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: ☐☐ ☐☐ 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 (>30cm$H_20$) 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) | $Pa0_2$ on 100% Oxygen (mmHg) | ☐☐☐ | ☐☐☐ | ☐☐☐ | ☐☐☐ | ☐☐☐ |
| v.(b) | PEEP ($cmH_20$) | ☐☐ | ☐☐ | ☐☐ | ☐☐ | ☐☐ |
| v.(c) | Lung compliance (ml/$cmH_20$) | ☐☐ | ☐☐ | ☐☐ | ☐☐ | ☐☐ |
| 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) _____

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# 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$H_20$) 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) $Pa0_2$ on 100% Oxygen ☐☐☐ (mmHg) v.(b) PEEP ☐☐ (cm$H_20$)

v.(c) Lung compliance ☐☐ (ml/cm$H_20$) 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 ☐☐ ☐☐ 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 <u>not</u> been randomised please keep this form in the patient's notes.

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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.