD A	STAGING SCA	N SINCE THE	IR LAST T	RIAL VISIT?			YES	ı	NO	UNKI	NOWN
If yes, when was the mos	t recent scan a	and what did	it show co	ompared to t	he pre	evious (one?	DD	MM	YYYY	
DISEASE PROGRESSION											
STABLE DISEASE											
PARTIAL DISEASE REMISSION											
COMPLETE REMISSION											
PLEASE ASK THE PATIENT VERTICAL MARK ON THE		HOW MUCH	I <u>CHEST P</u>	<u>AIN</u> THEY HA	VE AT	THE IV	IOMENT BY N	1AKIN	G A SIN	GLE	
No pain at all	—						—	Wors	st possi	ble pai	n
FOR OFFICE USE ONLY		Assessor 1 score	mm	Initials	D	Asso	essor ore	mm	Initi	als	Date
PLEASE ASK THE PATIENT		ноw мисн	I <u>BREATHI</u>	LESSNESS TH	EY HA	VE AT	THE MOMEN	ГВҮ М	IAKING	A SING	3LE
VERTICAL MARK ON THE	LINE BELOW										
No breathlessness at all Worst possible breathlessness											

FOR OFFICE USE ONLY

Assessor

1 score

Assessor

2 score

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		ite	

Patient's trial number	Date of Follow-up	MM	YYYY	Patient's initials			
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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 V	WITH A GP?	
9	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 OUTPATIEN	IT APPOINTMENT?	
	HOW MANY OF THESE APPOINTMENTS REQUIRED HOSPITAL TRANSPORT	?	
9	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	ON?	
	HOW MANY TIMES DID THE PATIENT USE THE AMBULANCE SERVICE TO A	TTEND A+E?	

Patient's trial				Patient's		l
number				initials		l
SECTION 4	4 – AD	MISSIC	NS 1	O ACUTE HOSPITAL		

SINCE THE LAST CRF WAS COMPLETED, HAS THE PATIENT HAD ANY YES NO **ADMISSIONS TO AN ACUTE HOSPITAL?** If yes, complete below, if no skip to question 5 HOW MANY TIMES HAS THE PATIENT BEEN ADMITTED? Please give details below Did the patient **Number of** Number of Type(s) of surgery days in ITU Reason for admission have days in Write 'not applicable' if needed or HDU hospital surgery? Tick if yes 1 2 3 4 5 SECTION 5 – ADMISSIONS TO REHABILITATION HOSPITAL SINCE THE LAST CRF WAS COMPLETED, HAS THE PATIENT HAD ANY YES NO **ADMISSIONS TO A REHABILITATION HOSPITAL?** If yes, complete below, if no skip to question 6 HOW MANY TIMES HAS THE PATIENT BEEN ADMITTED? Please give details below Number of days in Reason for admission hospital 1

2

3

4

Patient's trial number SECTION 6 — PALLIATIVE AND HOSPICE CARE	Patie init	nt's lials						
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 A	DMISSION)?							
HOW MANY NIGHTS HAS THE PATIENT SPENT AS AN INPATIENT AT A HOS	SPICE?							
HOW MANY TIMES HAS THE PATIENT SEEN A HOSPICE OR PALLIATIVE CA	RE 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								
HOW MANY TIMES HAS THE PATIENT SEEN A NURSE IN A HOSPITAL CLINI	C SETTING?							
HOW MANY TIMES HAS THE PATIENT SEEN A NURSE IN THEIR OWN HOM	E?							
HOW MANY TIMES HAS THE PATIENT SEEN AN NHS PHYSIOTHERAPIST?								
HOW MANY TIMES HAS THE PATIENT SEEN AN OCCUPATIONAL THERAPIS	ST?							

HOW MANY TIMES HAS THE PATIENT SEEN A PSYCHOLOGIST?

HOW MANY TIMES HAS THE PATIENT SEEN A COUNSELLOR?

13 HOW MANY TIMES HAS THE PATIENT ATTENDED A DAY HOSPITAL?

9

10

Patie	ent's trial number	Patie ini	ent's tials
14 HAS	THERE BEEN ANY OTHER CONTACT WITH HEALTHCARE SERVICES?	YES	NO
If ye	es, give details below, if no, please check document and sign at the end		
	Type of healthcare contact		Number of contacts
1			
2			

		DD	MM	YYYY
Name of researcher completing form	Signature		Da	te

Patient's trial		
number		

Date of	DD	MM	YYYY
Follow-up			

Patient's		
initials		

TAPPS TRIAL FORM 9 – MONTH 6 FOLLOW-UP

1	D THE PATIENT ATTEND THE FOLLOW-UP APPOINTMENT IN PERSON? no, go to question 2. If yes, skip to question 3. YES						NO	
2	2 WAS A TELEPHONE CONSULATION UNDERTAKEN? If no, give reason below by ticking in box. If yes, skip to question 4.					NO		
PA	FIENT HAS DIED (Complete section opposite)	Date of	death			DD MM	YYYY	
UN	ABLE TO CONTACT PATIENT			l a				
PA	TIENT TOO UNWELL	Cause o		۱b				
PA	TIENT DECLINED FOLLOW-UP	as per d		l c				
ОТІ	HER (Please specify)			II				
	1	Was a p	ost-mort	em pe	rformed?	YES	NO	
	Even if the patient has died, please comp	lete as r	nuch of	this (CRF as po	ssible.		
3	ARE THERE ANY ABNORMALITIES ON EXAMINING THE DRAIN SI If yes, tick below as appropriate.	TE?		YES		NO	N/A	
WC	OUND INFECTION							
WC	OUND BREAKDOWN OR MALUNION							
MA	LIGNANT INFILTRATION							
ОТІ	HER ABNORMALITY (Please specify)							
•		-			2			
4	CURRENT WHO PERFORMANCE STATUS	0	1		2	3	4	
5	HAS THE PATIENT SUFFERED ANY EXPECTED ADVERSE EVENTS S THE LAST CRF WAS COMPLETED? If yes, tick below as appropriate			YES		NO	UNKNOWN	
AN.	AEMIA NEEDING TRANSFUSION							
PO:	ST-PROCEDURE FEVER							
WC	OUND INFECTION							
EM	PYEMA							
BRO	ONCHOPLEURAL FISTULA							
ATE	ELECTASIS NEEDING BRONCHOSCOPY							
PN	EUMONIA NEEDING ANTIBIOTICS							
RES	SPIRATORY FAILURE							
DYS	SRHYTHMIA							
MY	OCARDIAL INFARCTION							
DEI	EP VEIN THROMBOSIS							

PULMONARY EMBOLUS
SURGICAL EMPHYSEMA

DRAIN DISLODGEMENT OR REPLACEMENT

	Patient's trial number							Patie ini	ent's tials	
6	HAS THE PATIENT SUFFERED ANY SINCE THE LAST CRF WAS COMPLE	NO	N/A							
Eor	each event above, also complete a	conarato a	dvorco	ovent	form and ontor	thon	umbor	of forms used	horo	
FUI	each event above, also complete a	separate at	uverse	event	ioriii and enter	then	umber	or forms used	nere	
	IF ANY COMPLICATION MIGHT I				A SERIOUS ADV RISTOL AND TH				PLETE AN SAI	FORM
7	SINCE THE LAST TRIAL VISIT, HAS THE FOLLOWING ON THE SAME SI If yes, complete below using code						Y	'ES	N	10
	Therapeutic aspiration of ≥100mls Insertion of an intercostal drain	Event		Da	ate	OCCU!	PYING <1	E DECISIONS WEI /3 OF THE HEMIT LINDED COLLEAG MADE?	HORAX, WAS A	DISCUSSION
for	fluid drainage		DD	MM	YYYY		YES	NO)	N/A
	Insertion of an indwelling pleural heter		DD	MM	YYYY		YES	NO)	N/A
	Medical or surgical thoracoscopy		DD	MM	YYYY	YES		NO)	N/A
			DD	MM	YYYY		YES	NO	כ	N/A
			DD	MM	YYYY		YES	NO	כ	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 II			NECESS	SARY, BUT NOT	CARR	IED	YES	NO	UNKNOWN
If y	es, piease give details	MM YYY								
		VIIVI								
9	HAS THE PATIENT RECEIVED RADIO THE SIDE OF THEIR PROCEDURE SI						Υ	'ES	N	Ю
10 HAS THE PATIENT RECEIVED ANY CANCER-MODULATING HORMONE THERAPY SINCE THE LAST CRF WAS COMPLETED? YES NO								10		
	If yes, what stage therapy was it?					1 st	LINE	2 nd LINE	3 rd LINE	OTHER
	When did this treatment start?					DD	MM	YYYY	UNKI	NOWN
	M/han did this treatment and?					DD	MM	YYYY	ONCOINC	LINIKNIOWANI

	number					ini	tials			
11	HAS THE PATIENT UNDERGONE ANY TREAM MONOCLONAL ANTIBODIES SINCE THE LAS				YES			NO		
	If yes, what stage therapy was it?			1 st	LINE	2 nd LINE	3 rd LINE		OTHER	
	When did this treatment start?			DD	MM	YYYY	UN	KNO\	٧N	
	When did this treatment end?			DD	MM	YYYY	ONGOIN	G U	NKNOWN	
12	HAS THE PATIENT RECEIVED ANY <u>CHEMOT</u> CRF WAS COMPLETED?	HERAPY SINCE TH	IE LAST		Υ	ES		NO		
	If yes, what stage therapy was it?			1 st	LINE	2 nd LINE	3 rd LINE		OTHER	
	When did this treatment start?			DD	MM	YYYY	UN	KNO\	WN	
	When did this treatment end?			DD	MM	YYYY	ONGOIN	G U	NKNOWN	
13	HAS THE PATIENT UNDERGONE ANY OTHE THERAPY SINCE THE LAST CRF WAS COMP		-CANCER	YES			NO			
	If yes, please specify and state what stage t	herapy it was								
	When did this treatment start?			DD	MM	YYYY	UN	KNO\	WN	
	When did this treatment end?			DD	MM	YYYY	ONGOIN	G U	NKNOWN	
14	HAS THE PATIENT HAD A STAGING SCAN S	INCE THEIR LAST	TRIAL VISIT?			YES	NO	U	NKNOWN	
	If yes, when was the most recent scan and	what did it show o	compared to	the pre	evious o	one?	DD MM	YY	YY	
DIS	EASE PROGRESSION									
STA	ABLE DISEASE									
PAI	RTIAL DISEASE REMISSION									
СО	MPLETE REMISSION									
15	PLEASE ASK THE PATIENT TO INDICATE HO VERTICAL MARK ON THE LINE BELOW	W MUCH <u>CHEST I</u>	PAIN THEY HA	AVE AT	THE M	IOMENT BY M	IAKING A S	INGL	E	
	No pain at all					—	Worst pos	sible	pain	
FO	R OFFICE USE UNLY	essor core mm	Initials	D	Asse ate 2 sc	essor ore	mm Ir	nitials	Date	
16	PLEASE ASK THE PATIENT TO INDICATE HO VERTICAL MARK ON THE LINE BELOW	W MUCH <u>BREATH</u>	<u>ILESSNESS</u> TH	HEY HA	VE AT	THE MOMENT			SINGLE	
N	o breathlessness at all					\dashv	Worst pos breathless			
FO	K OFFICE USE UNLY	essor core mm	Initials	D	Asse	essor ore	mm Ir	nitials	Date	

Patient's

Patient's trial

Patient's trial			Patient's		
number			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		
	C TOL					S EOLLON	 חוו	\

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

PPOINTMENTS WITH A GENERAL PRACTITIONER?	YES	NO
yes, complete below, if no skip to question 2		
OW MANY TIMES HAS THE PATIENT VISITED A GP?		
OW MANY TIMES HAS A GP VISITED THE PATIENT AT HOME?		
OW MANY TIMES HAS THE PATIENT HAD A TELEPHONE CONULTATION	WITH A GP?	
CTION 2 – OUTPATIENT ATTENDANCES		
·	YES	NO
yes, complete below, if no skip to question 3		
OW MANY TIMES HAS THE PATIENT ATTENDED A HOSPITAL OUTPATIEN	NT APPOINTMENT?	
OW MANY OF THESE APPOINTMENTS REQUIRED HOSPITAL TRANSPORT	r?	
CTION 3 – A+E ATTENDANCES		
·	YES	NO
yes, complete below, if no skip to question 4		
OW MANY TIMES HAS THE PATIENT ATTENDED A+E FOR A CONSULTAT	ION?	
OW MANY TIMES DID THE PATIENT USE THE AMBULANCE SERVICE TO A	ATTEND A+E?	
	CCTION 2 — OUTPATIENT ATTENDANCES NCE THE LAST CRF WAS COMPLETED, HAS THE PATIENT HAD ANY OSPITAL OUTPATIENT APPOINTMENTS? yes, complete below, if no skip to question 3 OW MANY TIMES HAS THE PATIENT ATTENDED A HOSPITAL OUTPATIENT OW MANY OF THESE APPOINTMENTS REQUIRED HOSPITAL TRANSPORT CCTION 3 — A+E ATTENDANCES NCE THE LAST CRF WAS COMPLETED, HAS THE PATIENT HAD ANY ITENDANCES AT ACCIDENT AND EMERGENCY? yes, complete below, if no skip to question 4 OW MANY TIMES HAS THE PATIENT ATTENDED A+E FOR A CONSULTATION.	OW MANY TIMES HAS THE PATIENT VISITED A GP? OW MANY TIMES HAS A GP VISITED THE PATIENT AT HOME? OW MANY TIMES HAS THE PATIENT HAD A TELEPHONE CONULTATION WITH A GP? CCTION 2 — OUTPATIENT ATTENDANCES NCE THE LAST CRF WAS COMPLETED, HAS THE PATIENT HAD ANY OSPITAL OUTPATIENT APPOINTMENTS? YES YES OW MANY TIMES HAS THE PATIENT ATTENDED A HOSPITAL OUTPATIENT APPOINTMENT? OW MANY OF THESE APPOINTMENTS REQUIRED HOSPITAL TRANSPORT? CCTION 3 — A+E ATTENDANCES NCE THE LAST CRF WAS COMPLETED, HAS THE PATIENT HAD ANY TIENDANCES AT ACCIDENT AND EMERGENCY?

Patient's trial number			Patient's initials		

YES

NO

SECTION 4 – ADMISSIONS TO ACUTE HOSPITAL

SINCE THE LAST CRF WAS COMPLETED, HAS THE PATIENT HAD ANY

ADMISSIONS TO AN ACUTE HOSPITAL?

If ye	es, complete below, if no skip to question 5									
НО	HOW MANY TIMES HAS THE PATIENT BEEN ADMITTED? Please give details below									
	Reason for admission	Did the patient have surgery?		pe(s) of surgery ot applicable' if needed	Number of days in ITU or HDU	Number of days in hospital				
1										
2										
3										
4										
5										
SEC	SECTION 5 – ADMISSIONS TO REHABILITATION HOSPITAL									
	SINCE THE LAST CRF WAS COMPLETED, HAS THE PATIENT HAD ANY ADMISSIONS TO A REHABILITATION HOSPITAL?									
If ye	es, complete below, if no skip to question 6									
НО	W MANY TIMES HAS THE PATIENT BEEN AD	MITTED? Plea	se give detail	s below						
	Reason	n for admissio	on		Number of days in hospital					
1										
2										
3										
4										

Patient's trial number				Patie init	nt's cials		
SECTION 6	– PALLIATI	VE AND HO	OSPICE CARE				
	CRF WAS COMPI		PATIENT HAD ANY RVICES?	YES	NO		
If yes, complete	below, if no skip	to question 7					
HOW MANY TIM	MES HAS THE PAT	IENT ATTENDED	A HOSPICE (WITHOUT	ADMISSION)?			
HOW MANY NI	GHTS HAS THE PA	TIENT SPENT AS	AN INPATIENT AT A HC	OSPICE?			
HOW MANY TIMES HAS THE PATIENT SEEN A HOSPICE OR PALLIATIVE CARE NURSE AT HOME?							
HOW MANY TIM		IENT SPOKEN TO	A HOSPICE OR PALLIA	TIVE CARE SPECIALIST			
SECTION 7	– OTHER H	EALTHCAR	E CONTACT				
SINCE THE LAST	CRF WAS COMPL	ETED					
HOW MANY TIM	MES HAS THE PAT	IENT SEEN A NUF	RSE IN A HOSPITAL CLIN	NIC SETTING?			
HOW MANY TIM	MES HAS THE PAT	IENT SEEN A NUF	RSE IN THEIR OWN HON	ME?			
HOW MANY TIM	MES HAS THE PAT	IENT SEEN AN NI	HS PHYSIOTHERAPIST?				

HOW MANY TIMES HAS THE PATIENT SEEN AN OCCUPATIONAL THERAPIST?

HOW MANY TIMES HAS THE PATIENT SEEN A PSYCHOLOGIST?

HOW MANY TIMES HAS THE PATIENT SEEN A COUNSELLOR?

13 HOW MANY TIMES HAS THE PATIENT ATTENDED A DAY HOSPITAL?

Patie	nt's trial number		Patient's initials					
14 HAS	THERE BEEN ANY OTHER CONTACT	NO						
If yes, give details below, if no, please check document and sign at the end								
	7	Number of contacts						
1								
2								
3								
4								
			DD M	M YYYY				
Name	e of researcher completing form	Signature		Date				

Patient's trial			Patient's		
number			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 FOL	LOW-UP	YES			
2	DATE OF PATIENT'S WITHDRA OR LOSS TO FOLLOW-UP?	WAL			DD	MM	YY	YY		
3	IS THE PATIENT HAPPY FOR THE COLLECTED PRIOR TO WITHD	YES	NO	N/A						
4	IS THE PATIENT HAPPY FOR TH	YES	NO	N/A						
5	IS THE PATIENT HAPPY FOR THE RESEARCH TEAM TO USE THE BLOOD SAMPLES COLLECTED FOR GENETIC ANALYSIS PRIOR TO WITHDRAWAL?						NO	N/A		
					PATIENT WITHDRE	EW CONSE	ENT			
					INELIGIBILITY					
6	(PLEASE TICK ONE BOX)	LOSS TO FOLLOW	V-UP		OTHER (please spe	THER (please specify):				

		DD	MM	YYYY
Name of researcher completing form	Signature		Date	