Conventional Ventilation or
ECMO for
Severe
Adult
Respiratory Failure

ISRCTN47279827

Guidelines for interviewing a patient in hospital at 6 months

Questionnaire order for people in hospital - advice on specific questions

1. EQ-5D

Question 3, page 1: Usual activities: ask this question, expect patient to answer
"I am unable to perform my usual activities"

2. Physical examination

Arm movements, Spirometer
Ask how tall they are if they are unable to stand – Spirometer measurements are every 5cm anyway, so does not have to be 100% accurate

3. Additional questions

Sleep questions – as normal

4. SGRQ

Part 1

Replace "Since returning home" with "since leaving intensive care".

Part 2

Section 2, 4, 6 and 7– try to relate activities to what they may be doing in hospital e.g. walking about ward, walking up stairs in ward.

5. SF-36

Question 3 apply to hospital situation, as for SGRQ
Question 4, 5 and 10 expect patient to say "all of time". Question 6 "extremely"

6. HAD

As normal

7. MMSE

As normal

8. Economic questions

2 page questionnaire replacing patient costs questionnaire

9. Carer questionnaire

Does not apply

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Guidelines for researchers conducting a 6 month follow-up assessment

Outline

Survivors at 6 months post randomisation will be assessed and examined at home by a researcher. In cases where this is not possible a telephone interview will be attempted. When a patient has agreed to the 6 month follow-up an assessment pack is sent to the researcher in Leicester by the Data Co-ordinating Centre in London. The patient's GP should be contacted by the researcher, on receipt of the assessment pack, to check that the patient is still alive, registered with that GP and that there are no reasons why it would be inappropriate to contact the patient. The researcher is then responsible for (in liaison with Hillary Watkinson):

- arranging the appointment with the patient (using the method indicated on the patient summary sheet)
- sending the confirmation letter (with the EQ-5D and SGHRQ to be completed and collected at the visit)
- notifying Steven Robertson at the Data Co-ordinating Centre of the appointment details.

In order to avoid researchers accidentally finding out patient allocation, all appointment arrangements will be made by Hillary Watkinson, in liaison with Steven Robertson and the assessment researchers.

The patient will also be sent a scarf to conceal any scars, so the researcher remains blinded to allocation. The patient will be asked to return the scarf in a freepost envelope after the researcher has left. During the visit the researcher will assess whether the patient has a carer and, if relevant, details will be collected on the 6 month follow-up assessment checklist. If a carer has been identified, and is present, a Caregiver Strain Index questionnaire will be given and the carer will be asked to complete this and return either before the researcher leaves or at a later date in a freepost envelope. If the carer is not present the researcher will write to the carer asking him/her to complete and return the questionnaire. When the interview has been conducted the researcher should photocopy all of the documents, complete the 6 month follow-up assessment checklist, and send the copies in the envelope provided to:

Steven Robertson

CESAR Data Co-ordinating Centre

Medical Statistics Unit

London School of Hygiene & Tropical Medicine

Keppel Street

London WC1E 7HT

The originals of <u>all</u> documents should be kept in the CESAR folder at the Department of General Practice and Primary Health Care at the University of Leicester.

Interview pack contents:

- Guidelines for conducting a 6 month follow-up
- Guidelines for researchers
- Patient summary sheet
- EQ-5D (send with confirmation letter)
- St George's Hospital Respiratory Questionnaire (send with confirmation letter)
- The SF-36v2™ Health Survey
- HAD Scale
- Patient Costs Questionnaire
- Additional questions and examination (including spirometry)
- Caregiver Strain Index
- 6 month follow-up assessment checklist
- Copy of signed patient agreement to CESAR accessing patient data from GP records

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CESAR 6-month follow-up: Guidelines for researchers

1. Introduction to patients

- Reinforce purpose of assessment – to assess long term outcomes for two different ways of treating respiratory failure.
- Recognise that patient has been very ill and they should say if they are feeling too tired to continue or would like to take a break.
- Emphasise the need not to know where or how patient was treated so researcher cannot be biased, hence the need for scarf to be worn for the duration of the assessment.
- Tell patient that interview will include a series of questions about specific aspects of their health and an assessment of their breathing. Some questions may not seem relevant to them but important all are answered so we can compare patients in the trial.
- If the patient is followed up in hospital please refer to ***Guidelines for interviewing a patient in hospital at 6 months July 2004*** for specific guidelines

2. Questionnaires sent to patients (if patient is in hospital these may not be posted but completed at interview instead)

- Check EQ-5D and SGRQ received.
- Ask if any problems completing and check responses.
- Ask patient to fill in any incomplete responses.

3. SF-36

- Explain this is a questionnaire designed to measure general health and whether there are any problems with activities, and that it was designed for self-completion.
- If patient asks for clarification re-read the question and response options but do not reword question (see detailed guidance in photocopy of chapter 4 from SF-36 manual).
- Check for completeness of responses and draw attention of patient to any omissions.

4. HAD Scale

- Explain that treatment in intensive care may affect the way people feel and that this self-completed questionnaire is designed to detect them.
- Respond to queries in same way as for SF-36.
- Please calculate the HAD score and enter onto the datasheet

5. Additional questions and examination

5.1 Sleep questions

- Explain sleep problems can occur after intensive care and that these questions are designed to detect them.
- Read questions and record responses.

5.2, 5.3 Examination

- Explain that you would now like to make a brief examination. Arm movement can be affected by intensive care treatments, so you would like to check this (no need for patient to undress). Secondly, you would like to test breathing, and finally measure height, as this determines their breathing scores.
- Show card to check no contraindications to spirometry.
- Repeat test until 3 readings which differ <10% obtained.
- Circle best of three for each variable.
- Calculate and record predicted values.

5.4 MMSE (use pad version)

- Explain some patients experience confusion after intensive care and that this is a standard questionnaire to detect it. Some of the questions may seem inappropriate but it is important that all are answered.
- Some of the questions are very easy, some are not so easy. Don't worry if you think you have "got any wrong".
- It is important to reassure the patient, as anxiety can affect performance.
- Aim to be neutral in feedback e.g. "thank you" not "yes that's right", or "no, that's wrong".
- If the patient gets distressed at being asked the questions, it is up to the interviewer's discretion whether you stop or not.

Guide to completing MMSE

Question 1	Season – use discretion e.g. different cultures have different seasons, may not know exactly when spring ends and summer begins.
Question 2	"Building/floor" – asking address is OK.
Question 3	"Apple, table penny", the order in which the patient repeats them is irrelevant.
Question 4	Ask the patient to spell "world" forwards If they don't understand the word describe it. If OK, then ask them to spell it backwards.
Question 8	Read out instruction all in one go, no prompts
Questions 9 and 10	If physically unable to write, read or is illiterate, then score out of 29 or 28.

6. Patient costs questionnaire

- Read out interviewer script on front page.
- Ask patient if they would prefer you to read out questions or complete it themselves.
- Note whether Events Diary was used on the checklist
- If patient fatigued offer later telephone administration and note on checklist.

7. Identifying carers

- Identify if patient has a carer, if yes record details on checklist
- If carer is present give them a Caregiver Strain Index questionnaire and ask to complete during visit.
- Give carer a freepost envelope in case they prefer to return at a later date
- If carer identified but not present collect details on checklist and write to them asking to complete the Caregiver Strain Index questionnaire.
- The patient should not see or be given a copy of the Caregiver Strain Index.

8. Finishing the interview

- Thank patient for their time and attention.
- Remind them that they will receive a copy of the trial results if requested.
- Remind the patient to keep the scarf on until after you have left and give the patient the freepost envelope to return it in.
- Note duration of interview on the checklist.
- Complete checklist and return a copy to DCC in London with copies of all other documents.

9. Potential problems

- Patient cannot read but is not mentally impaired. Administer all questionnaires orally.
- Patient appears too frail/unco-operative – restrict interview to EQ-5D, physical examination and SF-36 in that order.

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Patient summary sheet

CESAR study number: **Date of birth:** ☐☐ ☐☐ ☐☐☐☐ dd/mm/yyyy

Surname:
First name:

Date of randomisation: ☐☐ ☐☐ ☐☐☐☐ dd/mm/yyyy

Date of discharge: ☐☐ ☐☐ ☐☐☐☐ dd/mm/yyyy

Address: **Postcode:** **Telephone number:** **NHS number:** **GP's name:** **GP's address:** **Postcode:** **GP's telephone number:** **GP's fax number:**	

Method by which patient has requested contact:

Date 6 month assessment due: ☐☐ ☐☐ ☐☐☐☐ dd/mm/yyyy
(approximately 6 months post randomisation)

Date researcher should contact patient to make appointment: ☐☐ ☐☐ ☐☐☐☐ dd/mm/yyyy
(approximately 2 months before assessment is due)

Please contact GP before making direct contact with patient

EQ-5D Health Questionnaire

CESAR study number ☐☐☐☐☐☐

By placing a tick in one box in each group below, please indicate which statements best describe your own health state today.

Mobility

I have no problems in walking about ☐
I have some problems in walking about ☐
I am confined to bed ☐

Self-care

I have no problems with self-care ☐
I have some problems washing or dressing myself ☐
I am unable to wash or dress myself ☐

Usual Activities *(e.g. work, study, housework, family or leisure activities)*

I have no problems with performing my usual activities ☐
I have some problems with performing my usual activities ☐
I am unable to perform my usual activities ☐

Pain/Discomfort

I have no pain or discomfort ☐
I have moderate pain or discomfort ☐
I have extreme pain or discomfort ☐

Anxiety/Depression

I am not anxious or depressed ☐
I am moderately anxious or depressed ☐
I am extremely anxious or depressed ☐

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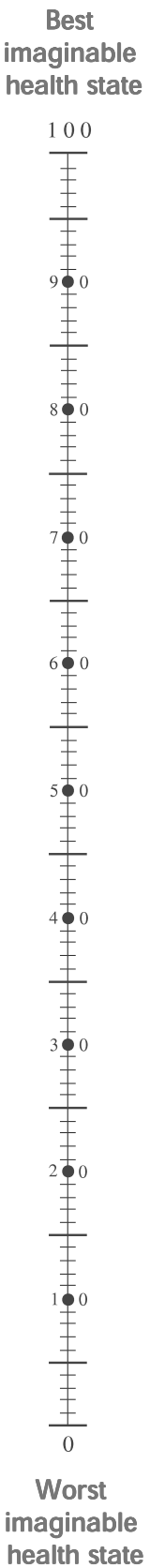
To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by marking a point on the scale which indicates how good or bad your health state is today.

Your own health state today



CESAR study number ☐☐☐☐☐☐

Background Information

1. Are you

a current smoker	☐
an ex smoker	☐
a never smoker	☐

2. Which of the following best describes your main activity?

in employment or self employment	☐
retired	☐
housework	☐
student	☐
seeking work	☐
other (please specify) _____	☐

	Yes	No
3. Did your education continue after the minimum school leaving age?	☐	☐
4. If Yes, do you have a degree or equivalent qualification?	☐	☐

Please complete this form and return it to the researcher when you have your assessment visit.

HAD Scale

CESAR study number ☐☐☐☐☐

Tick only one box for each question

I feel tense or 'wound up':

- Most of the time ☐
- A lot of the time ☐
- Time to time, occasionally ☐
- Not at all ☐

I still enjoy the things I used to enjoy:

- Definitely as much ☐
- Not quite so much ☐
- Only a little ☐
- Hardly at all ☐

I get a sort of frightened feeling as if something awful is about to happen:

- Very definitely and quite badly ☐
- Yes, but not too badly ☐
- A little, but it doesn't worry me ☐
- Not at all ☐

I can laugh and see the funny side of things:

- As much as I always could ☐
- Not quite so much now ☐
- Definitely not so much now ☐
- Not at all ☐

Worrying thoughts go through my mind:

- A great deal of the time ☐
- A lot of the time ☐
- From time to time but not too often ☐
- Only occasionally ☐

I feel cheerful:

- Not at all ☐
- Not often ☐
- Sometimes ☐
- Most of the time ☐

I can sit at ease and feel relaxed:

- Definitely ☐
- Usually ☐
- Not often ☐
- Not at all ☐

I feel as if I am slowed down:

- Nearly all the time ☐
- Very often ☐
- Sometimes ☐
- Not at all ☐

I get a sort of frightened feeling like 'butterflies' in the stomach:

- Not at all ☐
- Occasionally ☐
- Quite often ☐
- Very often ☐

I have lost interest in my appearance:

- Definitely ☐
- I don't take so much care as I should ☐
- I may not take quite as much care ☐
- I take just as much care as ever ☐

I feel restless as if I have to be on the move:

- Very much indeed ☐
- Quite a lot ☐
- Not very much ☐
- Not at all ☐

I look forward with enjoyment to things:

- As much as ever I did ☐
- Rather less than I used to ☐
- Definitely less than I used to ☐
- Hardly at all ☐

I get sudden feelings of panic:

- Very often indeed ☐
- Quite often ☐
- Not very often ☐
- Not at all ☐

I can enjoy a good book or radio or TV programme:

- Often ☐
- Sometimes ☐
- Not often ☐
- Very seldom ☐

For office use only: D (8-10)_ _ _ _ _ _ _ A (8-10)_ _ _ _ _ _ _

The St George's Hospital Respiratory Questionnaire (SGHRQ)

This questionnaire is designed to help us learn much more about how your breathing is troubling you and how it affects your life. We are using it to find out which aspects of your illness cause you most problems rather than what doctors and nurses think your problems are. Please read the instructions carefully but do not spend too long deciding about your answers. If there is anything you do not understand please ask the researcher at the time of the interview.

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PART 1

Questions about how much chest trouble you have had since returning home.
Please put a cross in one bubble for each question.

	most days a week	several days a week	a few days a month	only with chest infections	not at all
1) Since returning home, I have coughed	◯	◯	◯	◯	◯
2) Since returning home, I have brought up phlegm (sputum)	◯	◯	◯	◯	◯
3) Since returning home, I have had shortness of breath	◯	◯	◯	◯	◯
4) Since returning home, I have had attacks of wheezing	◯	◯	◯	◯	◯

5) Since returning home, how many severe or very unpleasant attacks of chest trouble have you had?

a) More than 3 attacks ◯
b) 3 attacks ◯
c) 2 attacks ◯
d) 1 attack ◯
e) No attacks ◯ (please go to question 7)

6) How long did the worst attack of chest trouble last?

a) A week or more ◯
b) 3 or more days ◯
c) 1 or 2 days ◯
d) Less than a day ◯

7) Since returning home, in an average week, how many good days (with little chest trouble) have you had?

a) None ◯
b) 1 or 2 ◯
c) 3 or 4 ◯
d) Nearly every day ◯

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8) If you have a wheeze, is it worse in the morning?

No ◯ Yes ◯ Not applicable ◯

.....

PART 2

The questions in this section relate to your current state of health and should reflect how you are these days.

Section 1

1) How would you describe your chest condition (please put a cross in 1 box)?

a) The most important problem I have ◯
b) Causes me quite a lot of problems ◯
c) Causes me a few problems ◯
d) Causes no problems ◯

2) If you were in paid employment around the time you were entered into the CESAR trial, please put a cross in one of the boxes below to tell us about the effect on your current situation.

a) My chest trouble made me stop paid work altogether ◯
b) My chest trouble interfered with my work or made me change my work ◯
c) My chest trouble does not affect my work ◯
d) Not applicable as I was not in paid work at the time ◯

Section 2

Questions about what activities usually make you feel breathless. Please put a cross in each box **that applies to you** these days.

a) Sitting or lying still ◯
b) Getting washed or dressed ◯
c) Walking around the home ◯
d) Walking outside on the level ◯
e) Walking up a flight of stairs ◯
f) Walking up hills ◯
g) Playing sports or games ◯

Section 3

Some more questions about your cough and breathlessness. Please put a cross in each box that applies to you these days.

a) My cough hurts ◯
b) My cough makes me tired ◯
c) I am breathless when I talk ◯
d) I am breathless when I bend over ◯
e) My cough or my breathing disturbs my sleep ◯
f) I get exhausted easily ◯

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Section 4

Questions about other effects that your chest trouble may have on you.
Please put a cross in each box that applies to you these days.

a) My cough or breathing is embarrassing in public ◯
b) My chest trouble is a nuisance to my family, friends and neighbours ◯
c) I get afraid or panic when I cannot get my breath ◯
d) I feel that I am not in control of my chest problem ◯
e) I do not expect my chest to get any better ◯
f) I have become frail or an invalid because of my chest problem ◯
g) Exercise is not safe for me ◯
h) Everything seems too much of an effort ◯

Section 5

Questions about your medication for your chest trouble. Please put a cross in each box that applies to you.

a) My medication does not help me very much ◯
b) I get embarrassed using my medication in public ◯
c) I have unpleasant side effects from my medication ◯
d) My medication interferes with my life a lot ◯
e) I am receiving no medication for my chest trouble ◯

Section 6

These are questions about how your activities might be affected by your breathing trouble. Please put a cross in each box which you think applies to you because of your breathing trouble.

a) I take a long time to get washed or dressed ◯
b) I cannot take a bath or shower or I take a long time ◯
c) I walk slower than other people or I stop for rests ◯
d) Jobs such as housework take a long time or I have to stop for rests ◯
e) If I walk up one flight of stairs I have to go slowly or stop ◯
f) If I hurry or walk fast I have to stop or slow down ◯
g) My breathing makes it difficult to do things such as walking up hills, carrying things upstairs, light gardening such as weeding, dance, play bowls or play golf ◯
h) My breathing makes it difficult to do things such as carrying heavy loads, dig the garden or shovelling snow, jog or walk at 5 miles per hour, play tennis or swim ◯
i) My breathing makes it difficult to do things such as very heavy manual work, run, cycle, swim fast or play competitive sports ◯

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Section 7

We would like to know how your chest trouble usually affects your daily life.
Please put a cross in each box that applies to you because of your chest trouble.

a) I cannot play sports or games ◯
b) I cannot go out for entertainment or recreation ◯
c) I cannot go out of the house to do the shopping ◯
d) I cannot do housework ◯
e) I cannot move far from my bed or chair ◯

Now please put a cross in the box next to the statement which best describes how your chest trouble affects you.

a) It does not stop me doing anything I would like to do ◯
b) It stops me doing one or two things I would like to do ◯
c) It stops me doing most of the things I would like to do ◯
d) It stops me doing everything I would like to do ◯

Please complete this form and return it to the researcher when you have your assessment visit.

The SF-36v2™ Health Survey

Instructions for completing the questionnaire

Please answer every question. Some questions may look like others, but each one is different. Please take time to read and answer each question carefully by putting a cross in the bubble that best represents your response.

EXAMPLE

This is an example. Do not answer this question. The questionnaire begins with the section *Your Health in General* on the next page.

For each question you will be asked to place a cross in a bubble on each line:

1. How strongly do you agree or disagree with each of the following statements?

	Strongly agree	Agree	Uncertain	Disagree	Strongly Disagree
a) I enjoy listening to music	○	⊗	○	○	○
b) I enjoy reading magazines	⊗	○	○	○	○

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Your Health in General

1. In general, would you say your health is:

Excellent	Very Good	Good	Fair	Poor
○	○	○	○	○

2. **Compared to one year ago**, how would you rate your health in general **now**?

Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago
○	○	○	○	○

3. The following questions are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?

		Yes, limited a lot	Yes, limited a little	No, not limited at all
a)	**Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports	○	○	○
b)	**Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling or playing golf	○	○	○
c)	Lifting or carrying groceries	○	○	○
d)	Climbing **several** flights of stairs	○	○	○
e)	Climbing **one** flight of stairs	○	○	○
f)	Bending, kneeling or stooping	○	○	○
g)	Walking more than a **mile**	○	○	○
h)	Walking **several** hundred yards	○	○	○
i)	Walking **one** hundred yards	○	○	○
j)	Bathing or dressing yourself	○	○	○

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4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a) Cut down on the amount of time you spent on work or other activities	○	○	○	○	○
b) Accomplished less than you would like	○	○	○	○	○
c) Limited in the kind of work or other activities	○	○	○	○	○
d) Had difficulty performing the work or other activities (e.g. it took extra effort)	○	○	○	○	○

5. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a) Cut down on the **amount of time** you spent on work or other activities	○	○	○	○	○
b) **Accomplished less** than you would like	○	○	○	○	○
c) Did work or other activities **less carefully than usual**	○	○	○	○	○

6. During the past 4 weeks, to what extent have your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours or groups?

Not at all	Slightly	Moderately	Quite a bit	Extremely
○	○	○	○	○

7. How much bodily pain have you had during the past 4 weeks?

None	Very mild	Mild	Moderate	Severe	Very severe
○	○	○	○	○	○

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
○	○	○	○	○

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9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a) did you feel full of life?	○	○	○	○	○
b) have you been very nervous?	○	○	○	○	○
c) have you felt so down in the dumps nothing could cheer you up?	○	○	○	○	○
d) have you felt calm and peaceful?	○	○	○	○	○
e) did you have a lot of energy?	○	○	○	○	○
f) have you felt downheartened and depressed?	○	○	○	○	○
g) did you feel worn out?	○	○	○	○	○
h) have you been happy?	○	○	○	○	○
i) did you feel tired?	○	○	○	○	○

10. During the past 4 weeks, how much of the time have your **physical or emotional problems** interfered with your social activities (like visiting friends, relatives etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
○	○	○	○	○

11. How TRUE or FALSE is each of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
a) I seem to get sick a little easier than other people	○	○	○	○	○
b) I am as healthy as anybody I know	○	○	○	○	○
c) I expect my health to get worse	○	○	○	○	○
d) My health is excellent	○	○	○	○	○

Thank you for taking time to complete this questionnaire, please now return it to the researcher.

Additional Questions and Examination

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1. Sleep Questions (FLP)

These statements describe your sleep and rest activities today.
If **AGREE, PROBE - "Is this due to your health?"**

				If yes, is this due to your health?	
		Yes	**No**	**Yes**	**No**
a)	I spend much of the day lying down to rest	☐	☐	☐	☐
b)	I sit for much of the day	☐	☐	☐	☐
c)	I sleep or doze most of the time, day and night	☐	☐	☐	☐
d)	I lie down to rest more often during the day	☐	☐	☐	☐
e)	I sit around half asleep	☐	☐	☐	☐
f)	I sleep less at night; for example I wake up easily, I don't fall asleep for a long time or I keep waking up	☐	☐	☐	☐
g)	I sleep or doze more during the day	☐	☐	☐	☐

2. Upper Limb Movement

			Yes	**No**
Is there a history of trauma to or pre-existing restriction of upper limbs?			☐	☐
If No:	a)	Can patient join hands behind back?	☐	☐
	b)	Can patient join hands behind head?	☐	☐
	c)	Can patient fully extend both arms?	☐	☐

CESAR study number ☐☐☐☐☐☐

3. Lung Capacity

Please allow the patient **3** attempts using the spirometer and record all 3 values for FEV_1, FVC, FER and PEF. Please then circle the **best** score for each.

	Predicted values				
FEV_1	☐.☐☐	☐.☐☐	☐.☐☐	☐.☐☐	litres
FVC	☐.☐☐	☐.☐☐	☐.☐☐	☐.☐☐	litres
FER	☐☐☐	☐☐☐	☐☐☐	☐☐☐	%
PEF	☐☐☐	☐☐☐	☐☐☐	☐☐☐	litres/min

Height of patient ☐☐☐ cms

Was new spirometer used? ☐ Yes ☐ No

4. Mini-Mental State Examination (MMSE) score

(please refer to the MMSE handout for details) ☐☐

University Hospitals of Leicester NHS

NHS Trust

ASSENT FORM

Assent by relative to participation in a clinical trial

Title of Project:

CESAR: Conventional ventilation or ECMO for Severe Adult Respiratory failure: A Collaborative Randomised Controlled Trial

PATIENT NAME: _____ Please initial the boxes

1. I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions. ☐

2. I understand that my relative's participation in this trial is voluntary and that he/she is free to withdraw at any time, without giving any reason, without his/her medical care or legal rights being affected. ☐

3. I understand that sections of my relative's medical notes may be looked at by responsible individuals from The CESAR Trial or from regulatory authorities where it is relevant to my relative's participation in research. I give permission for these individuals to have access to my relative's records. ☐

4. I understand and acknowledge that the investigation is designed to add to medical knowledge. I acknowledge that the purpose of the investigation, the risks involved from drugs or other procedures, and the nature and purpose of such procedures have been explained to me by discussion with the doctor caring for my relative. I have had the opportunity to discuss these matters with them. ☐

5. I have received a written explanation of these matters. ☐

6. I agree for my relative to take part in the above study and believe that my relative would not object to taking part in the study. ☐

Name of relative/next of kin who is giving assent	Date	Signature
_____	_____	_____
Name of assenting doctor	Date	Signature
_____	_____	_____
Name of assenting nurse	Date	Signature
_____	_____	_____

Please make 2 copies of this form. Send 1 copy to the CESAR Data Co-ordinating Centre, file 1 copy in the CESAR folder and keep the original with the patient's note.

Conventional Ventilation or ECMO for Severe Adult Respiratory Failure

ASSENT FORM

Assent by relative to participation in a clinical trial

Title of Project:

CESAR: Conventional ventilation or ECMO for Severe Adult Respiratory failure: A Collaborative Randomised Controlled Trial

PATIENT NAME: _____ Please initial the boxes

1. I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions. ☐

2. I understand that my relative's participation in this trial is voluntary and that he/she is free to withdraw at any time, without giving any reason, without his/her medical care or legal rights being affected. ☐

3. I understand that sections of my relative's medical notes may be looked at by responsible individuals from The CESAR Trial or from regulatory authorities where it is relevant to my relative's participation in research. I give permission for these individuals to have access to my relative's records. ☐

4. I understand and acknowledge that the investigation is designed to add to medical knowledge. I acknowledge that the purpose of the investigation, the risks involved from drugs or other procedures, and the nature and purpose of such procedures have been explained to me by discussion with the doctor caring for my relative. I have had the opportunity to discuss these matters with them. ☐

5. I have received a written explanation of these matters. ☐

6. I agree for my relative to take part in the above study and believe that my relative would not object to taking part in the study. ☐

Name of relative/next of kin who is giving assent	Date	Signature
_____	_____	_____
Name of assenting doctor	Date	Signature
_____	_____	_____
Name of assenting nurse	Date	Signature
_____	_____	_____

Please make 2 copies of this form. Send 1 copy to the CESAR Data Co-ordinating Centre, file 1 copy in the CESAR folder and keep the original with the patient's note.

FORM A

Registration form

This form should be completed by a member of the intensive care team at the participating hospital.

STEP 1 - Collect registration data

Data necessary in order to register a patient for trial entry (please print clearly and be ready to give the information over the telephone).

1. CESAR hospital code: ☐☐☐☐

2. CESAR hospital categorisation:

3. Hospital name:

4. Contact telephone number:_____

Please complete patient details or affix addressograph

5. Patient's first name:_____

6. Patient's surname: _____

7. Patient's date of birth: ☐☐ ☐☐ 1 9 ☐☐ (dd / mm / yyyy)

8. Patient's gender: Male ☐ Female ☐

Please complete questions i-vii and go to Step 2 on the next page.

For each attempted registration, please record the recruiting doctor's name, the date and the time.

		Doctor	_____	_____	_____	_____	_____
		Date	_____	_____	_____	_____	_____
		Time	_____	_____	_____	_____	_____
i.(a)	Duration of IPPV?		____ (hrs)	____ (hrs)	____ (hrs)	____ (hrs)	____ (hrs)
i.(b)	Duration of high pressure (>30cmH_2O) and/or high FiO_2 (>80% oxygen)?		____ (hrs)	____ (hrs)	____ (hrs)	____ (hrs)	____ (hrs)
ii.	Is there intra-cranial bleeding? (If yes, patient is not eligible for trial entry, at this time)		Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
iii.	Is there any other contra-indication to limited heparinisation? (If yes, patient is not eligible for trial entry)		☐☐	☐☐	☐☐	☐☐	☐☐
iv.	Is there any contra-indication to continuation of active treatment? (If yes, patient is not eligible for trial entry)		☐☐	☐☐	☐☐	☐☐	☐☐
v.(a)	PaO_2 on 100% Oxygen	(mmHg)	☐☐☐	☐☐☐	☐☐☐	☐☐☐	☐☐☐
v.(b)	PEEP	(cmH_2O)	☐☐	☐☐	☐☐	☐☐	☐☐
v.(c)	Lung compliance	(ml/cmH_2O)	☐☐	☐☐	☐☐	☐☐	☐☐
v.(d)	Number of quadrants with infiltration seen on chest x-ray?		☐	☐	☐	☐	☐
vi.	pH (uncompensated hypercapnoea)		☐.☐☐	☐.☐☐	☐.☐☐	☐.☐☐	☐.☐☐

vii. Diagnostic category:

1. Pneumonia ☐
2. Obstetric acute respiratory distress syndrome (ARDS) ☐
3. Other ARDS ☐
4. Trauma including surgery within 24 hours ☐
5. Other (please specify) _____ ☐

FORM A

STEP 5 - Randomisation

Please telephone 0116 287 1471 and ask the switchboard for the CESAR Trial Clinical Advisor. You will then be transferred to the CAT who will ask for confirmation that assent has been obtained. They will ask you for the information provided in STEP 4. The CAT will then telephone the randomisation service to enter the patient into the trial.

Name of recruiting doctor: _____ Contact telephone number:_____

Apache II Score * ☐☐

* Within 24 hours of admission to ICU, or at time of randomisation if this is less than 24 hours.

STEP 6 - Allocation

The CAT will then telephone you to inform you of:
(please write these in the appropriate spaces below)

Study number ☐☐☐☐☐☐ Allocation 1. Transfer for consideration of ECMO ☐
2. Conventional ventilation ☐

Date of randomisation ☐☐ ☐☐ 2 0 ☐☐
dd / mm / yyyy

Time of randomisation ☐☐ : ☐☐ 24 hour

If this hospital is a CTC and the patient is assigned to Conventional Ventilation please take a *'Level of Care and Organ Support'* datasheet from the CESAR trial folder and collect the data on a daily basis. In all other cases the patient is being transferred and the CAT will give an estimated time of arrival of the transport team.

Please ensure the relative has a copy of the further information about the allocated treatment.

If randomisation has been successfully achieved please complete the details on Page 4. Make 2 copies and return 1 copy of the completed form to the CESAR Data Co-ordinating Centre and file 1 copy in the CESAR folder. Please keep the original with the patient's notes.

If the patient has not been randomised please keep this form in the patient's notes.

For the purpose of CESAR, the following definitions are being used.

An organ can be considered to have failed if it meets the criteria set out below as defined by Moreno, R et al, Intensive Care Medicine 1999; 25:686-96:

		Criteria met? Yes	No
Respiratory:	PaO_2/FIO_2 < 200 mmhg with ventilatory support	☐	☐
Coagulation:	Platelet count < 50 x 10^3 / mm^3	☐	☐
Liver:	Bilirubin > 102 mmol/l	☐	☐
Cardiovascular:	Dopamine > 5 mcg/kg/min (or adrenaline/noradrenaline any dose)	☐	☐
Central Nervous System:	GCS (Glasgow Coma Score) ≤ 9	☐	☐
Renal:	Creatinine > 300 mmol/l or urine output < 500ml / day	☐	☐

Please complete this page only if a patient has been randomised to the CESAR Study.

FORM A

Identifying details

PATIENT

Surname: _____

Forename: _____

NHS number: _____
(if available)

Telephone no: _____

Home address: _____

_____

_____

Postcode: _____

NEXT OF KIN

Surname: _____

Forename: _____

Relationship to patient: _____

Telephone no: _____

Home address: _____
(if different to patient's address): _____

_____

Postcode: _____

FAMILY DOCTOR

Full name: _____

Telephone no: _____

Address: _____

_____

_____

Postcode: _____

Please remember to post a copy of the assent form completed by the patient's relative when returning this form.

Please post a copy of this form to:
CESAR Trial Data Co-ordinating Centre, Medical Statistics Unit, London School of Hygiene and Tropical Medicine, Keppel Street, London WC1E 7HT using the freepost envelope which is provided in the CESAR trial folder.

STEP 2 - Patient eligibility and bed availability

FORM A

Please now telephone 0116 287 1471 and ask the switchboard for the CESAR Trial Clinical Advisor. You will then be transferred to the CAT (Clinical Advisory Team). You will be asked to provide the information from Step 1. They will then call you back to let you know whether the patient is eligible and beds are available.

Date	_____	_____	_____	_____	_____
Time	_____	_____	_____	_____	_____
Is the patient eligible?	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Are beds available?					
Enter date and time beds are held until:					
Date	_____	_____	_____	_____	_____
Time	_____	_____	_____	_____	_____

If the answer to both of these questions is **Yes**, please continue with STEP 3, the assent procedure.

STEP 3 - Obtain assent

Please now talk to the relative(s) to tell them about CESAR and to seek their assent. Please give them a CESAR information pack* so that they have time to read the written information before being asked to sign the assent form.

* The CESAR information pack for relatives is kept in the CESAR trial folder.

Has assent been obtained? **Yes** ☐ **No** ☐

If **Yes**, from whom? (name) _____ Relationship to patient?_____

If NO: please telephone 0116 287 1471 and ask the switchboard for the CESAR Trial Clinical Advisor. You will then be transferred to the CAT. They will then remove the reserve on the beds. You are not required to continue with this form. Please keep this form with the patient's notes.

If YES: please proceed to STEP 4.

STEP 4 - Collect randomisation data

Randomisation will be based on the current condition of the patient, therefore we will be repeating some of the questions from STEP 1.

i.(a) **Total** duration of IPPV? _____ (hrs)

i.(b) **Total** duration of high pressure (>30cm$H_2$0) and/or high FiO_2 (>80% oxygen)? _____ (hrs)

ii. Is there intra cranial bleeding (Yes ☐ No ☐)
(If yes, patient is not eligible for trial entry, at this time)

iii. Is there any other contra-indication to limited heparinisation? (Yes ☐ No ☐)
(If yes, patient is not eligible for trial entry)

iv. Is there any contra-indication to continuation of active treatment? (Yes ☐ No ☐)
(If yes, patient is not eligible for trial entry)

v.(a) PaO_2 on 100% Oxygen ☐☐☐ (mmHg) v.(b) PEEP ☐☐ (cm$H_2$0)

v.(c) Lung compliance ☐☐ (ml/cm$H_2$0) v.(d) Number of quadrants with infiltration seen on chest x-ray ☐

vi. pH (uncompensated hypercapnoea) ☐.☐☐

vii. Diagnostic category:
1. Pneumonia ☐
2. Obstetric acute respiratory distress syndrome (ARDS) ☐
3. Other ARDS ☐
4. Trauma including surgery within 24 hours ☐
5. Other (please specify) _____ ☐

viii. Number of organs failed? ☐
An organ can be considered to have failed if it meets the criteria set out on page 3, as defined by Moreno, R et al, Intensive Care Medicine 1999; 25:686-96.

FORM B

Registration form – Clinical Advisory Team (CAT)

This form should be completed by a member of the CAT in Leicester **prior** to completing a trial entry form.

Please complete this form using information provided during the telephone conversation with the doctor at the participating hospital.

1. CESAR hospital code: ☐☐☐☐☐
2. CESAR hospital categorisation: _____
3. Hospital name:_____
4. Contact telephone number: _____

Please complete patient details:

5. Patient's first name:_____
6. Patient's surname: _____
7. Patient's date of birth: ☐☐ ☐☐ 19☐☐ (dd / mm / yyyy)
8. Patient's gender: **Male** ☐ **Female** ☐

Note for CAT advisor

Please inform the recruiting doctor that you will be asking for answers to questions i-vii from ***their*** registration form (FORM A), and you will then call them back as soon as possible to confirm patient eligibility and bed availability.

STEP 1 - Collect registration data

For each attempted registration, please record the recruiting doctor's name, the date and the time.

Doctor	_____	_____	_____	_____	_____
Date	_____	_____	_____	_____	_____
Time (24hr)	_____	_____	_____	_____	_____
i.(a) Duration of IPPV?	____ (hrs)	____ (hrs)	____ (hrs)	____ (hrs)	____ (hrs)
i.(b) Duration of high pressure (>30cm$H_2$0) and/or high FiO_2 (>80% oxygen)?	____ (hrs)	____ (hrs)	____ (hrs)	____ (hrs)	____ (hrs)
ii. Is there intra cranial-bleeding? (If yes, patient is not eligible for trial entry, at this time)	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
iii. Is there any other contra-indication to limited heparinisation? (If yes, patient is not eligible for trial entry)	☐☐	☐☐	☐☐	☐☐	☐☐
iv. Is there any contra-indication to continuation of active treatment? (If yes, patient is not eligible for trial entry)	☐☐	☐☐	☐☐	☐☐	☐☐
v.(a) PaO_2 on 100% Oxygen (mmHg)	☐☐☐	☐☐☐	☐☐☐	☐☐☐	☐☐☐
v.(b) PEEP (cm$H_2$0)	☐☐	☐☐	☐☐	☐☐	☐☐
v.(c) Lung compliance (ml/cm$H_2$0)	☐☐	☐☐	☐☐	☐☐	☐☐
v.(d) Number of quadrants with infiltration seen on chest x-ray?	☐	☐	☐	☐	☐
vi. pH (uncompensated hypercapnoea)	☐.☐☐	☐.☐☐	☐.☐☐	☐.☐☐	☐.☐☐

vii. Diagnostic category:

1. Pneumonia ☐
2. Obstetric acute respiratory distress syndrome (ARDS) ☐
3. Other ARDS ☐
4. Trauma including surgery within 24 hrs ☐
5. Other (please specify) _____ ☐

Please calculate the patient's Murray Score for each attempted registration.

FORM B

Murray Score	☐.☐	☐.☐	☐.☐	☐.☐	☐.☐
	Yes No	Yes No	Yes No	Yes No	Yes No
Is the patient eligible?	☐☐	☐☐	☐☐	☐☐	☐☐

STEP 2 - Bed availability

If the call is from a CTC please check the availability of an ECMO bed. If the call is from an RH you will also need to check the availability of CTC beds in the transfer hospitals. Please consult the list of CTC hospitals in your CAT folder or the ECMO office and record the name in the box below.

	Yes No	Yes No	Yes No	Yes No	Yes No
Are beds available?	☐☐	☐☐	☐☐	☐☐	☐☐
Enter date and time beds are held until: (please record the minimum date and time of bed availability)	Date _____	_____	_____	_____	_____
	Time _____	_____	_____	_____	_____
	Hospital _____	_____	_____	_____	_____

If **No**, you do not need to continue with this form at this point.

In both circumstances, you must now contact the participating hospital to inform the recruiting doctor about eligibility, bed availability and to instruct the recruiting doctor to obtain assent (where appropriate).

If the patient is eligible and beds are available, please continue with STEP 3, the assent procedure.

If appropriate, please give reason why referred patient was not accepted and randomised :

_____

STEP 3 - Assent procedure

The recruiting doctor at the participating hospital will now ask the patient's relative(s) for permission to enter the patient into the trial and will then telephone the CAT to confirm. If there has been no contact from the participating hospital by the end of the period for which beds are being held please call the recruiting doctor to find out the current status of the patient.

Has assent been obtained? Yes ☐ No ☐

If YES, please proceed to STEP 4.
If NO, please give reason and remove the reserve on beds for ECMO and CTC.

Reason assent not obtained: _____

Please keep this form in the CESAR box file in the ECMO office. Information collected on this form will be used to complete the log of eligible patients.

STEP 4 - Collect randomisation data

FORM B

The doctor at the participating hospital will telephone the CAT and provide the randomisation data which is based on the current condition of the patient.

i.(a) **Total** duration of IPPV? _____ (hrs)

i.(b) **Total** duration of high pressure (>30cm$H_2$0) and/or high FiO_2 (>80% oxygen)? _____ (hrs)

ii. Is there intra cranial bleeding? Yes ☐ No ☐
(If yes, patient is not eligible for trial entry, at this time)

iii. Is there any other contra-indication to limited heparinisation? Yes ☐ No ☐
(If yes, patient is not eligible for trial entry)

iv. Is there any contra-indication to continuation of active treatment? Yes ☐ No ☐
(If yes, patient is not eligible for trial entry)

v.(a) PaO_2 on 100% Oxygen ☐☐☐ (mmHg) v.(b) PEEP ☐☐ (cmH_2O)

v.(c) Lung compliance ☐☐ (ml/cmH_2O) v.(d) Number of quadrants with infiltration seen on chest x-ray ☐

vi. pH (uncompensated hypercapnoea) ☐.☐☐

vii. Diagnostic category:

1. Pneumonia ☐
2. Obstetric acute respiratory distress syndrome (ARDS) ☐
3. Other ARDS ☐
4. Trauma including surgery within 24 hrs ☐
5. Other (please specify) _____ ☐

viii. Number of organs failed? (please see page 4 for definitions) ☐

Please use question V parts a-d to calculate the patient's Murray Score. ☐☐

After completing STEP 4 please inform the doctor at the recruiting hospital that you will phone back in a few minutes. Please ask the recruiting doctor to complete the Apache II score on page 3 of their registration form in the meantime.

STEP 5 - Randomisation

Please complete a CESAR Trial ENTRY form (FORM C) and telephone 0800 387 444 to randomise the patient.

After the randomisation process is complete please do the following:

1. Phone the recruiting hospital to inform them of the patient's study number, allocation and estimated time of arrival of the transport team if relevant, and remember to note the Appache II score ☐☐

2. If the recruiting hospital is a CTC and the allocation is to Conventional Ventilation please remind the recruiting doctor to take a *Level of Care and Organ Support* datasheet from their trial folder

3. Give the entry form **(FORM C)** to Janice to fax to the DCC on 020 7637 2853 and then file in the CESAR CAT Entry Form folder

4. File the registration form in the CESAR box file in the ECMO office

5. Alert transport team if necessary and ensure you give them a transfer recruitment pack which is kept in the CAT folder

Definitions of failed organs

FORM B

For the purpose of CESAR, the following definitions are being used.

An organ can be considered to have failed if it meets the criteria set out below as defined by Moreno, R et al, Intensive Care Medicine 1999; 25:686-96:

		Tick if appropriate Yes
Respiratory:	PaO_2/FIO_2 < 200 mmhg with ventilatory support	☐
Coagulation:	Platelet count < 50 x 10^3 / mm^3	☐
Liver:	Bilirubin > 102 mmol/l	☐
Cardiovascular:	Dopamine > 5 mcg/kg/min (or adrenaline/noradrenaline any dose)	☐
Central Nervous System:	GCS (Glasgow Coma Score) ≤ 9	☐
Renal:	Creatinine > 300 mmol/l or urine output < 500ml / day	☐

FORM C

ENTRY FORM

Please complete this form **after** a CAT Registration form (FORM **B**) has been completed and the patient has satisfied all the trial entry criteria. When you have completed this form please telephone **0800 387444** and you will be taken through the randomisation process using a touchtone telephone system. This form must be completed by a member of the Clinical Advisory Team (CAT) in Leicester.

1. **CESAR** trial hospital code: ☐☐☐☐

2. Hospital name: _____

(the randomisation service will confirm this automatically)

3. Your advisory code number: ☐☐☐☐

You will now be asked for the first name initial then second name initial.

4. Patient's first name: _____

5. Patient's surname: _____

6. Patient's date of birth: ☐☐ / ☐☐ / 19☐☐ (dd / mm / yyyy)

7. Has assent been obtained from the patient's relative(s)? Yes ☐ No ☐

i. **Total** duration of high pressure (>30cm$H_2$0) and/or high FiO_2 (>80% oxygen)? ____ **(hrs)**

ii. Is there intra-cranial bleeding Yes ☐ No ☐
(If yes, patient is not eligible for trial entry, at this time)

iii. Is there any other contra-indication to limited heparinisation? Yes ☐ No ☐
(If yes, patient is not eligible for trial entry)

iv. Is there any contra-indication to continuation of active treatment? Yes ☐ No ☐
(If yes, patient is not eligible for trial entry)

v. Murray score (if ≥ 3, go to **vii**, if < 3 go to **vi**) ☐.☐

vi. pH (uncompensated hypercapnoea) ☐.☐☐

vii. Diagnostic category (tick one box only):

1. Pneumonia ☐
2. Obstetric acute respiratory distress syndrome (ARDS) ☐
3. Other ARDS ☐
4. Trauma including surgery within 24 hours ☐
5. Other (please specify) _____ ☐

viii. Number of organs failed? ☐

Study number: ☐☐☐☐☐☐ **Allocation:**

1. Transfer for consideration of ECMO ☐
2. Conventional ventilation ☐

Date of randomisation: ☐☐ / ☐☐ / 20☐☐ (dd / mm / yyyy)

Time of randomisation: ☐☐ : ☐☐ 24 hour

Additional Information **(these questions will not be asked by the automated randomisation service):**

1. Name of recruiting doctor: _____
2. Contact number (inc. code): _____
3. Patient's gender: Male ☐ Female ☐
4. **Total** duration of IPPV? ____ **(hrs)**
5. If patient is randomised at an RH and is allocated Conventional ventilation, please give name of CTC transferred to: _____
6. Signature: .....

Please fax a copy of this form to: **CESAR Data Co-ordinating Centre on 020 7637 2853** and file the original in the CESAR CAT Entry Form folder.

FORM A

Registration form

This form should be completed by a member of the intensive care team at the participating hospital.

STEP 1 - Collect registration data

Data necessary in order to register a patient for trial entry (please print clearly and be ready to give the information over the telephone).

1. CESAR hospital code: 8 3 1 6

2. CESAR hospital categorisation: RH

3. Hospital name: Glenfield Transport Team

4. Contact telephone number:_____

Please complete patient details or affix addressograph

5. Patient's first name:_____

6. Patient's surname: _____

7. Patient's date of birth: ☐☐ ☐☐ 19☐☐ (dd / mm / yyyy)

8. Patient's gender: Male ☐ Female ☐

Please complete questions i-vii and go to Step 2 on the next page.

For each attempted registration, please record the recruiting doctor's name, the date and the time.

Doctor	_____	_____	_____	_____	_____
Date	_____	_____	_____	_____	_____
Time	_____	_____	_____	_____	_____

i.(a)	Duration of IPPV?	____ (hrs)	____ (hrs)	____ (hrs)	____ (hrs)	____ (hrs)
i.(b)	Duration of high pressure (>30cmH_2O) and/or high FiO_2 (>80% oxygen)?	____ (hrs)	____ (hrs)	____ (hrs)	____ (hrs)	____ (hrs)
ii.	Is there intra-cranial bleeding? (If yes, patient is not eligible for trial entry, at this time)	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
iii.	Is there any other contra-indication to limited heparinisation? (If yes, patient is not eligible for trial entry)	☐☐	☐☐	☐☐	☐☐	☐☐
iv.	Is there any contra-indication to continuation of active treatment? (If yes, patient is not eligible for trial entry)	☐☐	☐☐	☐☐	☐☐	☐☐
v.(a)	PaO_2 on 100% Oxygen (mmHg)	☐☐☐	☐☐☐	☐☐☐	☐☐☐	☐☐☐
v.(b)	PEEP (cmH_2O)	☐☐	☐☐	☐☐	☐☐	☐☐
v.(c)	Lung compliance (ml/cmH_2O)	☐☐	☐☐	☐☐	☐☐	☐☐
v.(d)	Number of quadrants with infiltration seen on chest x-ray?	☐	☐	☐	☐	☐
vi.	pH (uncompensated hypercapnoea)	☐.☐☐	☐.☐☐	☐.☐☐	☐.☐☐	☐.☐☐

vii. Diagnostic category:

1. Pneumonia
2. Obstetric acute respiratory distress syndrome (ARDS)
3. Other ARDS
4. Trauma including surgery within 24 hours
5. Other (please specify) _____

☐

STEP 2 - Patient eligibility and bed availability

FORM A

Please now telephone 0116 287 1471 and ask the switchboard for the CESAR Trial Clinical Advisor. You will then be transferred to the CAT (Clinical Advisory Team). You will be asked to provide the information from Step 1. They will then call you back to let you know whether the patient is eligible and beds are available.

Date	_____	_____	_____	_____	_____
Time	_____	_____	_____	_____	_____
Is the patient eligible?	Yes No	Yes No	Yes No	Yes No	Yes No
Are beds available?	☐☐	☐☐	☐☐	☐☐	☐☐
Enter date and time beds are held until:	☐☐	☐☐	☐☐	☐☐	☐☐
Date	_____	_____	_____	_____	_____
Time	_____	_____	_____	_____	_____

If the answer to both of these questions is **Yes**, please continue with STEP 3, the assent procedure.

STEP 3 - Obtain assent

Please now talk to the relative(s) to tell them about CESAR and to seek their assent. Please give them a CESAR information pack* so that they have time to read the written information before being asked to sign the assent form.

* The CESAR information pack for relatives is kept in the CESAR trial folder.

Has assent been obtained? **Yes** ☐ **No** ☐

If **Yes**, from whom? (name) _____ Relationship to patient? _____

If NO: please telephone 0116 287 1471 and ask the switchboard for the CESAR Trial Clinical Advisor. You will then be transferred to the CAT. They will then remove the reserve on the beds. You are not required to continue with this form. Please keep this form with the patient's notes.

If YES: please proceed to STEP 4.

STEP 4 - Collect randomisation data

Randomisation will be based on the current condition of the patient, therefore we will be repeating some of the questions from STEP 1.

i.(a) **Total** duration of IPPV? _____ (hrs)

i.(b) **Total** duration of high pressure (>30cm$H_2$0) and/or high FiO_2 (>80% oxygen)? _____ (hrs)

ii. Is there intra cranial bleeding (Yes ☐ No ☐)
(If yes, patient is not eligible for trial entry, at this time)

iii. Is there any other contra-indication to limited heparinisation? (Yes ☐ No ☐)
(If yes, patient is not eligible for trial entry)

iv. Is there any contra-indication to continuation of active treatment? (Yes ☐ No ☐)
(If yes, patient is not eligible for trial entry)

v.(a) PaO_2 on 100% Oxygen ☐☐☐ (mmHg) v.(b) PEEP ☐☐ (cm$H_2$0)

v.(c) Lung compliance ☐☐ (ml/cm$H_2$0) v.(d) Number of quadrants with infiltration seen on chest x-ray ☐

vi. pH (uncompensated hypercapnoea) ☐.☐☐

vii. Diagnostic category:
1. Pneumonia ☐
2. Obstetric acute respiratory distress syndrome (ARDS) ☐
3. Other ARDS ☐
4. Trauma including surgery within 24 hours ☐
5. Other (please specify) _____ ☐

viii. Number of organs failed? ☐
An organ can be considered to have failed if it meets the criteria set out on page 3, as defined by Moreno, R et al, Intensive Care Medicine 1999; 25:686-96.

FORM A

STEP 5 - Randomisation

Please telephone 0116 287 1471 and ask the switchboard for the CESAR Trial Clinical Advisor. You will then be transferred to the CAT who will ask for confirmation that assent has been obtained. They will ask you for the information provided in STEP 4. The CAT will then telephone the randomisation service to enter the patient into the trial.

Name of recruiting doctor: _____ Contact telephone number:_____

Apache II Score * ☐☐

* Within 24 hours of admission to ICU, or at time of randomisation if this is less than 24 hours.

STEP 6 - Allocation

The CAT will then telephone you to inform you of:
(please write these in the appropriate spaces below)

Study number ☐☐☐☐☐☐ Allocation 1. Transfer for consideration of ECMO ☐
2. Conventional ventilation ☐

Date of randomisation ☐☐ ☐☐ 20☐☐
dd / mm / yyyy

Time of randomisation ☐☐ : ☐☐ 24 hour

If this hospital is a CTC and the patient is assigned to Conventional Ventilation please take a *'Level of Care and Organ Support'* datasheet from the CESAR trial folder and collect the data on a daily basis. In all other cases the patient is being transferred and the CAT will give an estimated time of arrival of the transport team.

Please ensure the relative has a copy of the further information about the allocated treatment.

If randomisation has been successfully achieved please complete the details on Page 4. Make 2 copies and return 1 copy of the completed form to the CESAR Data Co-ordinating Centre and file 1 copy in the CESAR folder. Please keep the original with the patient's notes.

If the patient has <u>not</u> been randomised please keep this form in the patient's notes.

For the purpose of CESAR, the following definitions are being used.

An organ can be considered to have failed if it meets the criteria set out below as defined by Moreno, R et al, Intensive Care Medicine 1999; 25:686-96:

		Criteria met? Yes	No
Respiratory:	PaO_2/FIO_2 < 200 mmhg with ventilatory support	☐	☐
Coagulation:	Platelet count < 50 x 10^3 / mm^3	☐	☐
Liver:	Bilirubin > 102 mmol/l	☐	☐
Cardiovascular:	Dopamine > 5 mcg/kg/min (or adrenaline/noradrenaline any dose)	☐	☐
Central Nervous System:	GCS (Glasgow Coma Score) ≤ 9	☐	☐
Renal:	Creatinine > 300 mmol/l or urine output < 500ml / day	☐	☐

Please complete this page only if a patient has been randomised to the CESAR Study.

FORM A

Identifying details

PATIENT

Surname: _____

Forename: _____

NHS number: _____
(if available)

Telephone no: _____

Home address: _____

_____

_____

Postcode: _____

NEXT OF KIN

Surname: _____

Forename: _____

Relationship to patient: _____

Telephone no: _____

Home address: _____
(if different to patient's address): _____

_____

Postcode: _____

FAMILY DOCTOR

Full name: _____

Telephone no: _____

Address: _____

_____

_____

Postcode: _____

Please remember to post a copy of the assent form completed by the patient's relative when returning this form.

Please post a copy of this form to:
CESAR Trial Data Co-ordinating Centre, Medical Statistics Unit, London School of Hygiene and Tropical Medicine, Keppel Street, London WC1E 7HT using the freepost envelope which is provided in the CESAR trial folder.

Transfer Outcome Datasheet

Patient Initials ☐☐ CESAR study number ☐☐☐☐☐☐

Patient name:_____

Name of this hospital: _____

Name of unit/ward: _____ Unit/ward specialty: _____

Contact name: _____ Contact tel. number: _____

Date of admission to this unit: ☐☐☐☐☐☐☐☐ dd/mm/yyyy

Details in the section above to be completed by the CESAR Data Co-ordinating Centre. Please amend or complete any information that is incorrect or missing.

Yes ☐ No ☐

During the period of admission to this unit has the patient been readmitted to any critical care unit and then returned to this unit?

If **YES**, please give the following details:

Name of unit:_____ Contact doctor:_____

Tel. number:_____

Date of admission to critical care: ☐☐☐☐☐☐☐☐ dd/mm/yyyy

Date of return to this unit/ward: ☐☐☐☐☐☐☐☐ dd/mm/yyyy

Please complete the following when the patient is transferred, discharged or has died

Date patient left this unit: ☐☐☐☐☐☐☐☐ dd/mm/yyyy

1. Yes ☐ No ☐

Has the patient been transferred to a department other than critical care in this hospital?

If **NO**, please go to Q2. If **YES**, please give the following details:

Name of unit:_____

Tel. number:_____ Contact doctor:_____

2. Yes ☐ No ☐

Has the patient been transferred to an intensive care or high dependency unit in this hospital?

If **NO**, please go to Q3. If **YES**, please give the following details:

Name of unit:_____

Tel. number:_____ Contact doctor:_____

3. Yes ☐ No ☐

Has the patient been transferred to a critical care unit in another hospital?

If **NO**, please go to Q4. If **YES**, please give the following details:

Name of unit:_____

Name of hospital:_____

Tel. number:_____ Contact doctor (if known):_____

Name of Ambulance Trust:_____

Name of contact person to collect transport details: _____

Contact telephone number for the above named person :_____

4. Has the patient been discharged to a department other than critical care in a different hospital to continue their treatment? Yes ☐ No ☐
If NO, please go to Q5. If YES, please give details:

Name of hospital:_____ Tel. number:_____
Contact doctor (if known):_____ Name of ambulance trust:_____
Name of contact person to collect transport details: _____
Contact telephone number for the above named person :_____

5. Has the patient been discharged from hospital? Yes ☐ No ☐
If NO, please go to Q6. If YES, was the patient discharged

a) Home ☐
b) To any type of residential care ☐

If the patient has been dischared to residential care please give the following:

Name of care organisation: _____
Address: _____
_____
Contact person: _____
Telephone number: _____

If the patient has been discharged, was hospital transport used? Yes ☐ No ☐
If YES, please give the following details:

Name of Ambulance Trust:_____
Name of contact person to collect transport details: _____
Contact telephone number for the above named person :_____

6. Has the patient died? Yes ☐ No ☐
If NO, please go to Q7. If YES, please give the following details:

Date of death: ☐☐☐☐☐☐☐☐ dd/mm/yyyy

Cause of death: _____ Was a post mortem carried out? Yes ☐ No ☐

7. Name of person completing this form: _____
Tel. number: _____ Fax number: _____
Email: _____

If you have any queries regarding this form please contact:
Steven Robertson, CESAR Data Co-ordinating Centre
Medical Statistics Unit
London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT
Telephone 020 7927 2075 Fax 020 7637 2853 Email steve.robertson@lshtm.ac.uk

On completion of this outcome page, please either return a copy in the freepost envelope or fax to :
CESAR Data Co-ordinating Centre on 020 7637 2853.
Please file the original with the patient's notes.

Level of Care and Organ Support Data Collection Sheet Days 1-7

1. Hospital name:

2a. Patient's surname:_____

2b. Patient's first name:_____

3. Patient's initials: ☐☐

4. CESAR study number: ☐☐☐☐☐☐

5. Date of birth: ☐☐ / ☐☐ / 1 9 ☐☐ (dd / mm / yyyy)

6. Date of randomisation: ☐☐ / ☐☐ / 2 0 ☐☐ (dd / mm / yyyy)

7. Time of randomisation: ☐☐ : ☐☐ 24 hour

N.B. Data collection must begin on the day that the patient is randomised **irrespective of the time of randomisation.**

Please record the following data on a daily basis until the patient is discharged from the critical care unit

Day number	1	2	3	4	5	6	7
Date	/ /	/ /	/ /	/ /	/ /	/ /	/ /
Level of care: only 1 box should be ticked for each day of stay, and the highest level of care within a day should be recorded:							
Level 3: Intensive Care[1*]	☐	☐	☐	☐	☐	☐	☐
Level 2: High Dependency Care[2*]	☐	☐	☐	☐	☐	☐	☐
Organ system support: more than one organ system support can be recorded:							
1. Basic respiratory support	☐	☐	☐	☐	☐	☐	☐
2. Advanced respiratory support	☐	☐	☐	☐	☐	☐	☐
3. Circulatory support	☐	☐	☐	☐	☐	☐	☐
4. Neurological support	☐	☐	☐	☐	☐	☐	☐
5. Renal Support	☐	☐	☐	☐	☐	☐	☐
6. ECMO	☐	☐	☐	☐	☐	☐	☐
7. Liver support	☐	☐	☐	☐	☐	☐	☐
8. No organ support	☐	☐	☐	☐	☐	☐	☐
9. Other (specify).....	☐	☐	☐	☐	☐	☐	☐
Location of care: only one box should be ticked for each day of stay. If a patient moves location (e.g. from the ICU to the HDU) please tick the box for the location where the patient has spent ≥ 50% of the day:							
Intensive Care Unit (ICU)	☐	☐	☐	☐	☐	☐	☐
High Dependency Unit (HDU)	☐	☐	☐	☐	☐	☐	☐
Combined ICU/HDU	☐	☐	☐	☐	☐	☐	☐
Combined ICU/HDU/Coronary Care Unit	☐	☐	☐	☐	☐	☐	☐
Cardiothoracic ICU	☐	☐	☐	☐	☐	☐	☐
Neurological ICU	☐	☐	☐	☐	☐	☐	☐
Theatre recovery area	☐	☐	☐	☐	☐	☐	☐
Other (please state).....	☐	☐	☐	☐	☐	☐	☐
Has plateau airway pressure exceeded 30 cmH_20 for more than 4 hours in last 24 hour period*? (If plateau not recorded has peak inspiratory pressure exceeded 30 cmH_20)[3]	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A

*The first 24 hour period is defined as the time from trial entry until the following morning. Thereafter each 24 hour period starts from the beginning of each morning/day shift. If you answer N/A please indicate reason e.g. patient not ventilated.

Primary diagnosis: _____

During days 1-7 in critical care has the patient required any of the following:

	Yes	No
1. Use of high frequency/oscillation/jet ventilation	☐	☐
2. Use of nitric oxide	☐	☐
3. Use of prone position	☐	☐
4. Use of steroids	☐	☐

NB: Level of care is not the same as the location of care. For definitions *1-3 and organ support please see Page 14.

If the patient is still receiving critical care **after day 7** please return the pages for Days 1-7 by fax to the CESAR Data Co-ordinating Centre on **020 7637 2853** and continue recording data on page 3, Critical Care – Days 8-14.

If the patient has been transferred, has died or has been discharged during Days 1-7, please complete the outcome page (page 13) and return this datasheet in full by fax to the CESAR Data Co-ordinating Centre on **020 7637 2853** with the **Days 1-7 page**.

Please keep the original form in the patient's notes and make a copy for your files.

N.B. If it is easier for you to post a copy of this datasheet back to the CESAR Data Co-ordinating Centre please use the freepost envelope which is in the trial folder. Please remember to make **2** copies of this form, send **1** copy to the CESAR Data Co-ordinating Centre, keep **1** copy in your trial folder and file the original in the patient's notes.

CESAR Data Co-ordinating Centre, Medical Statistics Unit, London School of Hygiene & Tropical Medicine, Keppel Street, London WC1E 7HT
Telephone: 020 7927 2376/2075
Fax: 020 7637 2853

Level of Care and Organ Support Data Collection Sheet Days 8-14

1. Hospital name:

2. CESAR Study number: ☐☐☐☐☐☐ 3. Patient's initials: ☐☐

Please record the following data on a daily basis until the patient is discharged from the critical care unit

Day number / Date	8 / /	9 / /	10 / /	11 / /	12 / /	13 / /	14 / /
Level of care: only 1 box should be ticked for each day of stay, and the highest level of care within a day should be recorded:							
Level 3: Intensive Care[1*]	☐	☐	☐	☐	☐	☐	☐
Level 2: High Dependency Care[2*]	☐	☐	☐	☐	☐	☐	☐
Organ system support: more than one organ system support can be recorded:							
1. Basic respiratory support	☐	☐	☐	☐	☐	☐	☐
2. Advanced respiratory support	☐	☐	☐	☐	☐	☐	☐
3. Circulatory support	☐	☐	☐	☐	☐	☐	☐
4. Neurological support	☐	☐	☐	☐	☐	☐	☐
5. Renal Support	☐	☐	☐	☐	☐	☐	☐
6. ECMO	☐	☐	☐	☐	☐	☐	☐
7. Liver support	☐	☐	☐	☐	☐	☐	☐
8. No organ support	☐	☐	☐	☐	☐	☐	☐
9. Other (specify).....	☐	☐	☐	☐	☐	☐	☐
Location of care: only one box should be ticked for each day of stay. If a patient moves location (e.g. from the ICU to the HDU) please tick the box for the location where the patient has spent ≥ 50% of the day:							
Intensive Care Unit (ICU)	☐	☐	☐	☐	☐	☐	☐
High Dependency Unit (HDU)	☐	☐	☐	☐	☐	☐	☐
Combined ICU/HDU	☐	☐	☐	☐	☐	☐	☐
Combined ICU/HDU/Coronary Care Unit	☐	☐	☐	☐	☐	☐	☐
Cardiothoracic ICU	☐	☐	☐	☐	☐	☐	☐
Neurological ICU	☐	☐	☐	☐	☐	☐	☐
Theatre recovery area	☐	☐	☐	☐	☐	☐	☐
Other (please state).....	☐	☐	☐	☐	☐	☐	☐
Has plateau airway pressure exceeded 30 cmH_20 for more than 4 hours in last 24 hour period*? (If plateau not recorded has peak inspiratory pressure exceeded 30 cmH_20)[3]	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A

*The first 24 hour period is defined as the time from trial entry until the following morning. Thereafter each 24 hour period starts from the beginning of each morning/day shift. If you answer N/A please indicate reason e.g. patient not ventilated.

During days 8-14 in critical care has the patient required any of the following:

	Yes	No
1. Use of high frequency/oscillation/jet ventilation	☐	☐
2. Use of nitric oxide	☐	☐
3. Use of prone position	☐	☐
4. Use of steroids	☐	☐

NB: Level of care is not the same as the location of care.

For definitions *1-3 and organ support please see Page 14.

If the patient is still receiving critical care **after day 14** please return the pages for Days 8-14 by fax to the CESAR Data Co-ordinating Centre on **020 7637 2853** and continue recording data on page 5, Critical Care – Days 15-21.

If the patient has been transferred, has died or has been discharged during Days 8-14, please complete the outcome page (page 13) and return this datasheet in full by fax to the CESAR Data Co-ordinating Centre on **020 7637 2853** with the **Days 8-14 page**.

Please keep the original form in the patient's notes and make a copy for your files.

N.B. If it is easier for you to post a copy of this datasheet back to the CESAR Data Co-ordinating Centre please use the freepost envelope which is in the trial folder. Please remember to make **2** copies of this form, send **1** copy to the CESAR Data Co-ordinating Centre, keep **1** copy in your trial folder and file the original in the patient's notes.

CESAR Data Co-ordinating Centre, Medical Statistics Unit, London School of Hygiene & Tropical Medicine, Keppel Street, London WC1E 7HT
Telephone: 020 7927 2376/2075
Fax: 020 7637 2853

Level of Care and Organ Support Data Collection Sheet Days 15-21

1. Hospital name:

2. CESAR Study number: ☐☐☐☐☐☐ 3. Patient's initials: ☐☐

Please record the following data on a daily basis until the patient is discharged from the critical care unit

Day number / Date	15 / /	16 / /	17 / /	18 / /	19 / /	20 / /	21 / /
Level of care: only 1 box should be ticked for each day of stay, and the highest level of care within a day should be recorded:							
Level 3: Intensive Care[1*]	☐	☐	☐	☐	☐	☐	☐
Level 2: High Dependency Care[2*]	☐	☐	☐	☐	☐	☐	☐
Organ system support: more than one organ system support can be recorded:							
1. Basic respiratory support	☐	☐	☐	☐	☐	☐	☐
2. Advanced respiratory support	☐	☐	☐	☐	☐	☐	☐
3. Circulatory support	☐	☐	☐	☐	☐	☐	☐
4. Neurological support	☐	☐	☐	☐	☐	☐	☐
5. Renal Support	☐	☐	☐	☐	☐	☐	☐
6. ECMO	☐	☐	☐	☐	☐	☐	☐
7. Liver support	☐	☐	☐	☐	☐	☐	☐
8. No organ support	☐	☐	☐	☐	☐	☐	☐
9. Other (specify).....	☐	☐	☐	☐	☐	☐	☐
Location of care: only one box should be ticked for each day of stay. If a patient moves location (e.g. from the ICU to the HDU) please tick the box for the location where the patient has spent ≥ 50% of the day:							
Intensive Care Unit (ICU)	☐	☐	☐	☐	☐	☐	☐
High Dependency Unit (HDU)	☐	☐	☐	☐	☐	☐	☐
Combined ICU/HDU	☐	☐	☐	☐	☐	☐	☐
Combined ICU/HDU/Coronary Care Unit	☐	☐	☐	☐	☐	☐	☐
Cardiothoracic ICU	☐	☐	☐	☐	☐	☐	☐
Neurological ICU	☐	☐	☐	☐	☐	☐	☐
Theatre recovery area	☐	☐	☐	☐	☐	☐	☐
Other (please state).....	☐	☐	☐	☐	☐	☐	☐
Has plateau airway pressure exceeded 30 cmH_2O for more than 4 hours in last 24 hour period*? (If plateau not recorded has peak inspiratory pressure exceeded 30 cmH_2O)[3]	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A

*The first 24 hour period is defined as the time from trial entry until the following morning. Thereafter each 24 hour period starts from the beginning of each morning/day shift. If you answer N/A please indicate reason e.g. patient not ventilated.

During days 15-21 in critical care has the patient required any of the following:

	Yes	No
1. Use of high frequency/oscillation/jet ventilation	☐	☐
2. Use of nitric oxide	☐	☐
3. Use of prone position	☐	☐
4. Use of steroids	☐	☐

NB: Level of care is not the same as the location of care.

For definitions *1-3 and organ support please see Page 14.

If the patient is still receiving critical care **after day 21** please return the pages for Days 15-21 by fax to the CESAR Data Co-ordinating Centre on **020 7637 2853** and continue recording data on page 7, Critical Care – Days 22-28.

If the patient has been transferred, has died or has been discharged during Days 15-21, please complete the outcome page (page 13) and return this datasheet in full by fax to the CESAR Data Co-ordinating Centre on **020 7637 2853** with the **Days 15-21 page**.

Please keep the original form in the patient's notes and make a copy for your files.

N.B. If it is easier for you to post a copy of this datasheet back to the CESAR Data Co-ordinating Centre please use the freepost envelope which is in the trial folder. Please remember to make **2** copies of this form, send **1** copy to the CESAR Data Co-ordinating Centre, keep **1** copy in your trial folder and file the original in the patient's notes.

CESAR Data Co-ordinating Centre, Medical Statistics Unit, London School of Hygiene & Tropical Medicine, Keppel Street, London WC1E 7HT
Telephone: 020 7927 2376/2075
Fax: 020 7637 2853

Level of Care and Organ Support Data Collection Sheet Days 22-28

1. Hospital name:

2. CESAR Study number: ☐☐☐☐☐☐ 3. Patient's initials: ☐☐

Please record the following data on a daily basis until the patient is discharged from the critical care unit

Day number / Date	22 / /	23 / /	24 / /	25 / /	26 / /	27 / /	28 / /
Level of care: only 1 box should be ticked for each day of stay, and the highest level of care within a day should be recorded:							
Level 3: Intensive Care[1*]	☐	☐	☐	☐	☐	☐	☐
Level 2: High Dependency Care[2*]	☐	☐	☐	☐	☐	☐	☐
Organ system support: more than one organ system support can be recorded:							
1. Basic respiratory support	☐	☐	☐	☐	☐	☐	☐
2. Advanced respiratory support	☐	☐	☐	☐	☐	☐	☐
3. Circulatory support	☐	☐	☐	☐	☐	☐	☐
4. Neurological support	☐	☐	☐	☐	☐	☐	☐
5. Renal Support	☐	☐	☐	☐	☐	☐	☐
6. ECMO	☐	☐	☐	☐	☐	☐	☐
7. Liver support	☐	☐	☐	☐	☐	☐	☐
8. No organ support	☐	☐	☐	☐	☐	☐	☐
9. Other (specify).....	☐	☐	☐	☐	☐	☐	☐
Location of care: only one box should be ticked for each day of stay. If a patient moves location (e.g. from the ICU to the HDU) please tick the box for the location where the patient has spent ≥ 50% of the day:							
Intensive Care Unit (ICU)	☐	☐	☐	☐	☐	☐	☐
High Dependency Unit (HDU)	☐	☐	☐	☐	☐	☐	☐
Combined ICU/HDU	☐	☐	☐	☐	☐	☐	☐
Combined ICU/HDU/Coronary Care Unit	☐	☐	☐	☐	☐	☐	☐
Cardiothoracic ICU	☐	☐	☐	☐	☐	☐	☐
Neurological ICU	☐	☐	☐	☐	☐	☐	☐
Theatre recovery area	☐	☐	☐	☐	☐	☐	☐
Other (please state).....	☐	☐	☐	☐	☐	☐	☐
Has plateau airway pressure exceeded 30 cmH_20 for more than 4 hours in last 24 hour period*? (If plateau not recorded has peak inspiratory pressure exceeded 30 cmH_20)[3]	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A

*The first 24 hour period is defined as the time from trial entry until the following morning. Thereafter each 24 hour period starts from the beginning of each morning/day shift. If you answer N/A please indicate reason e.g. patient not ventilated.

During days 22-28 in critical care has the patient required any of the following:

	Yes	No
1. Use of high frequency/oscillation/jet ventilation	☐	☐
2. Use of nitric oxide	☐	☐
3. Use of prone position	☐	☐
4. Use of steroids	☐	☐

NB: Level of care is not the same as the location of care.

For definitions *1-3 and organ support please see Page 14.

If the patient is still receiving critical care **after day 28** please return the pages for Days 22-28 by fax to the CESAR Data Co-ordinating Centre on **020 7637 2853** and continue recording data on page 9, Critical Care – Days 29-35.

If the patient has been transferred, has died or has been discharged during Days 22-28, please complete the outcome page (page 13) and return this datasheet in full by fax to the CESAR Data Co-ordinating Centre on **020 7637 2853** with the **Days 22-28 page**.

Please keep the original form in the patient's notes and make a copy for your files.

N.B. If it is easier for you to post a copy of this datasheet back to the CESAR Data Co-ordinating Centre please use the freepost envelope which is in the trial folder. Please remember to make **2** copies of this form, send **1** copy to the CESAR Data Co-ordinating Centre, keep **1** copy in your trial folder and file the original in the patient's notes.

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Telephone: 020 7927 2376/2075
Fax: 020 7637 2853

Level of Care and Organ Support Data Collection Sheet Days 29-35

1. Hospital name:

2. CESAR Study number: ☐☐☐☐☐☐ 3. Patient's initials: ☐☐

Please record the following data on a daily basis until the patient is discharged from the critical care unit

Day number / Date	29 / /	30 / /	31 / /	32 / /	33 / /	34 / /	35 / /
Level of care: only 1 box should be ticked for each day of stay, and the highest level of care within a day should be recorded:							
Level 3: Intensive Care[1*]	☐	☐	☐	☐	☐	☐	☐
Level 2: High Dependency Care[2*]	☐	☐	☐	☐	☐	☐	☐
Organ system support: more than one organ system support can be recorded:							
1. Basic respiratory support	☐	☐	☐	☐	☐	☐	☐
2. Advanced respiratory support	☐	☐	☐	☐	☐	☐	☐
3. Circulatory support	☐	☐	☐	☐	☐	☐	☐
4. Neurological support	☐	☐	☐	☐	☐	☐	☐
5. Renal Support	☐	☐	☐	☐	☐	☐	☐
6. ECMO	☐	☐	☐	☐	☐	☐	☐
7. Liver support	☐	☐	☐	☐	☐	☐	☐
8. No organ support	☐	☐	☐	☐	☐	☐	☐
9. Other (specify).....	☐	☐	☐	☐	☐	☐	☐
Location of care: only one box should be ticked for each day of stay. If a patient moves location (e.g. from the ICU to the HDU) please tick the box for the location where the patient has spent ≥ 50% of the day:							
Intensive Care Unit (ICU)	☐	☐	☐	☐	☐	☐	☐
High Dependency Unit (HDU)	☐	☐	☐	☐	☐	☐	☐
Combined ICU/HDU	☐	☐	☐	☐	☐	☐	☐
Combined ICU/HDU/Coronary Care Unit	☐	☐	☐	☐	☐	☐	☐
Cardiothoracic ICU	☐	☐	☐	☐	☐	☐	☐
Neurological ICU	☐	☐	☐	☐	☐	☐	☐
Theatre recovery area	☐	☐	☐	☐	☐	☐	☐
Other (please state).....	☐	☐	☐	☐	☐	☐	☐
Has plateau airway pressure exceeded 30 cmH_20 for more than 4 hours in last 24 hour period*? (If plateau not recorded has peak inspiratory pressure exceeded 30 cmH_20)[3]	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A

*The first 24 hour period is defined as the time from trial entry until the following morning. Thereafter each 24 hour period starts from the beginning of each morning/day shift. If you answer N/A please indicate reason e.g. patient not ventilated.

During days 29-35 in critical care has the patient required any of the following:

	Yes	No
1. Use of high frequency/oscillation/jet ventilation	☐	☐
2. Use of nitric oxide	☐	☐
3. Use of prone position	☐	☐
4. Use of steroids	☐	☐

NB: Level of care is not the same as the location of care.

For definitions *1-3 and organ support please see Page 14.

If the patient is still receiving critical care **after day 35** please return the pages for Days 29-35 by fax to the CESAR Data Co-ordinating Centre on **020 7637 2853** and continue recording data on page 11, Critical Care – Days 36-42.

If the patient has been transferred, has died or has been discharged during Days 29-35, please complete the outcome page (page 13) and return this datasheet in full by fax to the CESAR Data Co-ordinating Centre on **020 7637 2853** with the **Days 29-35 page**.

Please keep the original form in the patient's notes and make a copy for your files.

N.B. If it is easier for you to post a copy of this datasheet back to the CESAR Data Co-ordinating Centre please use the freepost envelope which is in the trial folder. Please remember to make **2** copies of this form, send **1** copy to the CESAR Data Co-ordinating Centre, keep **1** copy in your trial folder and file the original in the patient's notes.

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Telephone: 020 7927 2376/2075
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Level of Care and Organ Support Data Collection Sheet Days 36-42

N.B. If the patient is still receiving critical care after day 42 the CESAR Data Co-ordinating Centre will send additional data collection sheets as necessary.

1. Hospital name:

2. CESAR Study number: ☐☐☐☐☐☐ 3. Patient's initials: ☐☐

Please record the following data on a daily basis until the patient is discharged from the critical care unit

Day number / Date	36 / /	37 / /	38 / /	39 / /	40 / /	41 / /	42 / /
Level of care: only 1 box should be ticked for each day of stay, and the highest level of care within a day should be recorded:							
Level 3: Intensive Care[1*]	☐	☐	☐	☐	☐	☐	☐
Level 2: High Dependency Care[2*]	☐	☐	☐	☐	☐	☐	☐
Organ system support: more than one organ system support can be recorded:							
1. Basic respiratory support	☐	☐	☐	☐	☐	☐	☐
2. Advanced respiratory support	☐	☐	☐	☐	☐	☐	☐
3. Circulatory support	☐	☐	☐	☐	☐	☐	☐
4. Neurological support	☐	☐	☐	☐	☐	☐	☐
5. Renal Support	☐	☐	☐	☐	☐	☐	☐
6. ECMO	☐	☐	☐	☐	☐	☐	☐
7. Liver support	☐	☐	☐	☐	☐	☐	☐
8. No organ support	☐	☐	☐	☐	☐	☐	☐
9. Other (specify).....	☐	☐	☐	☐	☐	☐	☐
Location of care: only one box should be ticked for each day of stay. If a patient moves location (e.g. from the ICU to the HDU) please tick the box for the location where the patient has spent ≥ 50% of the day:							
Intensive Care Unit (ICU)	☐	☐	☐	☐	☐	☐	☐
High Dependency Unit (HDU)	☐	☐	☐	☐	☐	☐	☐
Combined ICU/HDU	☐	☐	☐	☐	☐	☐	☐
Combined ICU/HDU/Coronary Care Unit	☐	☐	☐	☐	☐	☐	☐
Cardiothoracic ICU	☐	☐	☐	☐	☐	☐	☐
Neurological ICU	☐	☐	☐	☐	☐	☐	☐
Theatre recovery area	☐	☐	☐	☐	☐	☐	☐
Other (please state).....	☐	☐	☐	☐	☐	☐	☐
Has plateau airway pressure exceeded 30 cmH_20 for more than 4 hours in last 24 hour period*? (If plateau not recorded has peak inspiratory pressure exceeded 30 cmH_20)[3]	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A

*The first 24 hour period is defined as the time from trial entry until the following morning. Thereafter each 24 hour period starts from the beginning of each morning/day shift. If you answer N/A please indicate reason e.g. patient not ventilated.

During days 36-42 in critical care has the patient required any of the following:

	Yes	No
1. Use of high frequency/oscillation/jet ventilation	☐	☐
2. Use of nitric oxide	☐	☐
3. Use of prone position	☐	☐
4. Use of steroids	☐	☐

NB: Level of care is not the same as the location of care.

For definitions *1-3 and organ support please see Page 14.

If the patient is still receiving critical care **after day 42** please return the pages for Days 36-42 by fax to the CESAR Data Co-ordinating Centre on **020 7637 2853** and continue recording data on the new datasheet pages which have been sent to you.

If the patient has been transferred, has died or has been discharged during Days 36-42, please complete the outcome page (page 13) and return this datasheet in full by fax to the CESAR Data Co-ordinating Centre on **020 7637 2853** with the **Days 36-42 page**.

Please keep the original form in the patient's notes and make a copy for your files.

N.B. If it is easier for you to post a copy of this datasheet back to the CESAR Data Co-ordinating Centre please use the freepost envelope which is in the trial folder. Please remember to make **2** copies of this form, send **1** copy to the CESAR Data Co-ordinating Centre, keep **1** copy in your trial folder and file the original in the patient's notes.

CESAR Data Co-ordinating Centre, Medical Statistics Unit, London School of Hygiene & Tropical Medicine, Keppel Street, London WC1E 7HT
Telephone: 020 7927 2376/2075
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1. Hospital name:
2. CESAR Study number: ☐☐☐☐☐☐
3. Patient's initials: ☐☐

Outcome Page

Date of admission to this unit: ☐☐ ☐☐ 2 0 ☐☐ dd / mm / yyyy

1. Is the patient alive? Yes ☐ No ☐ If **YES**, go to Q.2. If **NO**, please give the following:

   Date of death: ☐☐ ☐☐ 2 0 ☐☐ dd / mm / yyyy Cause of death: _____

   Was a Post Mortem carried out? Yes ☐ No ☐

   Please now go to the bottom of this page for instructions on returning this form.

2. Date patient left this unit: ☐☐ ☐☐ 2 0 ☐☐ dd / mm / yyyy

3. Has the patient been discharged to a department other than intensive care or high dependency in this hospital? Yes ☐ No ☐ If **YES**, please give the following, if **NO**, go to Q4:

   Name of unit: _____ Tel. number: _____

   Contact doctor: _____

   Please now go to Q6

4. Has the patient been transferred to a different critical care unit in this or another hospital? Yes ☐ No ☐

   If **YES**, please give the following details, if **NO** go to Q5:

   Name of unit: _____ Tel. number: _____

   Hospital: _____ Contact doctor (if known): _____

   Name of Ambulance Trust: _____

   Name of contact person to collect full details of transport arrangements: _____

   Contact telephone number for the above named person: _____

   Please now go to Q6

5. Has the patient been discharged to a department other than intensive care or high dependency in a different hospital, to continue their treatment? Yes ☐ No ☐

   If **YES**, please give the following details, if **NO** go to Q6:

   Name of unit: _____ Tel. number: _____

   Hospital: _____ Contact doctor (if known): _____

   Name of Ambulance Trust: _____

   Name of contact person to collect full details of transport arrangements: _____

   Contact telephone number for the above named person: _____

   Please now go to Q6

6. If the patient has been transferred please describe the reason for the transfer (please tick <u>one</u> box only):
   Clinical ☐
   Non-clinical (e.g. due to bed pressures in existing critical care unit) ☐

7. Ambulance booking reference number (if known): _____

On completion of this outcome page, please fax a copy to: CESAR Data Co-ordinating Centre on **020 7637 2853**, keep 1 copy in your trial folder and file the original with the patient's notes.

Definitions

Level of care

1 **Level 3 care** is for patients requiring one or more of the following:

- Advanced respiratory system monitoring and support alone
- Two or more organ systems being monitored and supported, one of which may be advanced respiratory support
- Patients with chronic impairment of one or more organ systems sufficient to restrict daily activity (co-morbidity) and who require support for an acute reversible failure of another organ.

2 **Level 2** care is for patients requiring one or more of the following:

- Single organ system monitoring and support, excluding advanced respiratory support
- General observation and monitoring: more detailed observation and the use of monitoring equipment that cannot safely be provided on a general ward. This may include extended post-operative monitoring for high-risk patients
- Step-down care: patients who no longer need intensive care but who are not well enough to be returned to a general ward.

Ventilation strategy

3 It is recommended that intensivists adopt the low volume and low pressure ventilation strategy as defined in the NIH ARDS Network Study. Adherence to this strategy is defined as a plateau pressure <30 cm H_2O (or, if plateau pressure is not measured, then use peak inspiratory pressure <30 cm H_2O). This will usually mean a tidal volume of 4-8ml/kg body weight as defined in the low tidal volume ventilation strategy according to the ARDS Network group.

Organ support

* For the purposes of this data collection sheet Organ Support will be defined using the Department of Health's Augmented Care Period (ACP) set of definitions as follows:

1. **Basic respiratory system monitoring/support** (indicated by one or more of the following)
   - More than 50% oxygen by fixed performance mask
   - The potential for deterioration to the point of needing advanced respiratory support
   - Physiotherapy to clear secretions at least two hourly, whether via tracheostomy, minitracheostomy, or in the absence of an artificial airway
   - Patients recently extubated after a prolonged period of intubation and mechanical ventilation
   - Mask CPAP or non-invasive ventilation
   - Patients who are intubated to protect the airway but needing no ventilatory support and who are otherwise stable

2. **Advanced respiratory system monitoring/support** (indicated by one or more of the following)
   - Mechanical ventilatory support (excluding mask (CPAP) by non-invasive methods e.g. mask ventilation)

3. **Circulatory system monitoring/support** (indicated by one or more of the following)
   - Vasoactive drugs used to support arterial pressure or cardiac output
   - Circulatory instability due to hypovolaemia from any cause
   - Patients resuscitated following cardiac arrest where intensive care is considered clinically appropriate
   - Intra aortic balloon pumping

4. **Neurological system monitoring/support** (indicated by one or more of the following)
   - Central nervous system depression, from whatever cause, sufficient to prejudice the airway and protective reflexes
   - Invasive neurological monitoring e.g. ICP, jugular bulb sampling

5. **Renal system monitoring/support** (indicated by)
   - Acute renal replacement therapy (haemodialysis, haemofiltration etc.)

6. **ECMO**
   - Extra-corporeal Membrane Oxygenation (Glenfield Hospital Only)

7. **Liver support** (indicated by)
   - Extra-corporeal liver replacement device i.e. MARS (Teraklin, Rostock, Germany), bioartificial liver or charcoal haemoperfusion

Other personal costs relating to your illness

Please note details of date and personal costs relating to your illness since you came home, and what they were for (see example in bold below).

Drugs or equipment costs	Travel/fares or mileage costs for health care	Childcare costs when needing health care	Private consultation	Home help, private nurse etc.	Other
e.g. £6 for prescription of antibiotics March 1-8					

Days off from work

If you have returned to work, please enter the date ☐☐☐☐☐☐☐☐ dd/mm/yyyy

If you have taken time off work due to illness since then, please complete the table below:

Please enter the start and stop dates for any period of absence from work	Number of days off sick	Reason for absence from work

Please keep this diary at home until you are visited 6 months after joining the study. If you have any queries please contact:

CESAR Data Co-ordinating Centre, Medical Statistics Unit, London School of Hygiene & Tropical Medicine, Keppel Street, London WC1E 7HT
Tel: 020 7927 2376/2075

Conventional Ventilation or ECMO for Severe Adult Respiratory Failure

CESAR

EVENTS DIARY

This *Events Diary* is for you to keep, in order that you may have a record of events related to your health from the time of your discharge from hospital.

In addition, as you may be aware, a study researcher will visit you at home about 6 months after you joined the study to ask you about events related to your health.

To keep track of these events you may find this *Events Diary* will help you answer the questions. This is partly so that we can estimate how much your illness cost in terms of time off work, personal expenses and cost of continuing care. Please have this *Diary* available when the researcher visits you.

If you require additional space to record details of health service use, please use the sheet entitled *Events Diary - additional information* which is included with this booklet.

Date of discharge from hospital ☐☐☐☐☐☐☐☐ dd/mm/yyyy

On the day you were discharged from hospital please tell us how you travelled home:

_____

General Practice

If you see the doctor, nurse, physiotherapist or occupational therapist from your general practice, please write the date of each visit, whom you see and where. Use one box for each visit.

Date of visit	Whom did you see (i.e. doctor, nurse, physiotherapist, occupational therapist, counselling or psychological treatments)	Where did you see them (practice or home visit, please specify)

Telephone Advice

If you have contacted any of the following for advice about your health by phone please give dates. Please exclude calls for arranging appointments and repeat prescriptions.

Date of phone advice	Whom did you call (e.g. NHS Direct, your GP, nurse etc.)

Hospital Admissions

If you are admitted to hospital, please write the name of the hospital and the dates of each admission and discharge. Use one box for each admission.

Name of hospital	Date of admission	Date of discharge

Hospital Visits (not inpatient)

If you have visited hospital as an **outpatient** or in an emergency (i.e. casualty/A&E), please write the name of the hospital or outpatient clinic with the date of each visit. Use one box for each visit.

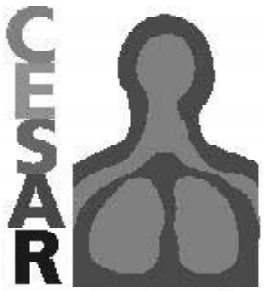
Date	Name of outpatient clinic and hospital	Emergency or routine?

Community and Social Services

If you have any visits from community or social service staff please give the date of each visit.

Date of visit	Who visited you (e.g. social worker, homecare worker or care attendant, health visitor)

Conventional Ventilation or
ECMO for
Severe
Adult
Respiratory Failure



EVENTS DIARY

Additional information

Please use this sheet to record details of health service use if there is not enough space on the *Events Diary*.

Please continue on the next page if necessary.

Please keep this additional sheet with your *Events Diary* until you are visited 6 months after joining the study. If you have any queries please contact:

CESAR Data Co-ordinating Centre, Medical Statistics Unit, London School of Hygiene & Tropical Medicine, Keppel Street, London WC1E 7HT

Tel: 020 7927 2376/2075

Patient Costs Questionnaire

Interviewer: The following explains the purpose of this interview and in particular the reasons for economic questions. You may either read out the following or use your own words to convey to the patient the reasons for the interview. The same questionnaire can be used for all patients whether they are living at home or in residential/nursing home care.

- I'm sure that the time you were ill was very difficult for you and the people close to you in many ways.
- This questionnaire will help us to understand how much your illness, following your time in intensive care, has cost you and your family financially.
- We are also interested in whether your treatment affected your use of other health and community services.
- We are also interested to know about any health, community or voluntary services that you may have used since your discharge from hospital.
- If you cannot remember the exact details please give your best estimates.
- When you came home from hospital you were sent an Events Diary to help you to record details of health-related events and personal costs.
- Did you use this?
- Have you got it handy as it may help in completing this questionnaire?
- The information provided will be confidential to the researchers and used only to contribute to overall study results.

CESAR study number ☐☐☐☐☐☐

CESAR study number ☐☐☐☐☐☐

Part One: Healthcare and Community Services

1. Transport

On the day you returned home after your stay in hospital, how did you travel home?

Ambulance ☐ Voluntary car services ☐ Taxi ☐
Own/family car ☐ Other (please specify) ☐ .....

Approximate distance (one-way): .....miles. If you used a taxi please give the fare you paid: £.....

2. General Practitioners

Since returning home from your time in hospital, have you consulted your GP? YES ☐ NO ☐

If NO, please go to QUESTION 3. If YES, please give details of the number of consultations you have had with your GP:

At the surgery ☐☐ At home ☐☐ By telephone* ☐☐ **Please exclude calls for arranging appointments and repeat prescriptions.*

How do you normally travel to see your GP? (e.g. Own car, taxi etc) .....

If you usually travel by car or ambulance, please give approximate return mileage to your GP surgery: .....miles

If you usually travel by public transport or taxi please give the usual return fare per visit: £.....

3. Other telephone advice

Since returning home from your time in hospital have you contacted any of the following by phone for advice about your health?

	Contact by telephone	If YES, how many times?
NHS Direct	YES ☐ NO ☐	
Other (please specify)	YES ☐ NO ☐	

CESAR study number ☐☐☐☐☐☐

4. Nursing, Therapy and Social Services

Since returning home from your time in hospital, have you received any of the following services? YES ☐ NO ☐

If NO, please go to QUESTION 5. If YES, please give further details below.

	Approx. number of visits	Location of visit (home, hospital, clinic etc)	Did you have to pay?	If yes, approx. cost per visit	Did you have private medical insurance to cover this cost?	If this invloved travelling, please give type of transport used (own car, ambulance etc.) or write N/A	If travelled by car / ambulance please give approx. return mileage	If you travelled by public transport / taxi please give return fare per visit
			Yes No		Yes No N/A			
Nurse			☐ ☐	£	☐ ☐ ☐			£
Physiotherapist			☐ ☐	£	☐ ☐ ☐			£
Occupational therapist			☐ ☐	£	☐ ☐ ☐			£
Counselling or psychological treatments			☐ ☐	£	☐ ☐ ☐			£
Social worker			☐ ☐	£	☐ ☐ ☐			£
Home care worker or care attendant			☐ ☐	£	☐ ☐ ☐			£
Health visitor			☐ ☐	£	☐ ☐ ☐			£
Other (please specify)			☐ ☐	£	☐ ☐ ☐			£

Interviewer: Please use this space to record any other services which could not be listed above .

CESAR study number ☐☐☐☐☐☐

5. Hospital care

Since returning home from your time in hospital:

Part A Have you been admitted to hospital? YES ☐ NO ☐ *If NO, please go to QUESTION 5 PART B.*

If YES, how many times? ☐☐

Please complete the following table as far as you are able to (for day procedures give the same date for admission and discharge).

	Date admitted	Date discharged	Name of hospital and town	Please describe how you travelled to the hospital (car, ambulance etc.)	If you travelled by car / ambulance please give approx. return mileage	If you travelled by public transport or taxi please give return fare	Did you have private medical insurance to cover this stay?
							Yes No N/A
Stay 1						£	☐ ☐ ☐
Stay 2						£	☐ ☐ ☐
Stay 3						£	☐ ☐ ☐
Stay 4						£	☐ ☐ ☐
Stay 5						£	☐ ☐ ☐

Part B Have you visited a hospital as an outpatient? YES ☐ NO ☐

If NO, please go to QUESTION 6. If YES, please give further details below.

	Approx. number of visits	Did you have to pay?	If Yes, approx. how much per visit	Did you have private medical insurance to cover this cost?	Please describe how you travelled for these visits (own car, ambulance etc.)	If you travelled by car or ambulance please give approx. return mileage	If you travelled by public transport or taxi please give return fare per visit
		Yes No		Yes No N/A			
Consultant clinic (with any doctor)		☐ ☐	£	☐ ☐ ☐			£
Visits to A & E		☐ ☐	£	☐ ☐ ☐			£
Day care/day hospital (e.g. for rehabilitation)		☐ ☐	£	☐ ☐ ☐			£
Other (please specify)		☐ ☐	£	☐ ☐ ☐			£

CESAR study number ☐☐☐☐☐☐

6. Nursing home or residential care

Since returning home from your time in hospital, have you been admitted to a nursing home or residential care? YES ☐ NO ☐

If NO, please go to QUESTION 7. If YES, please give further details below.

	Date admitted	Date discharged	Please tick type of care	Did you have to pay?	If yes, approx. cost per stay	Did you have private insurance to cover this cost?	Please describe how you travelled (taxi, ambulance etc.)	If you travelled by car / ambulance please give approx. return mileage	If you travelled by public transport or taxi please give return fare
				Yes No		Yes No N/A			
Stay 1			Nursing home ☐ Residential care ☐	☐ ☐	£	☐ ☐ ☐			£
Stay 2			Nursing home ☐ Residential care ☐	☐ ☐	£	☐ ☐ ☐			£
Stay 3			Nursing home ☐ Residential care ☐	☐ ☐	£	☐ ☐ ☐			£
Stay 4			Nursing home ☐ Residential care ☐	☐ ☐	£	☐ ☐ ☐			£

Interviewer: Please use separate sheet if there are more than 4 stays.

Part Two: Patient's Personal Costs

7. Personal expenditure on medication

Part A Since returning home from hospital, have you taken any medication? YES ☐ NO ☐

If NO, please go to QUESTION 8. If YES, go to PART B

CESAR study number ☐☐☐☐☐☐

Part B Was the medication provided by the hospital when you were discharged?

YES ☐ Please give details of any repeat prescriptions and any new medication in the tables below

NO ☐ Please give details of all medication taken in the tables below

Table 1

Prescription drugs from GP	Was the prescription NHS or private?	Approximately how long did you take this medication?	Approximate cost if paid for your medication including prescription charges	Are you currently taking this medication?
e.g. Ampicillin		e.g. Twice daily for a month	e.g. £5.50	

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Table 2

Non-prescription drugs i.e. over the counter medication	Approximately how long did you take this medication?	Approximate cost if paid for your medication including prescription charges
e.g. Aspirin	e.g. Twice daily for a month	e.g. £3.00

8. Personal expenditure on healthcare

Since returning home from your time in hospital, have you used any of the following services or items? YES ☐ NO ☐

(Interviewer: please read out list of items from the table below. Also include any item/adaptation that has been ordered/arranged but not yet received by patient.)

If NO, please go to QUESTION 9. If YES, please provide as many details as you can in the table on page 8.

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Personal expenditure on healthcare

Please give details of each item under each heading	Did you have to pay anything?	Approximate cost if known	Did you have private medical insurance to cover this cost?
A) Private medical care (e.g. any private treatment not included in Question 5B). Please specify:	Yes ☐ No ☐ N/A ☐		Yes ☐ No ☐ N/A ☐
B) Equipment (e.g. wheelchair). Please specify: N.B. If you used any equipment but did not pay for it please specify who arranged this for you (e.g. hospital, social services, voluntary sector etc.)	Yes ☐ No ☐ N/A ☐ Equipment was provided by :		Yes ☐ No ☐ N/A ☐
C) Childcare (any childcare arrangements you had to make due to your illness). Please specify:	Yes ☐ No ☐ N/A ☐		Yes ☐ No ☐ N/A ☐
D) Any adaptations to your home such as a ramp, stair lift, changes to the bathroom etc. Please specify: If you had any adaptations done to your home but did not pay for it please specify who provided this for you?	Yes ☐ No ☐ N/A ☐ Adaptations provided by:		Yes ☐ No ☐ N/A ☐
E) Any other items of health care. Please specify.	Yes ☐ No ☐ N/A ☐		Yes ☐ No ☐ N/A ☐

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Part Three: Employment

9. Employment before hospitalisation

Were you in employment before you were admitted to intensive care? Yes ☐ No ☐

If YES, was this:

Paid employment	Full time ☐	Part-time ☐
Unpaid employment (e.g. volunteer)	Full time ☐	Part-time ☐

If NO, please choose one or more of the following categories that best described your status before your time in hospital and go to QUESTION 12.

Retired ☐	Retired on medical grounds ☐	Unemployed ☐
Student ☐	Housewife/househusband ☐	Other (*please specify*) ..... ☐

10. Employment after discharge

Part A **Please tell us your current employment status by ticking one of the following boxes.**

Returned to paid work	☐	Date returned to work _ _ / _ _ / _ _ *(dd/mm/yy)*
Returned to unpaid work (volunteer)	☐	Date returned to work _ _ / _ _ / _ _ *(dd/mm/yy)*
Paid sick leave	☐	Please go to Q.12
Unpaid sick leave	☐	Please go to Q.12
Retired on medical grounds after discharge	☐	Please go to Q.12
Unemployed	☐	Please go to Q.12
Other (please specify)	☐	Please go to Q.12

_____

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Part B If you returned to work:

Is this job: Full time ☐ Part-time ☐

Is it the same employment that you had before your illness? YES ☐ NO ☐

11. Time off work

If you have returned to work since returning home, have you had to take any time off work because of further illness?

YES ☐ **NO** ☐ **Not Applicable** ☐

If NO, please go to question 12. If YES, how many days? ☐☐☐

12. Benefits and allowances

(Interviewer: please remind and reassure patient that all data will be kept confidential)

Are you currently receiving any government benefits or allowances? YES ☐ NO ☐

If YES, please give approximate date when you became eligible. _ _ / _ _ / _ _ *(dd/mm/yy)*

If NO, have you applied for any benefits or allowances since your discharge from hospital? YES ☐ NO ☐

(Interviewer: The following list of benefits/allowances might help remind the patient/carer about any benefits they might have applied for: housing benefit, incapacity benefit, severe disablement allowance, invalid care allowance, attendance allowance and disability allowance)

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13. Employment - additional information

Please give any comments on income, work etc. that were not covered in questions 9-12.

_____

_____

_____

14. Healthcare from family and friends

Since returning home from your time in hospital, have you received care from family members, relatives or friends as a result of illness? YES ☐ NO ☐

If NO, please go to QUESTION 15. If YES, please complete the following:

1)	Was this help from an unpaid carer?	YES ☐	NO ☐
2)	Did your carer have to take this time off work?	YES ☐	NO ☐
3)	Did your carer have to give up his/her employment?	YES ☐	NO ☐
4)	Did your carer have to take up a different job or switch to a part-time job to care for you?	YES ☐	NO ☐

Please describe the frequency of involvement by carers since discharge in the table below:

Total weekly hours of help (e.g. 2 hours help twice a week, total is 2x2 = 4)	Over what period did you receive this help? (e.g. 1 week)	Total hours of help
Any comments		

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5) Do you need regular daily help with things that fit and healthy people would normally do for themselves? YES ☐ NO ☐

(Interviewer: if YES please record carer details on checklist and issue a CSI if carer present)

15. Changes to family circumstances

Since you were admitted to intensive care, have there been any significant changes in your family circumstances? YES ☐ NO ☐

If NO, please go to QUESTION 16. If YES, please provide (approximate) costs for the following:
(Interviewer: Please try to establish any major changes and express costs as per month if possible, giving comments to explain if necessary. If patient is only able to give a total cost please make a note of this in the 'comments' column)

Description	Approximate monthly additional cost, if known	Comments
Change in residence (e.g. had to move to a different but own house, move to a relative's house etc.)		
Any other such as lost employment income through illness (please specify)		

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16. Do you have any health related insurance policy/plan? YES ☐ NO ☐

If No please go to QUESTION 17, if YES, please tell us what it covers by ticking one or more of the following options:

1) Health care costs ☐ 2) Income protection ☐

3) Any other (please specify) …….. ☐

17. Do you have any other comments about the cost of your health care that you'd like me to record? YES ☐ NO ☐

(*Interviewer: Please record any comments made by the patient or carer)*

_____

_____

_____

_____

_____

_____

_____

_____

_____

Economic questions if visited in hospital

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In addition to all the other issues you have had to face, we are aware that illness may lead people to have extra costs. We want to understand how much your illness cost you and your family, so the following questions will address this.

1. Employment before hospitalisation

	Yes	No
Were you in employment before you were admitted to intensive care?	☐	☐

If YES, was this:

a) Paid employment — Full time ☐ Part time ☐

b) Unpaid employment (e.g. volunteer) — Full time ☐ Part time ☐

If NO, please choose one or more of the following categories that best described your status before your time in hospital.

1. Retired ☐
2. Retired from work on medical grounds ☐
3. Student ☐
4. Housewife/househusband ☐
5. Unemployed ☐
6. Other (please specify) ..... ☐

2. Benefits and allowances

(Interviewer: please remind and reassure patient that all data will be kept confidential)

	Yes	No
Are you currently receiving any government benefits or allowances?	☐	☐

If YES, please give the approximate date you became eligible. ☐☐☐☐☐☐☐☐ dd/mm/yyyy

	Yes	No
If NO, have you applied for any benefits or allowances since you were admitted to hospital?	☐	☐

(Interviewer: The following list of benefits/allowances might help remind the patient/carer about any benefits they might have applied for: housing benefit, incapacity benefit, severe disablement allowance, invalid care allowance, attendance allowance and disability allowance)

3. Changes to family circumstances

Since you were admitted to intensive care, have there been any significant changes in your family circumstances? Yes ☐ No ☐

If NO, please go to Question 4.

If YES, please provide (approximate) costs for the following:

(Interviewer: Please try to establish any major changes and express costs as per month if possible, giving comments to explain if necessary. If patient is only able to give a total cost please make a note of this in the comments column)

Description	Approximate monthly additional cost if known	Comments
Any adaptations to the home		
Any other (e.g.lost employment income through illness, please specify)		

4. Health Insurance

Do you have any health related insurance policy/plan? Yes ☐ No ☐

If YES, please tell us what it covers by ticking one or more of the following options:

1. Health care costs ☐ 2. Income protection ☐

3. Any other (please specify) ☐ .....

Caregiver Strain Index

The following questions have been designed to find out how carers are affected by looking after someone who has been discharged from hospital or who has an illness.

Name of carer: _____

Age: ☐☐

Sex: Male ☐ Female ☐

CESAR study number ☐☐☐☐☐☐

CESAR study number ☐☐☐☐☐☐

Please answer every question. If any of the questions do not seem appropriate to your own personal circumstances, please respond by ticking the NO box.

	YES	NO
1. Sleep is disturbed (e.g. because care is needed at night or because the patient is in and out of bed or wanders around at night).	☐	☐
2. It is inconvenient (e.g. because helping takes so much time or it's a long way over to help).	☐	☐
3. It is a physical strain (e.g. because of lifting in and out of a chair; effort or concentration is required).	☐	☐
4. It is confining (e.g. helping restricts free time, or cannot go visiting).	☐	☐
5. There have been family adjustments (e.g. because helping has disrupted routine; there has been no privacy).	☐	☐
6. There have been changes in personal plans (e.g. had to turn down a job; could not go on holiday).	☐	☐
7. There have been other demands on my time (e.g. from other family members).	☐	☐
8. There have been emotional adjustments (e.g. severe argument; relationship with other family members).	☐	☐
9. Some behaviour is upsetting (e.g. due to incontinence and need for intimate personal care; memory problems; accusations of stealing).	☐	☐
10. It is upsetting to find that the patient has changed so much from his/her former self (e.g. is a different person than they used to be).	☐	☐
11. There have been work adjustments (e.g. because of having to take time off).	☐	☐
12. It is a financial strain.	☐	☐
13. Feeling completely overwhelmed (e.g. because of worry about the patient; concern about how you will manage).	☐	☐

Thank you for taking time to complete this questionnaire

Please give the completed form directly to the researcher or use the stamped addressed envelope (S.A.E.) and return to:

Dr Andy Wilson
Senior Lecturer
Department of GP and PHC
University of Leicester
Gwendoline Rd
Leicester LE5 4PW

6 Month Follow-Up Assessment Checklist

This checklist should be completed by the Follow-up Assessment Researcher

Patient Initials ☐☐ CESAR study number ☐☐☐☐☐☐

Date of follow-up appointment: ☐☐☐☐☐☐☐☐ dd/mm/yyyy

How was the appointment conducted? ☐ Home visit ☐ Telephone ☐ Postal

Does the patient have a carer? ☐ Yes ☐ No

If Yes, please give:

Name: _____ Address: _____

_____

Tel. number: _____ _____

If the patient has a carer, has a CSI been completed and returned? ☐ Yes, completed at assessment ☐ Yes, returned by post ☐ No, carer refused ☐ No, form not returned

Was the events diary used? ☐ Yes ☐ No

Duration of interview? _____

Was the interview completed? ☐ Yes ☐ No

If No, please give the following details:

1) Reason interview not completed? _____

2) Were any arrangements made for a telephone follow-up? Yes ☐ No ☐

If Yes, please give details: _____

Please indicate which follow-up forms have been completed and returned with this checklist:

	Yes	No	If not returned please give reason
1. EQ-5D	☐	☐	_____
2. SGHRQ	☐	☐	_____
3. SF-36v2	☐	☐	_____
4. HAD	☐	☐	_____
5. Patient Costs Questionnaire	☐	☐	_____
6. Additional Questions and Examination	☐	☐	_____

Was the researcher blind to the patient's allocation up to the PCQ? YES ☐ NO ☐

Was the researcher blind to the patient's allocation at the end of the interview YES ☐ NO ☐

If you have answered NO to either (or both) questions about allocation, please record what you think the patient's allocation is:

ECMO ☐ Conventional ☐ No idea ☐

Is there evidence of post illness hearing impairments? YES ☐ NO ☐

Date checklist completed: ☐☐☐☐☐☐☐☐ dd/mm/yyyy

Researcher's name: _____ Researcher's signature: _____

Please photocopy this form and all the follow-up documents, send the copies to:

Steven Robertson, CESAR Data Co-ordinating Centre
Medical Statistics Unit, London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT

and file the originals in the CESAR folder.

Health Service Use of Patients in CESAR Trial

Patient Initials ☐☐ CESAR study number ☐☐☐☐☐☐

Name of GP surgery: .....

Name of patient: .....

Date of birth: ☐☐☐☐☐☐☐☐ dd/mm/yyyy

Data required from: start date ☐☐☐☐☐☐☐☐ dd/mm/yyyy

to

finish date ☐☐☐☐☐☐☐☐ dd/mm/yyyy (6 months after entry into trial)

We would be grateful if you are able to provide the following details for the above patient. Information collected from questions 1-2 below form part of the primary outcome for the clinical aspect of the study. Information collected on pages 2-4 will be used as part of the CESAR economic evaluation.

1. Was the patient alive at ☐☐☐☐☐☐☐☐ dd/mm/yyyy

   YES ☐ If YES, please go to Question 2.
   NO ☐ If NO, please complete the following and go to page 2:

   Date of death: ☐☐☐☐☐☐☐☐ dd/mm/yyyy

   Cause of death:_____

2. If YES, please select the option which best describes the patient's mobility and self-care status on ☐☐☐☐☐☐☐☐ dd/mm/yyyy

   Mobility

   Patient has no problems in walking about ☐
   Patient has some problems in walking about ☐
   Patient is confined to bed ☐
   Patient's mobility status not known ☐

   Self-care

   Patient has no problems with self-care ☐
   Patient has some problems washing or dressing ☐
   Patient is unable to wash or dress ☐
   Patient's self-care status not known ☐

Patient Initials ☐☐ CESAR study number ☐☐☐☐☐☐

Instructions for table 1: Please enter '0' in the appropriate column if no visits or telephone contacts were made by the above patient to any particular professional group. Please put a tick (✔) in the **fourth** column if data on visits and telephone contact to some professionals is not available from your records.

Table 1: Consultations at GP surgery and community clinics			
Professional consulted	Number of consultations at surgery/clinic	Number of telephone contacts	Data for this not available from GP records
GP			
Nurse			
Physiotherapist			
Occupational therapist			
Provider of counselling or psychological treatments			
Any other (please specify)			

Instructions for table 2: Please enter '0' if no visits were made by any particular professional group. Please put a tick (✔) in the **third** column if data on visits by some professionals is not available from your records.

Table 2: Home visits by the following professionals		
	Number of home visits	Data for this not available from GP records
GP		
Nurse		
Physiotherapist		
Occupational therapist		
Provider of counselling or psychological treatments		
Any other (please specify)		

Table 3: Outpatient clinic visits. If no visits tick box ☐	
Specialty	Number of visits
.....	.....
.....	.....
.....	.....
.....	.....
.....	.....

Patient Initials ☐☐ CESAR study number ☐☐☐☐☐☐

Table 4: Other hospital visits by patient including investigations etc.		
	Number of visits	If none tick box
A & E		☐
Day care / day hospital		☐
Investigations, physio, occupational therapy etc.		☐
Any other (please specify)		☐

Table 5: Hospital admissions.

	Specialty	Dates admitted and discharged
Inpatient admission If none tick box ☐	....	dd / mm / yy Admitted ☐☐ ☐☐ ☐☐ Discharged ☐☐ ☐☐ ☐☐ Admitted ☐☐ ☐☐ ☐☐ Discharged ☐☐ ☐☐ ☐☐ Admitted ☐☐ ☐☐ ☐☐ Discharged ☐☐ ☐☐ ☐☐ Admitted ☐☐ ☐☐ ☐☐ Discharged ☐☐ ☐☐ ☐☐ Admitted ☐☐ ☐☐ ☐☐ Discharged ☐☐ ☐☐ ☐☐
Day case procedures If none tick box ☐	....	dd / mm / yy Date ☐☐ ☐☐ ☐☐ Date ☐☐ ☐☐ ☐☐ Date ☐☐ ☐☐ ☐☐ Date ☐☐ ☐☐ ☐☐

Table 6: Nursing home or residential care admissions. If none tick box ☐

Type of home		Dates admitted and discharged
Nursing home ☐	Residential care ☐	dd / mm / yy Admitted ☐☐ ☐☐ ☐☐ Discharged ☐☐ ☐☐ ☐☐
Nursing home ☐	Residential care ☐	Admitted ☐☐ ☐☐ ☐☐ Discharged ☐☐ ☐☐ ☐☐
Nursing home ☐	Residential care ☐	Admitted ☐☐ ☐☐ ☐☐ Discharged ☐☐ ☐☐ ☐☐
Nursing home ☐	Residential care ☐	Admitted ☐☐ ☐☐ ☐☐ Discharged ☐☐ ☐☐ ☐☐
Nursing home ☐	Residential care ☐	Admitted ☐☐ ☐☐ ☐☐ Discharged ☐☐ ☐☐ ☐☐

Patient Initials ☐☐ CESAR study number ☐☐☐☐☐☐

Table 7: Other health related referrals.		
	If none tick box	Date of referral
Social services referral by GP	☐	dd / mm / yy ☐☐/☐☐/☐☐
Any other referral by GP for services not provided within this surgery e.g. physiotherapy, occupational therapy (please specify)	☐	☐☐/☐☐/☐☐ ☐☐/☐☐/☐☐ ☐☐/☐☐/☐☐

If possible please send a printout of all medication prescribed between the **start** and **finish** dates as listed on page 1. If this is not possible please complete table 8.

Please tick box if printout is enclosed ☐

Table 8: Prescriptions		
Date prescribed	Name of medication	Period for which the medication was prescribed (e.g. 2 weeks)

Thank you for completing this form. Please return it in the enclosed freepost envelope to:

CESAR Trial Data Co-ordinating Centre
Medical Statistics Unit, London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT