Standard	Description
	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.
2.8	Each centre will have a named 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 7-day physiotherapy service .
2.9	Each centre will have at least twice-daily consultant led ward rounds of ECMO inpatients.
2.10	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.
2.11	Each centre will generate specific patient-centred guidelines and protocols of care. These must take account of relevant guidance including from the Intensive Care Society ,Faculty of Intensive Care Medicine and ELSO on the expert management of severe respiratory failure including evidence of a multidisciplinary weaning strategy.
2.12	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 two working days.
2.13	Each centre will have adequate dedicated accommodation for: ECMO specialist nurses/ co-ordinators, patient files, secretarial support, data clerk support and MDT meetings.

Standard 3 Physical Facilities/Equipment

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.

Standard	Description
3.1	ECMO will be conducted within a tertiary ICU which has expertise in the specialist management of patients with acute respiratory failure using relevant therapies and the management of bronchopleural fistulae.
3.2	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
3.3	A device for monitoring the level of anticoagulation with appropriate supplies will available. There will be identified 24-hour access to haematology laboratory support.
3.4	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.

Standard 4: ECMO Care Pathway – including access, assessment and post ECMO support

Patients are entitled to high quality, safe and expert care at all stages of the care pathway.

Standard	Description
4.1	Patients with potentially reversible severe respiratory failure referred for ECMO will be assessed by a specialist ECMO clinician.
4.2	The ECMO clinician will work as part of a multidisciplinary team including critical care specialists. The ECMO clinician must have training and experience obtained at an ECMO centre in which he/she had personal experience of caring for patients receiving ECMO support. Other participating physicians, surgeons and non-physician staff will have knowledge in and experience of, the care of ECMO patients.
4.3	Patient care will be provided within an ICU which is a respiratory failure specialist management centre (as defined by the Faculty of Intensive Care Medicine) and is part of the local critical care network.
4.4	Cardiothoracic surgery must be co-located and the service available 24 hours a day, seven days a week.
4.5	Decisions on referrals will be made within one hour and patients managed within a period of time consistent with clinical urgency.
4.6	The ECMO Centre will participate with other centres in a National Network to cope with fluctuating demand and to ensure that referred patients have access to ECMO.
4.7	Assessment will be based on the set of agreed objective referral criteria for the service. The referral criteria are based on the CESAR physiological eligibility criteria. Providers who wish to accept a referral outside the agreed criteria are expected to discuss the case with a minimum of one other centre. These cases will be discussed at annual meeting where all centres are expected to be represented. Referral data will be clearly recorded in a proforma which will available at the multidisciplinary assessment meeting and filed in the patients notes.
4.8	Follow up by physicians with expertise in ECMO (with support available from members of the MDT) will be provided to patients when requested by local clinicians.Follow up discharge summary and recommendations will be sent to general practitioners and to referring physicians.

	Follow up by physicians with expertise in ECMO (with support available from members of the MDT) will be provided to patients when requested by local clinicians.

Standard 5: Retrieval of Patients

Patients accepted by the ECMO service must be retrieved from the referring hospital in a safe and timely manner by a specialist retrieval team who are deemed competent in transporting critically sick patients.

Standard	Description
5.1	Providers must have the capacity to retrieve patients safely from referring hospitals to the receiving ECMO centre. Except in exceptional circumstances, the ECMO centre will retrieve all patients who are accepted for treatment / consideration of ECMO.
5.2	The transport team will include at least a consultant and nurse specialist/doctor/perfusionist who have been deemed competent in the transport of critically ill patients.
5.3	Centres will demonstrate links with ambulance providers who will be partners in the service.
5.4	Retrieval teams will document informed assent.
5.5	There will be documentation of the entire procedure.
5.6	Centres will be able to provide safe mobile ECMO for patients who are clinically eligible. This must be undertaken in the same time frame as a standard conventional transfer. It is recommended that a perfusionist form part of the transfer team when mobile ECMO is proposed
5.7	Transport and transfer of patients will be a standing agenda item at the annual all-centre meeting.
5.8	Centres will make arrangements for the safe repatriation of patients from the ECMO centre to an appropriate hospital near their home.
5.9	The ECMO service requires timely access to both fixed and rotary wing air ambulance. Aircraft must be of sufficient size to transport the ECMO team and provide ease of access for the patient. It must be equipped with suitable facilities for safe mounting and storage of essential equipment. The decision to transfer by air must be made on clinical need but must also take account of any geographical factors.

Standard 6: 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
6.1	Each ECMO centre will have access to a well-defined programme for staff training, certification and re-certification.
6.2	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.
6.3	ECMO consultants will have undergone sufficient practical & theoretical training to be deemed competent by two ECMO consultants (one of whom may be from another ECMO centre). An ECMO Consultant must also be qualified as an ECMO specialist.
6.4	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.
6.5	Continuing education/professional development will include: • formal team meetings every two months • training and assessment on dummy circuit at least once per year • minimum 24 hours of ECMO patient care every 3 months • simulation training.

Standard 7: Research and Development

Research and development is necessary:

- to ensure practice is based on reliable evidence of needs and of what works best to meet those needs
- to improve the quality, access and efficiency of the service and enable service development.

Standard	Description
7.1	**Research Strategy** Each centre to have and regularly update an ECMO Research Strategy and Programme which documents the current and planned activity, the resources needed to support activity in terms of staffing and objectives for development.
7.2	**Research Governance** Evidence of compliance with research governance requirements: • systems are in place to ensure that an appropriate member of staff is notified of, and has approved, all research in the organisation • systems are in place to ensure all ongoing research has ethics committee approval • arrangements are in place to ensure that an identified individual is responsible for making sure that informed consent and procedures in the protocol approved by the ethics committee are being adhered to. Evidence of compliance with the Mental Capacity Act 2005 which provides safeguards for a person who lacks capacity to consent to research.
7.3	**Research Outputs and Outcomes** Regular participation in national and international ECMO conferences.
7.4	ECMO-related peer-reviewed publications will be reported annually to NHS England or its successor.
7.5	Clinical practice is informed by regular review of research evidence derived from local, national or international research activity.

Standard 8: Wider Networks

The provision of care for this group of patients will be improved by locating ECMO services in a tertiary intensive care unit which has expertise in the specialist management of acute respiratory failure and is part of the wider critical care network.

Standard	Description
8.1	Referring physicians must receive adequate feedback for patients not accepted by the ECMO centres with clear reasons for declining the referral.
8.2	Hospital doctors and other health care professionals at the repatriating hospital, with questions about any aspect of post-ECMO care will be able to contact the ECMO team for advice. A member of the ECMO team (the ECMO Director, the duty ECMO consultant, or co-ordinator) needs to be available 24 hours, 7 days a week to receive calls about patients.
8.3	Centres will identify themselves as part of the local critical care network and with other relevant networks in the future; for example the Faculty of Intensive Care Medicine proposed acute respiratory failure network.
8.4	Centres will collaborate with other national providers of adult respiratory ECMO to minimise potential delays in patients accessing respiratory ECMO care and to share best practice.

Standard 9: Management and Organisation of Adult Respiratory ECMO Programmes

Effective organisation and strong clinical leadership of the adult respiratory ECMO programme is central to ensure the quality and safety of care being provided and to deliver 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.

Standard	Description
9.1	Nationally designated ECMO centres will be located in a tertiary level intensive care unit which has expertise in the specialist management of critically ill patients with severe respiratory failure and is part of the local critical care network.
9.2	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.
9.3	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.
9.4	**Leadership and Accountability** There must be clear and accountable leadership of the ECMO service within each Centre with a named Director notified to the NHS England or its successor. There must be adequate time available to the lead clinician and manager to perform this role.
9.5	**Lead Clinician and Manager Responsibilities** The ECMO director, who is accountable for governance issues, will have overall responsibility for ensuring staff are fully aware of the standards against which centres will be assessed and that mechanisms are in place to achieve compliance with the standards. Other responsibilities will include: • To take part in the Trust's clinical governance activities, which are of relevance to the ECMO service. • To ensure effective communication with all members of the ECMO service and to facilitate multidisciplinary team working in the delivery of ECMO services. • To meet regularly with colleagues from other ECMO Centres and with the NHS England to address regional and national service delivery issues.

9.6	**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 relevant professional organisations including 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.
9.7	**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).
9.8	**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.
9.9	**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.
9.10	**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 NHS England. 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.
9.11	**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 NHS England or its successor under agreed reporting mechanisms.

Standard 10: Audit

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. The service will be actively reviewing and, where necessary, improving the service delivery and clinical outcomes.

Standard	Description
10.1	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.
10.2	Centres must collaborate and participate with all other national providers of adult ECMO in joint audit and service development.
10.3	The ECMO Audit full year report will incorporate time period and cumulative data on patients assessed for ECMO as well as data on outcomes.
10.4	Each centre will have a robust internal database and outcome monitoring tool. The ICU must participate in the agreed national Critical Care data reporting system (when established) and until then report outcome data from their internal database or to ICNARC.
10.5	Each centre will hold clinico-pathological conferences to discuss all deaths and other cases of interest (minimum quarterly).

Appendix Two

Quality standards specific to the service using the following template:

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
Domain 1: Preventing people dying prematurely			
Participation in the Extracorporeal Life Support Organisation (ELSO) database which provides bench-marked outcomes including survival and suite of morbidity measures	Bench marking in existence	ELSO database	
Measurement of numbers of patients who are not accepted for ECMO due to lack of capacity (expressed as % of referred patients).	Data not available yet	Prospective Audit	
Referring critical care units (or appropriate designated unit in local Adult Critical Care ODN) to receive back their patients within 48hours of decision to repatriate by the ECMO centre.	Data not available yet	ICNARC Case Mix Programme	
Domain 2: Enhancing the quality of life of people with long-term conditions			
Assessment of long term outcome measures following ECMO eg Quality of Life between 3 and 12 months after ECMO.	Data not available yet	Prospective data audit	

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
Domain 3: Helping people to recover from episodes of ill-health or following injury			
Participation in the Extracorporeal Life Support Organisation (ELSO) database which provides bench-marked outcomes including survival and suite of morbidity measures	Bench marking in existence	ELSO database	
Domain 4; Helping people have a positive experience of care			
Assessment of long term outcome measures following ECMO eg Quality of Life between 3 and 12 months after ECMO.	Data not available yet	Prospective Audit	
Domain 5: Treating and caring for people in a safe environment and protecting them from avoidable harm			
Participation in the Extracorporeal Life Support Organisation (ELSO) database which provides bench-marked outcomes including survival and suite of morbidity measures	Benchmarking already in existence for survival and suite of morbidity.	ELSO database	
Compliance with tidal volume below 6ml/kg.	Data not available yet	Prospective Audit	

Appendix 3 – Service Peer Review Arrangements

Peer review process will be:
1 Attendance and submission of activity and outcome data to the biannual ECMO centre meetings
2 Review visit by another ECMO centre annually. Visit to include:
Visiting team of at least one consultant, senior ECMO specialist nurse, perfusionist and manager
Standard agenda
ICU visit, including meeting ECMO staff
Review of ECMO centre portfolio (staff / activity / outcomes / quality metrics / ACEs / complaints / audits / research).
Review of centre self assessment against the service standards (appendix 2), carried out using the assessment template example below:

Standard	Description	Comments	Status
1.1	Example standard 1	Very good	
1.2	Example standard 2	Work in progress	
1.3	Example standard 3	Needs putting in place	

Visiting centre will provide a report to the visited centre and commissioners using standardised format. Visited centre will be given opportunity to review report and respond to inaccuracies etc before final sign off.

Suggested timetable for peer review visits:

Year	*13/14*	*14/15*	*15/16*	*16/17*
Visiting	*Visited*	*Visited*	*Visited*	*Visited*
G&ST	Papworth	Brompton	UHSM	Glenfield
UHSM	Brompton	G&ST	Glenfield	Papworth
Glenfield	G&ST	UHSM	Papworth	Brompton
Papworth	UHSM	Glenfield	Brompton	G&ST
Brompton	Glenfield	Papworth	G&ST	UHSM

NHS

Specialised Services

Invitation to Tender for Adults with Potentially Reversible Severe Respiratory Failure

VOLUME 1

25 July 2011

TABLE OF CONTENTS

1. INTRODUCTION AND OVERVIEW

1.1 Background and Context

Invitation to Submit Bids

These Instructions to Bidders form Volume 1 of the Invitation to Tender (the ITT) issued by NHS London on behalf of the National Specialised Commissioning Team (NSCT) to seek proposals for the provision of a range of services for Adults with Potentially Reversible Severe Respiratory Failure, **as more particularly described in Volume 2 of this Invitation to Tender.**

The procurement is for Part B Services and the NSCT is not bound to follow the Regulations in their entirety. However, this Procurement will follow the Restricted Procedure. The NSCT may deviate from the selected procedure.

Violation of the terms of this ITT by any Bidder may result in the NSCT disqualifying that Bidder from the procurement.

Bids will only be considered from the Bidders pre-selected by the NSCT based on:

- the advertisement published via Supply2Health on 14th June 2011 (reference CP2/11/0054) and
- the Pre-Qualification Questionnaire (the **PQQ**) submitted by those Bidders in response to the advertisement issued by the NSCT on the 14th June 2011.

1.2 Objectives of the Procurement

The key objectives of the Procurement are defined in Volume 2 of this ITT.

1.3 Disclaimers

The information contained in this ITT is presented in good faith and does not purport to have been independently verified.

Interested parties and their advisers must therefore take their own steps to verify the accuracy of any information that they consider relevant (see 3.3 Bidder due diligence and clarification periods).

The NSCT shall not be obliged to appoint any of the Bidders and reserves the right not to proceed with the Procurement, or any part thereof, at any time. Nothing in this ITT should be interpreted as a commitment to award the Procurement.

Nothing in this ITT is, nor shall be relied upon as, a promise or representation as to any decision by the NSCT in relation to the Procurement. No person has been authorised by the NSCT or its advisers or consultants to give any information or make any representation not contained in this ITT and, if given or made, any such information or representation (express or implied) shall not be relied upon as having been so authorised.

Nothing in this ITT or any other pre-contractual documentation shall constitute the basis of an express or implied contract that may be concluded in relation to the Procurement, nor shall such documentation/information be used in construing any such contract. Each Bidder must rely on the terms and conditions contained in any contract when, and if, finally executed, subject to such limitations and restrictions that may be specified in such contract. No such contract will contain any representation or warranty (express or implied) in respect of the ITT or other pre-contract documentation.

In this section, references to this ITT include all information contained in it and any other information (whether written, oral or in machine-readable form) or opinions made available

by or on behalf of the NSCT or any of their advisers or consultants in connection with this ITT or any other pre-contract documentation.

2. PURPOSE, STRUCTURE AND GENERAL PROVISIONS

2.1 Purpose

The purpose of the ITT is to provide Bidders with information on the Procurement and the requirements of the NSCT to enable them to compile a comprehensive Bid that meets the requirements set out in this ITT.

In summary, this ITT:

- requests detailed proposals from Bidders for the delivery of the Services;
- sets out the instructions for submitting a Bid;
- sets out the key assumptions and constraints which each Bidder is required to take into account when submitting a Bid;
- provides detailed information in relation to the Bid Requirements;
- sets out the framework and information requirements within which the Bids are to be made;
- sets out the evaluation approach which will be applied to each Bid to assist the NSCT in selecting a Provider; and
- outlines the timeframe within which the selection process will take place.

Some elements of the PQQ may require due diligence, for example the NSCT may review any new financial information such as published audited accounts or other such information that is in the public domain since the submission of PQQ responses.

Other than where specifically stated, the ITT supersedes all previous published documentation relating to the Procurement (including the MOI and the PQQ) and should be read as a stand-alone document. In evaluating Bids from Bidders, the NSCT will only consider information provided in response to the ITT.

2.2 Structure of the ITT

The ITT consists of the following documents:

- Volume 1 – These Instructions to Bidders (an introduction to, and overview of, the Procurement, a list of the NSCT's procurement rules that all Bidders must comply with, instructions on completing the Bid Requirements);
- Volume 2 – Bid Requirements (a list of the administrative, technical commercial and financial Bid Requirements along with detailed background information on all aspects of the Procurement for Bidders to consider when responding to the ITT);
- Volume 3 – The Contract and associated Variation Agreement (the contract to be signed by the NSCT and the Provider);

2.3 Bidder Due diligence information

Throughout the tendering process and as part of the Bidder due diligence process, the NSCT may publish additional information using the Bravo e-Tendering portal.

For the avoidance of doubt, **all** correspondence will be issued and received utilising the Bravo e-Tendering portal.

The Bravo tool can be accessed by logging onto:

https://www.pctalliance.bravosolution.co.uk

3. PROCUREMENT PROCESS

3.1 Overview and Timetable

This Section provides an overview of the remainder of the Procurement. Table 1 below sets out a summary of the Procurement and an indicative timetable. More detail on the Procurement is provided in Sections 0 to 0 below.

Bidders are reminded that the NSCT may vary the Procurement in order to support continued competition, avoid unnecessary costs associated with a Bid and adhere to technical, legal or commercial guidance issued subsequent to the ITT, as set out in Section 0. However, as stated, this procurement will follow the negotiated procedure.

Stage	Description	Due Date
ITT issued to Bidders	ITT issued to Bidders who were short-listed following the PQQ evaluation.	25th July 2011
ITT Bidder Clarification period ends	Deadline by which Bidders must have submitted any clarification questions	8th August 2011
Bid Deadline	Final date and time for submission of Bids.	Midday on 15th August 2011
ITT Bid Evaluation Stage	Period during which the Bids will be evaluated. During this period, NSCT may require Bidders to clarify information set out in their Bids. Bidders will then be invited to a Panel interview with a short presentation.	17th – 24th August 2011
Stakeholder Evaluation Panel Event	The date that Bidders will be interviewed and invited to give a presentation.	30th – 31st August 2011
Selection of Preferred Bidders	The date by which NSCT will aim to select Bidders to proceed to Preferred Bidder stage.	31st August 2011
AGNSS Meeting	**AGNSS meeting to consider Panel recommendation**	26 September
AGNSS Recommendation	**AGNSS recommendation forwarded for Ministerial approval**	27 September

Stage	Description	Due Date
Notice of award decision	The NSCT informs the following of its decision in relation to the proposed award of the contract: (a) any entity who submitted a Bid; and (b) any entity who applied to be amongst those selected to tender.	Tbc - Dependant upon response from Ministers
10 Day Standstill Period	Period during which unsuccessful Bidders have the opportunity to obtain more information on the proposed award of the contract.	Tbc
Contract award	The signature of the Contract between the NSCT and the Provider.	Tbc

Table 1: Procurement Summary and Indicative Timetable

3.2 Confirmation of Receipt of ITT

Bidders do not need to confirm receipt of the ITT, as the Bravo e-tendering portal keeps a fully auditable record of when the ITT is accessed and downloaded by the Bidder.

3.3 ITT Bidder due diligence and clarification periods

Due Diligence

Each Bidder is expected to examine carefully each volume of the ITT, including information that is published on Bravo and to conduct such further due diligence review of information or investigation, as it considers necessary before submitting a Bid. By submitting a Bid, each Bidder will be deemed to have made such examination and to have satisfied itself as to the conditions to be encountered in providing the Services under the Contract.

Clarification

The objective of the ITT Bidder clarification period is to give Bidders the opportunity to submit questions to the NSCT where they require clarification on the information contained in the ITT or otherwise provided by the NSCT or received by the Bidder.

Important Note: The NSCT will not respond to clarification questions received after the date specified in Table 1 above.

Bidders must submit clarifications questions on the ITT Clarification Question Template provided at **Annex B to this ITT Volume 1**.

Each completed ITT Clarification Question Template should be submitted via the Bravo portal by logging on to: https://www.pctalliance.bravosolution.co.uk . The NSCT will endeavour to respond to each clarification question received during the ITT Bidder clarification stage within 3 business days of receipt. Subject to the following paragraph on confidentiality of clarification questions, the NSCT will anonymously distribute **all** clarification questions raised by Bidders, and corresponding responses from the NSCT, to all other Bidders on a rolling basis during the ITT Bidder clarification stage.

Confidentiality of Clarification Questions

Where Bidders consider that a clarification question and/or the response to such question is commercially confidential, that request must be indicated "Commercial in Confidence"