

**Children's Medical Services (CMS)  
Regional Perinatal Intensive Care Center (RPICC)  
Neonatal Extracorporeal Life Support (ECLS) Centers  
Questionnaire**

Date: \_\_\_\_\_

RPICC Facility: \_\_\_\_\_

<i>CMS use only</i>	<b>Include the following information with the ECLS questionnaire: (*Or make available at the time of the on-site visit.)</b>
	Identification of all ECLS program staff, their roles, and copies of their board certification.
	A list of staff educational opportunities in the last twelve months.
	A listing of both pediatric and neonatal patients (by initials if private and name if RPICC) and hospital/medical record number who were enrolled in the ECLS program in the last twelve months including name, DOB, diagnoses and patient status, including an indication of the active involvement of the Early Intervention Program.
	Current patient selection criteria.
	Most recent report submitted to ELSO.
	Staffing report of the ECLS staff for last three patients on ECLS.
	Quality assurance review procedures for multi-disciplinary ECLS team.
	Formal policy and procedures outlining the indications and contraindications for ECLS clinical management of the ECLS patient, maintenance of equipment, termination of ECLS therapy, and follow-up of the ECLS patient.
	ECLS CMS neonatologist 24-hour in-house schedule for ECLS neonatal patients during procedures.
	ECLS-trained physician 24-hour on-call schedule for ECLS neonatal patients during procedures.
	The list of additional support personnel from the permanent hospital staff available on a 24-hour/day on-call basis such as physicians, biomedical engineer, respiratory therapists, and consultants skilled in nephrology, occupational/physical therapist, and development specialist.
	Protocols, staff training, and list of staff for transport of patients who need ECLS services.

**Comments (put comments for the on-site review team here):**

Please answer as appropriate. To be completed by existing CMS RPICC approved ECLS Center or hospitals requesting CMS RPICC approval to provide ECLS services. All standards are subject to inspection by the on-site reviewers.

	Yes	No	<i>Provide explanation for all no responses or use this area to provide comments in this section when requested:</i>
1. The neonatal ECLS center is located in a geographic area that can support a minimum of 12 ECLS pediatric and neonatal patients per center per year.	<input type="checkbox"/>	<input type="checkbox"/>	Provide number for both neonatal and pediatric ECLS patients served in the last twelve months Number of neonatal patients: Number of pediatric patients:
2. The neonatal ECLS center is actively involved in the Extracorporeal Life Support Organization (ELSO) including participating in the Central Registry.	<input type="checkbox"/>	<input type="checkbox"/>	Provide date of last report submitted to ELSO:
<b>Organization:</b>	<i>Yes</i>	<i>No</i>	<i>Provide explanation for all no responses or provide additional comments in this section:</i>
<b>A. General Structure:</b>			
3. Name of the ECLS program director with responsibility for the overall operation of the center who is a CMS physician provider.			
4. Name of pediatric surgeon in the neonatal ECLS center who is a CMS physician provider.			
5. Name of pediatric cardiologist in the neonatal ECLS center who is a CMS physician provider.			
6. Name of ECLS coordinator with responsibility for the supervision and training of the technical staff, maintenance of equipment, and collection of patient data.			
7. The neonatal ECLS center has quality assurance review procedures for multi-disciplinary ECLS team.	<input type="checkbox"/>	<input type="checkbox"/>	
8. The neonatal ECLS center has formal policy and procedures outlining the indications and contraindications for ECLS clinical management of the ECLS patient, maintenance of equipment,	<input type="checkbox"/>	<input type="checkbox"/>	

	<i>Yes</i>	<i>No</i>	<i>Provide explanation for all no responses or use this area to provide comments in this section when requested:</i>
termination of ECLS therapy, and follow-up of the ECLS patient.			
9. The neonatal ECLS center has appropriate laboratory space for training and continuing medical education.	<input type="checkbox"/>	<input type="checkbox"/>	
10. The neonatal ECLS center submits a neonatal morbidity of ECLS patients in a format designated by CMS.	<input type="checkbox"/>	<input type="checkbox"/>	
11. The director of the neonatal ECLS program submits an annual summary report in the format required by CMS.	<input type="checkbox"/>	<input type="checkbox"/>	
<b>B. Staffing Issues:</b>	<i>Yes</i>	<i>No</i>	<i>Provide explanation for all no responses or provide additional comments in this section:</i>
12. The ECLS staff meets the requirements of their subspecialty training.	<input type="checkbox"/>	<input type="checkbox"/>	
13. The ECLS program medical director is a board certified neonatologist, a board certified critical care specialist, or a board certified pediatric, cardiovascular, or thoracic surgeon and is also a CMS physician provider.	<input type="checkbox"/>	<input type="checkbox"/>	
14. The ECLS coordinator is an experienced neonatal or pediatric intensive care registered nurse or registered respiratory therapist with a strong NICU background or a certified clinical perfusionist with neonatal experience.	<input type="checkbox"/>	<input type="checkbox"/>	Provide name and title of ECLS Coordinator:
15. An ECLS-trained physician provides 24-hour, 7 days a week, in-house coverage medical coverage for ECLS patients during ECLS procedures who is a CMS physician provider. (Neonatologist, pediatric critical care specialist, neonatology or critical care fellow, or physician)	<input type="checkbox"/>	<input type="checkbox"/>	
16. An ECLS clinical specialist provides 1:1 or 1:2 care throughout the course of ECLS.	<input type="checkbox"/>	<input type="checkbox"/>	
17. The ECLS specialist has a strong intensive care background and meets board certification from one of the following: Board of Nursing, National Board of Respiratory Care, American Board of	<input type="checkbox"/>	<input type="checkbox"/>	

	<i>Yes</i>	<i>No</i>	<i>Provide explanation for all no responses or use this area to provide comments in this section when requested:</i>
Cardiovascular Perfusion or a physician who meets the training requirements.			
18. In addition to the ECLS specialist, a NICU nurse with neonatal intensive care nursing experience provides 1:1 or 1:2 care throughout the course of ECLS.	<input type="checkbox"/>	<input type="checkbox"/>	
19. Physicians or other medical personnel who routinely care for pediatrics or neonates are available from the following disciplines: cardiology, cardiovascular surgery, surgery, cardiovascular perfusion, neonatal anesthesia, neurology, neurosurgery, radiology, genetics, and nephrology.	<input type="checkbox"/>	<input type="checkbox"/>	
20. Additional support personnel from the permanent hospital staff should be available on a 24-hour/day on-call basis such as biomedical engineer, social services, psychology, respiratory therapists, occupational/physical therapist, development specialist, and pastoral care.	<input type="checkbox"/>	<input type="checkbox"/>	
21. A fully trained neonatal transport team that meets the requirements of 64E-2 and 64C-6 is available 24-hours a day.	<input type="checkbox"/>	<input type="checkbox"/>	
<b>C. Physical Facilities and Equipment:</b>	<i>Yes</i>	<i>No</i>	<i>Provide explanation for all no responses or provide additional comments in this section:</i>
22. The space allocated for ECLS is located inside the NICU unit.	<input type="checkbox"/>	<input type="checkbox"/>	
23. The ECLS system consists of a suitable blood pump, a system for servo-regulation to balance venous drainage rate from the patient and blood return to the patient, an appropriate heat exchanger and warming unit, appropriate disposable materials including membrane oxygenator tubing packs, and connectors.	<input type="checkbox"/>	<input type="checkbox"/>	Provide type and specifications:
24. An activated clotting time device with appropriate supplies is at the bedside. Provide type and specifications of the equipment used in the ECLS system.	<input type="checkbox"/>	<input type="checkbox"/>	

	<i>Yes</i>	<i>No</i>	<i>Provide explanation for all no responses or use this area to provide comments in this section when requested:</i>
25. The following support services with staff is available on a 24 hour basis: radiographic support including cranial ultrasound, CAT scan, and MRI.	<input type="checkbox"/>	<input type="checkbox"/>	
26. The neonatal ECLS center must be a CMS approved Class III Pediatric Cardiovascular Surgical facility with the a cardiovascular operating room available 24 hours a day with cardiopulmonary bypass capabilities that has readily accessible echocardiography, EKG with printout capability, and a defibrillator.	<input type="checkbox"/>	<input type="checkbox"/>	
27. The following support facilities with staff is available on a 24 hour basis: blood gas laboratory, laboratory for blood chemistry and hematologic testing, blood bank, radiographic support including cranial ultrasound and CAT scan, and cardiovascular operating room facilities with cardiopulmonary bypass capabilities located within the hospital doing ECLS and is available 24 hours a day.	<input type="checkbox"/>	<input type="checkbox"/>	
<b>D. Each ECLS patient station in the RPICC Level III unit contains the following minimum requirements:</b>	<i>Yes</i>	<i>No</i>	<i>Provide explanation for all no responses or provide additional comments in this section:</i>
28. At least 100 square feet per infant.	<input type="checkbox"/>	<input type="checkbox"/>	
29. Not less than 2 wall mounted suction outlets equipped with an alarm to signal loss of vacuum.	<input type="checkbox"/>	<input type="checkbox"/>	
30. Not less than 16 electrical outlets, including provision for emergency operation and a non-interruptible backup power source for all monitoring equipment.	<input type="checkbox"/>	<input type="checkbox"/>	
31. Not less than 2 oxygen outlets and an equal number of compressed air outlets with adequate provision for mixing of these gases.	<input type="checkbox"/>	<input type="checkbox"/>	
32. Provision for administration and monitoring inline of nitric oxide (NO) administration.	<input type="checkbox"/>	<input type="checkbox"/>	
33. Conventional and High Frequency Oscillatory Ventilator (HFOV) or High Frequency Jet Ventilator (HFJV0).	<input type="checkbox"/>	<input type="checkbox"/>	

	<i>Yes</i>	<i>No</i>	<i>Provide explanation for all no responses or use this area to provide comments in this section when requested:</i>
34. Radiant warmer.	<input type="checkbox"/>	<input type="checkbox"/>	
35. Oxygen saturation monitor.	<input type="checkbox"/>	<input type="checkbox"/>	
36. One resuscitation bag and mask.	<input type="checkbox"/>	<input type="checkbox"/>	
37. Cardio-respiratory monitor.	<input type="checkbox"/>	<input type="checkbox"/>	
38. Continuous online pressure, temperature and oxygen concentration monitoring.	<input type="checkbox"/>	<input type="checkbox"/>	
39. Two or more infusion pumps.	<input type="checkbox"/>	<input type="checkbox"/>	
40. One servo-controlled roller pump with a system for servoregulation to balance venous drainage rate from the patient and blood return to the patient.	<input type="checkbox"/>	<input type="checkbox"/>	
41. An appropriate blood heat exchanger and warming unit with inline monitoring and alarm system.	<input type="checkbox"/>	<input type="checkbox"/>	
42. Circuit pressure monitors.	<input type="checkbox"/>	<input type="checkbox"/>	
43. Backup battery power source for roller pump.	<input type="checkbox"/>	<input type="checkbox"/>	
44. Appropriate disposable materials including membrane oxygenator, tubing packs, and connectors, all suitable for prolonged extracorporeal support.	<input type="checkbox"/>	<input type="checkbox"/>	
45. Appropriate devices to measure activated clotting time with appropriate supplies at the bedside.	<input type="checkbox"/>	<input type="checkbox"/>	
46. Devices to regulate the blending of carbon dioxide and oxygen for the membrane oxygenator.	<input type="checkbox"/>	<input type="checkbox"/>	
47. Availability of devices capable of measuring continuous arterial or venous oxygenation and/or saturation of the patient (inline SvO2 monitor).	<input type="checkbox"/>	<input type="checkbox"/>	
48. One backup ECLS system and supplies for all current components.	<input type="checkbox"/>	<input type="checkbox"/>	

	<i>Yes</i>	<i>No</i>	<i>Provide explanation for all no responses or use this area to provide comments in this section when requested:</i>
49. Adequate lighting to support surgical interventions.	<input type="checkbox"/>	<input type="checkbox"/>	
50. Surgical instrument set for revision of cannulae or exploration for bleeding complications.	<input type="checkbox"/>	<input type="checkbox"/>	
<b>E. Staff Training and Continuing Education:</b>	<i>Yes</i>	<i>No</i>	<i>Provide explanation for all no responses or provide additional comments in this section:</i>
51. The neonatal ECLS center has a well defined program for staff training, certification and re-certification that includes didactic lectures, laboratory training with the ECLS equipment, bedside training, and a defined system for testing proficiency of the team members.	<input type="checkbox"/>	<input type="checkbox"/>	
52. Each member of the neonatal ECLS center team has successfully completed your facility's training and education program.	<input type="checkbox"/>	<input type="checkbox"/>	
53. Each member of the neonatal ECLS center team has successfully passed the ELSO examination.	<input type="checkbox"/>	<input type="checkbox"/>	
54. The neonatal ECLS center has a well defined program for staff continuing education and emergency training on a routine basis with documenting participation by active team members.	<input type="checkbox"/>	<input type="checkbox"/>	
55. Each member not involved in ECLS pump management for more than three months has been re-certified.	<input type="checkbox"/>	<input type="checkbox"/>	
<b>F. Patient Eligibility:</b>	<i>Yes</i>	<i>No</i>	<i>Provide explanation for all no responses or provide additional comments in this section:</i>
56. All neonates who meet the established medical criteria as defined in Chapter 64C-6, F.A.C., and, in addition, meet the specified medical criteria for ECLS, upon direct referral by the attending physician, are admitted to the neonatal ECLS center, regardless of geographic origin in Florida or financial eligibility.	<input type="checkbox"/>	<input type="checkbox"/>	
57. All neonates admitted to the neonatal ECLS center are evaluated for	<input type="checkbox"/>	<input type="checkbox"/>	

	<i>Yes</i>	<i>No</i>	<i>Provide explanation for all no responses or use this area to provide comments in this section when requested:</i>
RPICC Program eligibility.			
58. All demographic, medical, and fiscal data is collected on all RPICC Program patients and entered into the RPICC data system.	<input type="checkbox"/>	<input type="checkbox"/>	
<b>G. Selection Criteria:</b>	<i>Yes</i>	<i>No</i>	<i>Provide explanation for all no responses or provide additional comments in this section:</i>
59. ECLS services are provided to selected newborns with severe, acute cardiac and/or respiratory failure that have failed to respond to conventional medical management.	<input type="checkbox"/>	<input type="checkbox"/>	
60. The neonatal ECLS center has developed and annually reviewed and revised institutional criteria for ECLS therapy, including indications and contraindications.	<input type="checkbox"/>	<input type="checkbox"/>	
61. The neonatal ECLS center has developed guidelines for transfer of ECLS patients.	<input type="checkbox"/>	<input type="checkbox"/>	
62. <i>(It is recognized that the medical criteria for ECLS will be dynamic and are subject to change.)</i> The neonatal ECLS center considers the following diagnoses for the initiation of ECLS: meconium aspiration syndrome including other aspirations; primary pulmonary hypertension including disorders due to sepsis, severe pneumonia, and respiratory distress syndrome; congenital diaphragmatic hernia; congenital massive pulmonary cysts; specific pulmonary hypoplasia; non-immune hydrops; congenital heart disease with specific conditions; an adjunct to cardiovascular surgery; or an adjunct to lung or heart transplantation.	<input type="checkbox"/>	<input type="checkbox"/>	
<b>H. Patient Follow-up:</b>	<i>Yes</i>	<i>No</i>	<i>Provide explanation for all no responses or provide additional comments in this section:</i>
63. A developmental follow-up team that is composed of either neonatology or developmental specialist is in place and capable of long-term follow-up of the ECLS patient.	<input type="checkbox"/>	<input type="checkbox"/>	Identify team members and provide follow-up activities:

	<i>Yes</i>	<i>No</i>	<i>Provide explanation for all no responses or use this area to provide comments in this section when requested:</i>
<b>I. Program Evaluation:</b>	<i>Yes</i>	<i>No</i>	<i>Provide explanation for all no responses or provide additional comments in this section:</i>
64. The neonatal ECLS center has a well defined system instituted for assuring that formal meetings of key ECLS team members occurs on a routine basis to review cases, equipment needs, administrative needs, and other pertinent issues.	<input type="checkbox"/>	<input type="checkbox"/>	
65. The neonatal ECLS center reviews any major complication or death with both the ECLS team members and the hospital Morbidity and Mortality Committee according to the relevant quality assurance laws in Florida.	<input type="checkbox"/>	<input type="checkbox"/>	
66. The neonatal ECLS center regularly conducts formal clinical-pathological case reviews with a multi-disciplinary approach as outlined by JCAHO regulations.	<input type="checkbox"/>	<input type="checkbox"/>	
67. The neonatal ECLS center prepares an Annual Data Report utilizing the center's collated data or the collated report of data submitted to the ELSO Neonatal ECLS Registry.	<input type="checkbox"/>	<input type="checkbox"/>	
68. The neonatal ECLS center maintains records documenting maintenance of equipment as per JCAHO regulations.	<input type="checkbox"/>	<input type="checkbox"/>	

This questionnaire was completed by \_\_\_\_\_