SECTION C – Governance

(Including management and organisation of the adult ECMO programme)

When completing your responses to the questions in section C please refer to the standards schedule and ensure you have provided the additional evidence to meet the standards, where specified.

Section C: Questions 1

C1 Organisational arrangements for the ECMO service.

The response should make reference, but not be limited, to:

a. Corporate governance structure:
   - Process to meet standard NHS governance requirements
   - Details of accountability pathways and processes
   - Business conduct

Maximum 1500 words (the use of bullet points is acceptable)
One A4 attachment of clinical governance chart may be submitted

Question C1a Response

b. Clinical governance including leadership of the ECMO service:
- Details of the clinical and management structure that demonstrates lines of accountability to the ECMO programme director and within the Trust
- Organisation chart
- Process for effective communication with all members of the ECMO service and other clinical specilaities

Maximum 1500 words (the use of bullet points is acceptable)
One A4 attachment of organisation chart may be submitted

Question C1 b Response

c. **Board support and strategic fit**

The Bidder should provide a letter or statement from the Chief Executive to confirm that the provison of an ECMO service fits with the strategic priorities of the Trust. This should reference the strategic plans of the Trust – maximum 500 words.

Submit Chief Executive statement / letter as an attachment;

	Yes	**No**
Confirm Chief Executive statement / letter provided		

Section C: Standards to be met and evidence to be provided

Effective organisation and strong clinical leadership of the adult respiratory ECMO programme is central to ensuring the quality and safety of care being provided and to delivering good clinical outcomes.

The ECMO service will ensure that it has in place, effective processes and structures that are recognised, understood and owned by the team.

Governance

Standard	Description	Met Yes / No	Evidence to submit
C1	Nationally designated ECMO centres will have the capacity to treat a minimum of 20 adult ECMO patients per centre per year under non-surge conditions.		None Information should form part of the response to Question A2
C2	ECMO centre will be expected to: • Anticipate, plan for and manage seasonal variation • Respond and collaborate on a national basis to unanticipated surges in demand, over and above the seasonal demands, if required. This may impact on the Trust's capacity to provide elective services.		Letter from the Chief Executive of the Trust confirming that centre will participate in providing surge capacity
C3	**Leadership and Accountability** There must be clear and accountable leadership of the ECMO service within each Centre with a named Director notified to the National Specialised Commissioning Team or its successor. There must be adequate time available to the lead clinician and manager to perform this role.		None Information should form part of the response to Question C1b Job plan and CV for the ECMO Programme Director submitted as evience for Standard B5
C4	**Evidence Based Services/Protocols** There will be evidence based service protocols, which are reviewed and updated regularly covering all aspects of the service. This will include guidance from the Intensive Care Society and Faculty of Intensive Care Medicine on the expert management of severe respiratory failure. These will be available to all new staff joining the service and will form part of a formal induction to the ECMO service.		No response required with regard to protocols (answered in PQQ) Submit Trust policy for induction of new staff and details of ICU process for induction of new staff

Standard	Description	Met Yes / No	Evidence to submit
C5	**Clinical Governance** Providers will meet standard NHS governance requirements. Providers will comply with legislation and statutory guidance to safeguard children and young people (Children Act 1989 and 2004, Working Together to Safeguard Children, 2006). Providers will comply with the legislation and statutory guidance - Protection of Vulnerable Adults.		None Information should form part of the response to Question C1a and C1b
C6	**Workforce Planning** There will be effective and sustainable workforce planning covering all professional disciplines forming part of the multidisciplinary team and succession issues. All staff will have regular appraisal and agreed professional development plans.		Current ICU rotas for senior and junior staff from January–March 2011. Proposed consultant rotas for ECMO service with named individuals Letter from Medical Director confirming plans in place
C7	**Business Conduct** There will be regular business meetings within the Centre to address issues specific to the ECMO. This will include financial reporting, activity reporting, education, audit, and clinical governance and research issues.		None Information should form part of the response to Question C1a
C8	**Resource Use** There will be clear accounting for all income to the Trust that is for the delivery of ECMO services in accordance with the fiscal guidance set out by the National Commissioning Group. This will include finance directly managed by the ECMO service and that, which is managed by the finance infrastructure within the Trust. Methods will be used to ensure there is equitable comparison of costs of the service between the Centres.		A letter from the Director of Finance to confirm that service will submit financial reports and activity reports to the National Specialised Commissioning Team as requested and participates in any review of price change.
C9	**Data Collection** Robust arrangements will be in place for timely and accurate collection of activity and outcome data. Data will be made available to the National Specialised Commissioning Team or its successor under agreed reporting mechanisms.		A letter from the Director of Finance to confirm that agree to data submission to the National Specialised Commissioning Team as per contract

SECTION D – Workforce

(Including the specialist multi-disciplinary team education and training)

Section D: Questions 1-2

D1 Numbers and Grades of Staff

The Bidder must provide evidence, consistent with standards from the Royal Colleges, professional bodies and best practice guidance, that appropriate numbers of staff in the multi-disciplinary team will be in place to provide a safe adult respiratory ECMO Service.

The response should make reference, but not be limited, to:

a. Under normal conditions – 'business as usual' to:
- support the effective delivery of the services
- attract and retain suitably qualified, experienced and competent staff in the numbers required to deliver safe and high quality services
- staff mix
- provide the necessary staff support services
- cover any identified risks and uncertainties including business continuity planning relating to staffing
- support services

The detailed submission of workforce data (whole time equivalents) will be requested and marked in Section 3.

Maximum 2000 words (the use of bullet points is acceptable)
One attachment comprising a maximum of two staffing structure charts may be submitted

Question **D1a Response**

b. In response to fluctuations in demand; either anticipated seasonal variation or in response to a surge demand:
   - support the effective delivery of the local and national ECMO service
   - quantify any additional staff
   - ensure support is available for staff working at a time of surge

Maximum 1000 words (the use of bullet points or a table is acceptable)

Question D1b Response

D2 Training

The Bidder must provide evidence that all clinical staff will be trained in accordance with requirements for the service and competency is maintained.

The response should make reference, but not be limited, to:

a. Training needs for staff in ECMO service:

- Details of ECMO training requirements for each relevant group of staff providing care to adults supported with respiratory ECMO
- How gaps in training will identified
- Plan of proposed training schedule with milestones

Maximum 1500 words (the use of bullet points or a table is acceptable)

Question D2a Response

b.Maintenance of multi-disciplinary team ECMO competencies:

- Training policy/procedures
- Maintenance of skills
- Evidence that training records are maintained
- Supervision of clinical practice

Maximum 1500 words (the use of bullet points is acceptable)

Question D2b Response

Section D: Standards to be met and evidence to be provided

Workforce

Patients are entitled to high quality, safe care which is delivered by an expert workforce, who have specialist knowledge and training and work collaboratively.

Standard	Description	Met Yes / No	Evidence to submit
D1	**The Specialist Multidisciplinary Team (MDT)** Core members of the Specialist MDT will include: named specialist ECMO clinicians, intensivists, cardiothoracic surgeons, perfusionists, ECMO coordinator and ECMO specialist nurses. In addition, the MDT will include, as required, members from physiotherapy, haematology, biochemistry, microbiology, radiology and blood bank. (The composition of the MDT may vary according to the needs of the different aspects of the service e.g. assessment, follow-up, clinico-pathological conferences etc). The attendance and activities of the MDT will be maintained in a register. All MDT members will be invited to take part in clinical governance meetings (held at least quarterly). All medical MDT members will have an annual appraisal.		None Information should form part of the response to Question D1a and D1b No answer required (answered in PQQ)
D2	**Essential staffing levels:** • Consultant Clinician ECMO Programme Director • Three associate ECMO consultants (Programme Director and ECMO consultants act as four ECMO consultants, as a minimum, providing 24-hour cover) • One clinical fellow (minimum) or non-consultant grade support • ECMO Coordinator and deputy • ECMO nurse specialists to provide 1:1 care throughout the course of ECMO. Named additional support personnel from permanent hospital staff 24 hour on-call basis • Clinicians: (cardiology, cardiothoracic surgery,	•	Information on essential staffing levels should form part of the response to Standard B5 and C6 and Question D1a Information on WTE staffing levels should form part of the response to Section 3

Standard	Description	Met Yes / No	Evidence to submit
	general surgery, vascular surgery, cardiovascular perfusion, anaesthetics, neurosurgery, radiology) • Palliative Care • Biomedical engineer • Physiotherapist experienced in intensive care Other clinical staff to be available when needed: • Neurology • Nephrology • OT/physiotherapy • Speech therapy • Rehabilitation • Orthopaedics.		Letter from Chief Operating Officer to confirm 24 hour on call availability of these additional support services.
D3	**Laboratory and other Diagnostic Facilities** Each centre will have access to a 24-hour microbiology (including virology), biochemistry and haematology service. Each centre will have access to prompt provision of blood and blood related products. A comprehensive infection control service will available that complies with HSC2001/002 (*The Management and Control of Hospital Infection*) and has evidence of continual improvement to the meet the NHS Executive Controls Assurance Standard in Infection Control.		Letter from Chief Operating Officer to confirm 24 hour on call availability. Copy of policy on massive haemorrhage Copy of Infection Control Policy
D4	All laboratories will be Clinical Pathology Accreditation (CPA) laboratory accredited. All laboratories will meet the requirements of the Health and Safety Good Practice Guidelines and the Royal College of Pathologists Standards. All laboratories will participate in National External Quality Assurance Schemes.		Copy of current Trust accreditation certificates
D5	Each centre will have access to a range of diagnostic imaging 24 hours a day 7 days a week including cardiac catheterisation, angiography, echocardiography, bronchoscopy, ultrasound and CT scanning. They will also have elective access to MR imaging and radionuclide imaging.		Letter from Chief Operating Officer to confirm 24 hour on call arrangements
D6	Each centre will have full facilities for comprehensive pulmonary function testing. Quality control audits will be available to the MDT.		Letter from Chief Operating Officer to confirm arrangements.

Standard	Description	Met Yes / No	Evidence to submit
D7	**Patient Care:** Each centre will have named (appropriately trained and experienced) specialist nurse/nurse consultants/clinical assistants/ co-ordinators involved in the administration of all aspects of care. These named nurses are members of the MDT. Each centre will have 24 hours a day 7 days a week availability of an ECMO coordinator, consultant and perfusionist in addition to in-house presence of ECMO specialist nurse, perfusionist when required) and medical support. There will be facilities and support for continuing professional development relevant to the programme.		Job description and CV for lead nurse for ECMO service Information should form part of the response to Question D1a and D2. Letter from the Trust Medical Director
D8	Each centre will have a named respiratory physiotherapist and dietician as members of the MDT. These members will facilitate best management of ECMO patients according to their national professional good practice guidelines. The named physiotherapist is responsible for the co-ordination of physiotherapy services to the ECMO patient and supervision of staff in training. There will be a regular weekday 5-day physiotherapy service and an emergency weekend and on-call physiotherapy service.		None Information should form part of the response to Question D1a
D9	Each centre will have at least once-daily consultant led ward rounds of ECMO inpatients.		None Information should form part of the response to Question D1a
D10	There will be weekly MDT meetings to include ECMO coordinator, specialist nurse and consultant to discuss referrals, assessments, ICU and ward patients. A record of MDT attendance will be maintained in hard copy or computerised format.		None Information should form part of the response to Question D1a
D11	Each centre will generate specific patient-centred guidelines and protocols of care. These must take account of relevant guidance from the Intensive Care Society and Faculty of Intensive Care Medicine on the expert management of severe respiratory failure including evidence of a multidisciplinary weaning strategy.		None Information should form part of the response to Question D1a

Standard	Description	Met Yes / No	Evidence to submit
D12	Each centre will have access to secretarial support to provide a clinical summary to accompany patients back to the referring hospital and a discharge summary despatched to GPs within a 48 hour period (two working days).		Letter from Chief Operating Officer
D13	Each centre will have adequate dedicated accommodation for: ECMO specialist nurses/ co-ordinators, patient files, secretarial support, data clerk support and MDT meetings.		Letter from Chief Operating Officer

Education and training

Patients will be cared for by a specialised multidisciplinary team who are deemed competent to provide respiratory ECMO which is a complex, high risk specialist intervention.

Standard	Description	Met Yes / No	Evidence to submit
D14	Each ECMO centre will have access to a well-defined programme for staff training, certification and re-certification.		None Information should form part of the response to Question D2
D15	An ECMO specialist will have: • a perfusion, medical or nursing qualification • a strong critical care background • satisfactorily completed a specialist course in adult ECMO including a period of specific training in an established ECMO centre. The ECMO consultant **must** be a specialist prior to taking up appointment		None Information should form part of the response to Question D2
D16	ECMO consultants will have undergone sufficient practical & theoretical training to be deemed competent by two ECMO consultants (at least one of whom must be from another ECMO centre). An ECMO Consultant must also be qualified as an ECMO specialist.		None Information should form part of the response to Question D2
D17	An ECMO nurse specialist will have undergone training to manage the ECMO system and the clinical needs of the patient on ECMO under the direction of an ECMO consultant and co-ordinator.		None Information should form part of the response to Question D2
D18	All staff involved in the care of ECMO patients (medical and nursing) will receive training on the basic principles of ECMO		None Information should form part of the response to Question D2
D19	Continuing education/professional development will include: • formal team meetings every two months • six-monthly specialist meetings • water drills: • dummy circuit once a month (plus one working shift a month) reduced to once every six months after experience of thirty cases • minimum hours of pump time (12 hours per month) • and /or simulation training equivalent to pump time.		None Information should form part of the response to Question D2

SECTION E – Facilities

(Including physical facilities and equipment)

Section E: Questions 1-3

E1 Flexibility of facilities

The Bidder must demonstrate that the proposed facilities are adaptable to the potential changes to demand outlined in the service specification and to normal fluxes in activity.

The response should make reference, but not be limited, to:

- Physical location of ECMO service
- Flexibility of facilities taking account of changes in activity and potential need for isolation
- Effective working practice including location of other specialities

Maximum 1500 words (the use of bullet points is acceptable)
One A4 attachment of the layout plan of the intensive care unit may be

Question E1 Response

E2 Equipment

The bidder must describe their arrangements for ensuring that the specialist technical equipment required for ECMO will be available at the date of service commencement.

The response should make reference, but not be limited, to:

- Details of proposed ECMO circuit including pump and oxygenator
- Details of other equipment
- Continuity plans on management of stock including under surge conditions
- Maintenance of equipment

Maximum 1000 words (the use of bullet points is acceptable)

Question E2 Response

E3 New Technology

The Bidder must demonstrate how they apply appropriate new technologies or innovative practice to the management of patients with severe respiratory failure, to improve patient outcomes, including but not limited to ECMO.

The response should make reference, but not be limited, to:

- Specific examples of new technologies or innovative practice that are used in the management of patients with severe respiratory failure
- Improving outcomes of patients
- Horizon scanning

Maximum 1000 words (the use of bullet points is acceptable)

Question E3 Response

Section E: Standards to be met and evidence to be provided

Patients will be cared for in a tertiary level ICU which has the specialist technical equipment and skills necessary for the expert care of patients with acute severe respiratory failure.

Facilities and Equipment

Standard	Description	Met Yes / No	Evidence to submit
E1	ECMO will be conducted within a tertiary ICU which has expertise in the specialist management of patients with acute respiratory failure including technologies and skills such as high frequency oscillatory ventilation and the management of bronchopleural fistulae.		No answer required (answered in PQQ)
E2	The ECMO system consists of a suitable blood pump, a system to balance venous drainage rate from the patient and blood return to the patient, an appropriate blood heat exchanger and warming unit, appropriate disposable materials including membrane oxygenator tubing packs, and connectors, all suitable for prolonged extracorporeal support. All equipment must be CE marked.		Information should form part of the response to Question E2 Letter from Chief Operating Officer that appropriate equipment will be in place by date of service commencing
E3	A device for monitoring the level of anticoagulation with appropriate supplies will available in the ICU. There will be identified 24-hour access to haematology laboratory support.		Letter from Chief Operating Officer appropriate devices and supplies in place by date of service commencing Information should form part of the response to Standard D3
E4	The following equipment will be readily available: • Back up components of the ECMO system and supplies for all circuit components • Adequate lighting to support surgical interventions • Surgical instrument set for revision of cannulae or exploration for bleeding complications.		Letter from Chief Operating Officer that appropriate devices and supplies in place by date of service commencing

SECTION F – Quality of care

Section F: Questions 1

F1 Quality Outcomes

The Bidder must demonstrate that ECMO care is focused on high quality outcomes and describe how this will be achieved.

The response should make reference, but not be limited, to:

a. Describing high quality outcomes including:
   - An outline description of what the Bidder considers high quality outcomes for the ECMO service
   - Healthcare Associated Infection surveillance and outcomes
   - Longer term outcomes including arrangements for follow up

Maximum 1500 words (the use of bullet points is acceptable)

Question F1a Response

b. Developing a high quality ECMO service:
    - How the Bidder proposes to ensure the quality of care in relation to this service
    - How the Bidder currently delivers or intends to deliver internationally comparable outcomes for adults receiving respiratory ECMO and critical care
    - Systems which will be in place to monitor quality of care
    - How the Bidder drives continuous improvement across the national service

Maximum 1500 words(the use of bullet points is acceptable)

Question F1b Response

Section F: Standards to be met and evidence to be provided

Quality of Care

The service will be actively reviewing and, where necessary, improving the service delivery and clinical outcomes. Clinical audit is a quality improvement process that aims to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change.

Standard	Description	Met Yes / No	Evidence to submit
F1	Each centre will be actively involved in the Extracorporeal Life Support Organisation (ELSO) including participation in the Central Registry, submitting data according to ELSO guidelines.		Letter from the Medical Director to confirm membership of ELSO or intention to join ELSO.
F2	Centres must collaborate and participate with all other national providers of adult ECMO in joint audit and service development.		Letter from the Medical Director to confirm that the provider will participate in regular national meetings and national audit projects, including the Annual meeting and the Annual ECMO Forum.
F3	The ECMO Audit full year report will incorporate time period and cumulative data on patients assessed for ECMO as well as data on outcomes.		Letter from the Medical Director to submit reports to the National Specialised Commissioning Team
F4	Each centre will have a robust internal database and outcome monitoring tool. The ICU must participate in the Intensive Care National Audit and Research Centre's (ICNARC) Case Mix Programme or report outcome data from the internal database.		No answer required (answered in PQQ)
F5	Each centre will hold clinico-pathological conferences to discuss all deaths and other cases of interest (minimum quarterly).		Minutes of last ICU M&M / clinic pathological meeting and dates for the annual programme

SECTION G – Transport and Retrieval of Patients

Section G: Questions 1-2

G1 Retrieval

Bidders are required to describe the proposed transport arrangements that will deliver the requirements of the Service Specification (see Appendix 1) and the Standards (see Appendix 2) . Bidders must also provide evidence to demonstrate how this model will achieve the objectives outlined in the Service Specification. Services that do not currently have a mobile ECMO capability will be required to agree interim arrangements for a maximum of 12 months from commencement of service. Services that currently have a mobile ECMO capability will be expected to agree interim arrangements for a maximum of 12 months with those that do not have this capability.

The response should make reference, but not be limited, to:

a. Retrieval arrangements:
   - Transport team members
   - Proposed on call arrangements including maximum muster time
   - Protocol based on best practice gudance
   - Documentation arrangements
   - Transport arrangements including links to ambulance trusts / air ambulance
   - Sharing best practice / innovation

Maximum 2000 words(the use of bullet points is acceptable)

Question G1a Response