Adult Heart and Hea

Form Section
Status 3 Justification Form Section IV
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OMB No. 0915-0157; Expiration Date: XX/XX/20X

PUBLIC BURDEN STATEMENT:

The private, non-profit Organ Procurement and Tr
functions: to assess whether applicants meet OPT
organizations with OPTN Obligations. An agency m
unless it displays a currently valid OMB control nu
XX/XX/202X. This information collection is require
Act protection (Privacy Act System of Records #09-
Contractor's security features. The Contractor's se
Security of Federal Automated Information Syster
reporting burden for this collection of information
searching existing data sources, and completing ar
other aspect of this collection of information, inclu
Fishers Lane, Room 14N39, Rockville, Maryland, 2

rtLung Status 3 Initial Justification Form Medical Urgency Data

Fields to be completed by members

Field Label	Notes
Dischargeable left ventricular assist device (LVAD) for discretionary 30 days	
Multiple inotropes or a single high dose inotrope and hemodynamic monitoring	
Select one of the following	
Candidate is supported by either	
A continuous infusion of at least one high dose intravenous inotrope	
Was the candidate on inotropic or mechanical support at the time cardiac index was obtained?	
Cardiac index	
Cardiac index - Test Date	
Cardiac index - Test Time	
Pulmonary capillary wedge pressure	
Pulmonary capillary wedge pressure - Test Date	
Pulmonary capillary wedge pressure - Test Time	
Systolic blood pressure	
Systolic blood pressure - Test Date	
Systolic blood pressure - Test Time	
Mechanical circulatory support device (MCSD) with hemolysis	
Two separate samples collected within 48 hours of each other confirming markers of active hemolysis as evidenced by at least two of the following	
Mechanical circulatory support device (MCSD) with pump thrombosis	
Mechanical circulatory support device (MCSD) with right heart failure	

Dobutamine	
Dobutamine - Date of Initiation	
Dopamine	
Dopamine - Date of Initiation	
Epinephrine	
Epinephrine - Date of Initiation	
Milrinone	
Milrinone - Date of Initiation	
Inhaled nitric oxide	
Inhaled nitric oxide - Date of Initiation	
Intravenous prostacyclin	
Intravenous prostacyclin - Date of Initiation	
Pulmonary capillary wedge pressure	
Pulmonary capillary wedge pressure - Test Date	
Pulmonary capillary wedge pressure - Test Time	
Central venous pressure	
Central venous pressure - Test Date	
Central venous pressure - Test Time	
Mechanical circulatory support device (MCSD) with device infection	
Mechanical circulatory support device (MCSD) with mucosal bleeding	
Number of hospitalizations for mucosal bleeding within the past six months	
Mechanical circulatory support device (MCSD) with aortic insufficiency (AI)	
Veno-arterial extracorporeal membrane oxygenation (VA ECMO) after 7 days	

Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device (LVAD) after 14 days	
Percutaneous endovascular circulatory support device after 14 days	
Intra-aortic balloon pump after 14 days	
Mechanical Circulatory Support Device (MCSD) with life threatening ventricular arrhythmia after 7 days	
Select at least one of the following	
Exception for status 3	
This exception request is specifically related to a device recall	
Clinical Narrative	

ansplantation Network (OPTN) collects this information in order to perform the following OPTN
N Bylaw requirements for membership in the OPTN; and to monitor compliance of member
ay not conduct or sponsor, and a person is not required to respond to, a collection of information
nber. The OMB control number for this information collection is 0915-0157 and it is valid until
d to obtain or retain a benefit per 42 CFR §121.11(b)(2). All data collected will be subject to Privacy
-15-0055). Data collected by the private non-profit OPTN also are well protected by a number of the
curity system meets or exceeds the requirements as prescribed by OMB Circular A-130, Appendix III,
ns, and the Departments Automated Information Systems Security Program Handbook. The public
is estimated to average 0.27 hours per response, including the time for reviewing instructions,
nd reviewing the collection of information. Send comments regarding this burden estimate or any
ding suggestions for reducing this burden, to HRSA Information Collection Clearance Officer, 5600
)857 or paperwork@hrsa.gov.