OMB No. 0915-0157; Expiration Date: XX/XX/20XX

# **Adult Heart Candidate Listing Registration**

The fields on the Heart Candidate Registration Form contain demographic and basic clinical information about candidates on the national waiting list.

# **Add New Candidate Registration**

**Transplant Hospital**: Confirm the name of the transplant hospital.

Organ: Select Heart.

### **Candidate Add**

**Center**: Confirm the name of the transplant hospital.

**Organ**: Confirm organ selection.

**Age group**: Select the candidate's age group.

SSN: Enter the candidate's SSN number.

**Note:** SSN cannot:

- Contain 00 in the 4th and 5th place (e.g. XXX-00-XXXX is invalid)
- Contain 0000 in the last 4 places (e.g. XXX-XX-0000 is invalid)
- Begin with 666

Confirm SSN: Confirm the candidate's SSN number.

### **Provider Information**

<u>Transplant Center</u>: Verify the transplant center name, and that the provider number is the 6-character Medicare identification number of the hospital where the transplant candidate is listed.

**24 Hour Contact Phone Number**: Verify the transplant center phone number.

# **Demographic Information**

**SSN**: Enter the candidate's SSN number.

Note: SSN cannot:

- Contain 00 in the 4th and 5th place (e.g. XXX-00-XXXX is invalid)
- Contain 0000 in the last 4 places (e.g. XXX-XX-0000 is invalid)
- Begin with 666

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Confirm SSN: Confirm the candidate's SSN number.

<u>Last Name</u>: Enter the last name of the candidate. This is a **required** field. <u>First Name</u>: Enter the first name of the candidate. This is a **required** field.

MI: Enter the candidate's middle initial.

**DOB**: Enter the candidate's date of birth. This is a **required** field.

<u>Birth sex</u>: Indicate if the patient is **Male** or **Female**. Report patient sex (male or female), based on biologic and physiologic traits at birth. This is a **required** field.

<u>Center's Patient ID</u>: Enter the candidate's patient identification number that is assigned by your center, if applicable.

<u>State of Permanent Residence</u>: Select the full name of the state where the candidate's home is located.

<u>Permanent Zip Code</u>: Enter the 5-digit U.S. postal zip code for the address where the candidate's home is located. *Note*: Make corrections to an incorrect permanent zip code on the Transplant Candidate Registration (TCR) form in TIEDI<sup>®</sup>. This field cannot be updated from the active list.

**Ethnicity:** The Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity (Office of Management and Budget (OMB) <u>Statistical Policy Directive No. 15</u>) define the minimum standards for collecting and presenting data on race and ethnicity for all Federal reporting. The OPTN collection of ethnicity is aligned to this standard.

OMB defines ethnicity to be whether a person self-identifies as Hispanic origin or not. For this reason, ethnicity is broken out in two categories, (1) Hispanic or Latino or (2) Not Hispanic or Latino. Select one ethnicity category or select 'Ethnicity Not Reported' if the candidate did not self-identify. This field is **required**.

**Hispanic or Latino** – A person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race.

### **Not Hispanic or Latino**

### **Ethnicity Not Reported**

**Race:** The Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity (Office of Management and Budget (OMB) <u>Statistical Policy Directive No. 15</u>) define the minimum standards for collecting and presenting data on race and ethnicity for all Federal reporting. The OPTN collection of race is aligned to this standard. OMB defines race as a person's self-identification with one or more social groups.

An individual can select one or more race categories (1) White, (2) Black or African American, (3) Asian, (4) American Indian or Alaska Native, (5) Native Hawaiian or Other Pacific Islander. Select 'Race Not Reported' if the candidate's race is not reported. This field is **required**.

**Note:** A person may report multiple races. Persons reporting Hispanic or Latino ethnicity may report themselves as any race category or report no race at all.

Select one or more race sub-categories or origins. Select 'Other Origin' if origin is not listed. Select 'Origin Not Reported' if the origin was not self-identified by the person.

**White** – A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

#### **European Descent**

**Arab or Middle Eastern** 

**North African (non-Black)** 

**Other Origin** 

**Origin Not Reported** 

**Black or African American** – A person having origins in any of the Black racial groups of Africa.

**African American** 

**African (Continental)** 

**West Indian** 

Haitian

**Other Origin** 

**Origin Not Reported** 

**American Indian or Alaska Native** – A person having origins in any of the original peoples of North and South America (including Central America) and who maintains tribal affiliation or community attachment.

**American Indian** 

**Eskimo** 

Aleutian

Alaska Indian

**Other Origin** 

**Origin Not Reported** 

**Asian** – A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.

Asian Indian/Indian Sub-Continent

Chinese

**Filipino** 

**Japanese** 

Korean

Vietnamese

**Other Origin** 

**Origin Not Reported** 

**Native Hawaiian or Other Pacific Islander** – A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.

**Native Hawaiian** 

**Guamanian or Chamorro** 

Samoan

**Other Origin** 

**Origin Not Reported** 

**Race Not Reported –** Select if person did not self-identify a race category or origin.

# **Clinical Information**

**ABO**: Select the candidate's blood type. This is a required field.

**Note:** A2 is used as shorthand for any blood type A subtype other than A1 (i.e., non-A1, negative for A1). A2B is used as shorthand for any blood type AB subtype other than A1B (i.e., non-A1B, negative for A1B). Policy **requires** at least two (2) separate blood typings prior to listing. Policy also **requires** you to review all known available blood type source documents to verify the candidate's blood type. See <a href="OPTN Policies">OPTN Policies</a> for additional information. Use the search feature to locate specific policy information on ABO Typing.

O

Α

В

AB

Z (in Utero Only)

<u>Accept an Intended Blood Group Incompatible Organ?</u>: Indicate whether the candidate will accept an incompatible blood type by selecting **Yes** or **No**. This field is for pediatric candidates less than 2 years old at time of registration.

*Note:* For candidates with ABO type AB, you must select **No**.

**Eligibility status to receive offers on A organs:** If the candidate has missing or expired anti-A titer data, the candidate is ineligible to receive an incompatible blood type offer.

**Eligibility status to receive offers on B organs:** If the candidate has missing or expired anti-B titer data, the candidate is ineligible to receive an incompatible blood type offer.

**Eligibility status to receive offers on AB organs:** If the candidate has missing or expired anti-A and anti-B titer data, the candidate is ineligible to receive an incompatible blood type offer.

**Note:** In order for a candidate to receive an intended blood group incompatible heart, he or she must satisfy the following criteria: candidate must be less than 1 year old and be listed as a Status 1A or 1B, or must have been listed prior to turning 2 years old, must have the most recent anti-A and/or anti-B titer value(s) reported, which are less than or equal to 1:16 and must not have received any treatments within the prior 30 days that could have reduced the candidate titer(s) to 1:16 or less.

**Most Recent Anti-A Titer:** If the candidate has an ABO blood type of B, select the most recent anti-A titer value from the drop-down list, then enter the corresponding **Sample Date**. This is a **required** field.

**Anti-A Titer Evaluation Due Date:** If new anti-A titer data is not entered by the due date, the candidate will become ineligible to receive incompatible blood type offers.

**Most Recent Anti-B Titer:** If the candidate has an ABO blood type of A, select the most recent Anti-B titer value from the drop-down list, then enter the corresponding **Sample Date**. This is a **required** field.

**Anti-B Titer Evaluation Due Date:** If new anti-B titer data is not entered by the due date, the candidate will become ineligible to receive incompatible blood type offers.

**Most Recent Anti-A and Anti-B titers:** If the candidate has an ABO blood type of O select the most recent Anti-A and Anti-B titers from the drop-down list, then enter the corresponding **Sample Dates.** This is a **required** field.

Anti-A and Anti-B Titer Evaluation Due Dates: If new anti-A and anti-B titer data is not entered by the due date, the candidate will become ineligible to receive incompatible blood type offers.

Has candidate received any treatments that may have reduced the titer values to 1:16 or less within 30 days of when the blood sample was collected? Indicate whether the candidate has or has not received treatments by selecting YES or NO. This is a required field.

**<u>Height</u>**: Enter the height of the candidate at the time of listing in the appropriate space, in feet and inches or centimeters. The height must fall between 0 and 7 feet or 1 and 241 centimeters. This is a **required** field.

<u>Weight</u>: Enter the weight of the candidate at the time of listing in the appropriate space, in pounds or kilograms. The weight must fall between 0 and 650 pounds or 0 and 295 kilograms. This is a **required** field.

#### **HLA Class I**

**HLA**: Histocompatibility antigens are currently not required when adding candidates for extra renal organs (LI, IN, HR, HL and LU) to the active list. If histocompatibility antigens are entered, at least one value is required for each antigen (**A, B, Bw4, Bw6** and **DR**). The order in which the antigens are entered does not affect the matching and screening process.

Α

Α

В

В

BW4

BW<sub>6</sub>

C

C

### **HLA Class II**

**HLA**: Histocompatibility antigens are currently not required when adding candidates for extra renal organs (LI, IN, HR, HL and LU) to the active list. If histocompatibility antigens are entered, at least one value is required for each antigen (**A, B, Bw4, Bw6** and **DR**). The order in which the antigens are entered does not affect the matching and screening process.

DR

DR

**DR51** 

**DR51** 

**DR52** 

**DR52** 

**DR53** 

**DR53** 

DQB1

DQB1

DQA1

DQA1

DPB1

DPB1

DPA1

DPA1

# **Organ Information**

<u>Candidate Medical Urgency Status</u>: Indicate the candidate's medical urgency status. If one of the Active statuses is selected, the candidate is eligible to appear on a UNet match run. If **Temporarily inactive** is selected, the candidate is non-eligible to appear on the UNet match run. This is a **required** field.

**Note:** See OPTN Policies for definitions of the Candidate Medical Urgency Status. Use the search feature to locate specific policy information on medical urgency.

Select one of the following for pediatric candidates:

Status 1A

Status 1B

Status 2

Temporarily Inactive

Select one of the following for adult candidates:

Adult Status 1

Adult Status 2

Adult Status 3

Adult Status 4

Adult Status 5

Adult Status 6 Temporarily Inactive

**Inactive reason:** Select the reason the candidate is inactive.

Inactive Reason Code	Description
1	Candidate cannot be contacted
2	Candidate choice
3	Candidate work-up incomplete
4	Insurance issues
5	Medical non-compliance
6	Inappropriate substance use
7	Temporarily too sick
8	Temporarily too well
9	Weight currently inappropriate for transplant
10	Transplanted - removal pending UNET data correction
11	Inactivation due to VAD implantation and/or VAD complication
12	TX Pending
13	Physician/Surgeon unavailable
14	Candidate for living donor transplant only
15	Administrative: Waiting time/ped-adult adjustment
16	COVID-19 Precaution

**Note:** The inactive reason TX'ed - removal pending UNet<sup>™</sup> data correction is only to be used when a transplant center removed the incorrect candidate from Waitlist due to transplant and is waiting for UNOS to correct the data so that the correct candidate can be removed with the right donor ID. Candidates should not be set to inactive for this reason for more than 5 days.

**Note:** To reactivate an adult heart candidate that has been temporarily inactive, click **Select Status** button from the candidate view page. Select the candidate's medical urgency status from the **Candidate Medical Urgency Status** dropdown and proceed to submit the justification form. See <u>Justification Forms</u> for more information.

<u>Heart Diagnosis Code</u>: Indicate the candidate's heart diagnosis code. This is a **required** field. For more details, see <u>Thoracic Codes</u>.

<u>Preliminary Crossmatch Required</u>: Select **Yes**, if a preliminary cross-match is required. If it is not, select **No**.

**Number of previous Heart Transplants:** Indicate the number of candidate's previous heart transplants. This is a **required** field.

<u>Is the candidate listed for a vascularized composite allograft (VCA)?</u>: Select **Yes**, if the candidate is listed for a VCA. If not, select **No**.

# **Additional Organs**

Check any additional organs that the candidate may need. Checking organ(s) within this section will not register the candidate on the checked organ waiting list. You will need to complete a registration and verify the accuracy of donor acceptance criteria for each additional organ checked.

**Kidney** 

**Pancreas** 

**Pancreas Islet** 

Intestine

Liver

Heart/Lung

Lung

### **Donor Characteristics**

The following fields are evaluated when running a match to determine if this candidate will appear in the match list. If the donor does not meet the acceptance criteria for this candidate, the candidate will be screened off (not appear on) the match results.

### **Donor Characteristics**

<u>Minimum acceptable donor age</u>: Enter the minimum donor age that the candidate can accept. The age must fall between 0 and 99 years. This field is **required**.

Maximum acceptable donor age: Enter the maximum donor age that the candidate can accept. The age must fall between 0 and 99 years. The maximum value must only be entered in months if the minimum value is also entered in months (e.g. you are able enter that you will accept donors from 3 months to 3 years in age, but you may NOT enter that you would accept a donor from 1 year to 36 months in age). This field is **required**.

Minimum acceptable donor height: Enter the minimum donor height that the candidate can accept in inches (in) or centimeters (cm). The height must fall between 0 to 305 inches, or 0 to 305 centimeters. The minimum acceptable donor height must be equal to or no more than 12 in. less than the candidate's listing height. This field is **required**.

<u>Maximum acceptable donor height:</u> Enter the maximum donor height that the candidate can accept in inches (in) or centimeters (cm). The height must fall between 0 to 305

inches, or 0 to 305 centimeters. The maximum acceptable donor height must be equal to or no more than 12 in. greater than the candidate's listing height. This field is **required**.

Minimum acceptable donor weight: Enter the minimum donor weight that the candidate can accept. The weight must be a whole number that falls between 0 and 440 pounds (lbs), or 0 and 200 kilograms (kg). The minimum acceptable donor weight should be no more than 30 percent (30%) below the candidate's listing weight. To eliminate the possibility of conversion or rounding issues, the match system adds .5 kg when comparing this value to the donor weight. This field is **required**.

Maximum acceptable donor weight: Enter the maximum donor weight that the candidate can accept. The weight must be a whole number that falls between 0 and 440 pounds (lbs), or 0 and 200 kilograms (kg). The maximum acceptable donor weight must be more than the candidate's listing weight, and must be greater than the minimum acceptable donor weight. To eliminate the possibility of conversion or rounding issues, the match system adds .5 kg when comparing this value to the donor weight. This field is **required**.

**Donor birth sex requirements:** Select whether the matching donor must be **male**, **female**, or **either** birth sex (male or female).

**Accept DCD donor:** If the candidate will accept a DCD (Donation after Circulatory Death) donor, select **Yes**. If not, select **No**. Donation after Circulatory Death (DCD) describes the organ recovery process that may occur following death by irreversible cessation of circulatory and respiratory functions. A DCD donor may also be called a non-heartbeating, asystolic, or donation after cardiac death donor. This field is **required**.

### **Medical and Social History**

Accept a donor with a history of coronary artery disease?: If the candidate will accept a donor with a history of coronary artery disease, select Yes . If not, select No.

### **Infectious Diseases**

<u>Accept a Hepatitis B Core antibody positive donor?</u> Select **Yes** if the candidate will accept a Hepatitis B core antibody positive donor. If not, select **No**. This field is **required**.

Accept an HBV NAT positive donor? Select Yes if the candidate will accept an HBV NAT positive donor. If not, select No This field is required.

Accept an HCV antibody positive donor? Select Yes if the candidate will accept an HCV antibody positive donor. If not, select No. This field is required.

Accept an HCV NAT positive donor? Select Yes if the candidate will accept an HCV NAT positive donor. If not, select No. This field is required.

### Recovery

<u>Maximum miles the organ or recovery team will travel</u>: Enter the maximum miles the organ recovery team will travel. The number must fall between 0 and 9,999 miles. This field is required.

The matching system calculates mileage between the donor hospital and the recipient center based on the hospitals' zip codes. This distance is measured in nautical miles (a measure of flight distance), not in statute miles (a measurement of driving distance).

### **Conversion Table for Nautical and Statute Miles**

Nautical Miles	Statute Miles
250	287.7
500	575.4
1000	1150.8
1500	1726.2
2000	2301.6
2500	2876.9

### **Unacceptable Antigens**

Select all of the unacceptable antigens and then click the "Calculate" button for the CPRA score.

**CPRA:** Calculated Panel Reactive Antibody (CPRA) is the percentage of deceased donors expected to have one or more of the unacceptable antigens indicated on the waiting list for the candidate. The CPRA is derived from HLA antigen, allele, and epitope genotype frequencies for the different populations in proportion to their representation in the national deceased donor population.

**Percent CPRA:** The value rounded to the nearest one-hundredth and displayed with a % symbol.

**Detailed CPRA:** The value displayed as a decimal to 6 digits of precision.

<u>Select all A unacceptable antigens</u>: Select the candidate's A unacceptable antigens, if applicable. Make your selections from the left-hand column and click the arrow to add or remove them to the right-hand column.

<u>Select all B unacceptable antigens</u>: Select the candidate's B unacceptable antigens, if applicable. Make your selections from the left-hand column and click the arrow to add or remove them to the right-hand column.

<u>Select BW unacceptable antigen</u>: Select the candidate's BW unacceptable antigen, if applicable. Make your selections from the left-hand column and click the arrow to add or remove them to the right-hand column.

<u>Select all C unacceptable antigens</u>: Select the candidate's C unacceptable antigens, if applicable. Make your selections from the left-hand column and click the arrow to add or remove them to the right-hand column.

<u>Select all DR unacceptable antigens</u>: Select the candidate's DR unacceptable antigens, if applicable. Make your selections from the left-hand column and click the arrow to add or remove them to the right-hand column.

<u>Select all DR 51/52/53 unacceptable antigens</u>: Select the candidate's DR 51, 52 and 53 unacceptable antigens, if applicable. Make your selections from the left-hand column and click the arrow to add or remove them to the right-hand column.

<u>Select all DQB1 unacceptable antigens</u>: Select the candidate's DQB1 unacceptable antigens, if applicable. Make your selections from the left-hand column and click the arrow to add or remove them to the right-hand column.

<u>Select all DQA1 unacceptable antigens</u>: Select the candidate's DQA1 unacceptable antigens, if applicable. Make your selections from the left-hand column and click the arrow to add or remove them to the right-hand column.

<u>Select all DPB1 unacceptable antigens</u>: Select the candidate's DPB1 unacceptable antigens, if applicable. Make your selections from the left-hand column and click the arrow to add or remove them to the right-hand column.

<u>Select all DPB1 unacceptable epitopes</u>: Select the candidate's DPB1 unacceptable epitopes, if applicable. Make your selections from the left-hand column and click the arrow to add or remove them to the right-hand column.

<u>Select all DPA1 unacceptable antigens</u>: Select the candidate's DPA1 unacceptable antigens, if applicable. Make your selections from the left-hand column and click the arrow to add or remove them to the right-hand column.

### **Risk Stratification Data**

The goal of collecting the risk stratification data is to potentially inform future heart allocation policy. The data has no bearing on allocation in terms of where the candidate is placed on a match. Per OPTN Policy, this data must be submitted at time of registering the candidate and each time a status justification form is submitted.

<u>Total number of prior sternotomies</u>: Enter the total number of any prior sternotomies into the space provided. The entry must fall between 0 and 10. Check **Not available** if the information is not accessible. This is a **required** field.

**Any prior history of stroke?**: If the candidate has ever had a stroke, select **Yes**. If not, select **No**. If unknown, select, **Unknown**. This is a **required** field.

<u>Any prior history of peripheral thromboembolic events?</u>: If the candidate has ever experienced peripheral thromboembolic events, select **Yes**. If not, select **No**. If unknown, select, **Unknown**. This is a **required** field.

Number of hospitalizations for heart failure in last 12 months: Enter the number of times the candidate has been hospitalized for heart failure in the last twelve months. The entry must fall between 0 and 50. Check **Not available** if the information is not accessible. This is a **required** field.

<u>Is the candidate on a diuretic?</u>: If the candidate is currently on a diuretic, select **Yes**. If not, select **No**. If unknown, select, **Unknown**. This is a **required** field.

<u>Furosemide – Amount</u>: Enter the dosage of furosemide in mg. The entry must fall between 1 and 200. If the value exceeds the maximum acceptable limit, enter the maximum acceptable limit. If the value falls below the minimum allowed value, enter the minimum allowed value.

Furosemide - IV/PO: Select IV (intravenous) or PO (per os (by mouth)).

<u>Torsemide – Amount</u>: Enter the dosage of torsemide in mg. The entry must fall between 1 and 400. If the value exceeds the maximum acceptable limit, enter the maximum acceptable limit. If the value falls below the minimum allowed value, enter the minimum allowed value.

Torsemide - IV/PO: Select IV (intravenous) or PO (per os (by mouth)).

<u>Bumetanide – Amount:</u> Enter the dosage of bumetanide in mg. The entry must fall between 1 and 50. If the value exceeds the maximum acceptable limit, enter the maximum acceptable limit. If the value falls below the minimum allowed value, enter the minimum allowed value.

**Bumetanide - IV/PO**: Select **IV** (intravenous) or **PO** (per os (by mouth)).

<u>Chlorothiazide – Amount</u>: Enter the dosage of chlorothiazide in mg. The entry must fall between 1 and 200. If the value exceeds the maximum acceptable limit, enter the maximum acceptable limit. If the value falls below the minimum allowed value, enter the minimum allowed value.

**Chlorothiazide - IV/PO**: Select **IV** (intravenous) or **PO** (per os (by mouth)).

<u>Metolazone – Amount</u>: Enter the dosage of metolazone in mg. The entry must fall between 1 and 50. If the value exceeds the maximum acceptable limit, enter the maximum acceptable limit. If the value falls below the minimum allowed value, enter the minimum allowed value.

Metolazone - IV/PO: Select IV (intravenous) or PO (per os (by mouth)).

Other diuretic - Name: Enter the name of the diuretic in the space provided.

<u>Other diuretic – Amount</u>: Enter amount of the other diuretic (mg). The entry must fall between 1 and 400. If the value exceeds the maximum acceptable limit, enter the maximum acceptable limit. If the value falls below the minimum allowed value, enter the minimum allowed value.

Other diuretic - IV/PO: Select IV (intravenous) or PO (per os (by mouth)).

**Is the candidate on vasoactive support?**: If the candidate is currently on vasoactive support, **Yes**. If not, select **No**. If unknown, select, **Unknown**. This is a **required** field.

If yes, enter the additional information:

**Dobutamine**: Enter the dosage of dobutamine in mcg/kg/min. The entry must fall between 0.001 and 999.

**Dopamine**: Enter the dosage of dopamine in mcg/kg/min. The entry must fall between 0.001 and 999.

**Milrinone**: Enter the dosage of milrinone in mcg/kg/min. The entry must fall between 0.001 and 999.

**Epinephrine**: Enter the dosage of epinephrine in mcg/kg/min. The entry must fall between 0.001 and 999.

**Norepinephrine**: Enter the dosage of norepinephrine in mcg/kg/min. The entry must fall between 0.001 and 999.

**Vasopressin**: Enter the dosage of vasopressin in units/min. The entry must fall between 0.001 and 999.

<u>Is the candidate on anti-arrhythmics?</u>: If the candidate is currently on anti-arrhythmics, select **Yes**. If not, select **No**. If unknown, select, **Unknown**. This is a **required** field.

<u>Is the candidate on pulmonary vasodilators?</u>: If the candidate is on pulmonary vasodilators, select the from the list of options. One or more options may be selected. If not, select **No**. If unknown, select, **Unknown**. This is a **required** field.

IV Inhaled Oral

<u>Is the candidate on dialysis?</u>: If the candidate is currently on dialysis, select **Yes**. If not, select **No**. If unknown, select, **Unknown**. This is a **required** field.

<u>Is the candidate on continuous invasive mechanical ventilation?</u>: If the candidate is currently on continuous invasive mechanical ventilation, select **Yes**. If not, select **No**. If unknown, select, **Unknown**. This is a **required** field.

# Most recent cardiopulmonary stress test

Enter the most recent cardiopulmonary stress test date and the data obtained. If a certain test in this category has not been performed since the last time you reported the data, check "Not Performed" to indicate the same. If no new tests have been performed since the last time the data was reported, click "Not Performed" at the category level to indicate that no new values are available for any of the fields in this category.

### Example:

- 1. The first time that you report this data, you are reporting values obtained from a test performed on 09/15/2018. You have provided data in all of the fields (Peak O2 consumption, RER and VE/VCO2).
- 2.A new status justification form is being submitted on 09/20/2018.
- 3. New tests have been performed on 09/18/2018 for Peak O2 Consumption and RER but not for VE/VCO2.
- 4.On the new form being submitted, enter 09/18/2018 as the Assessment Date and provide the new values obtained for Peak O2 consumption and RER.
- 5. Since no test was performed for VE/VCO2, click "Not Performed" to indicate that a new test was not performed on 09/18/2018.

Assessment Date: Enter the assessment date the stress test was performed. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Check **Not performed** if no test was performed. This is a **required** field.

Peak  $O_2$  consumption: Enter the peak oxygen ( $O_2$ ) consumption in ml/kg/min. The entry must fall between 0 and 50. Check **Not performed** if no test was performed. This is a **required** field.

Respiratory exchange ratio (RER): Enter the ratio between the amount of carbon dioxide  $(CO_2)$  produced in metabolism and oxygen  $(O_2)$  used into the space provided. The entry

must fall between 0 and 2. Check **Not performed** if no test was performed. This is a **required** field.

VE/VCO<sub>2</sub>: Enter the carbon dioxide output per unit of time into the space provided. The entry must fall between 0 and 200. Check **Not performed** if no test was performed. This is a **required** field.

### **Most Recent Sensitization Data**

Enter the most recent sensitization test date and the data obtained. If a certain test in this category has not been performed since the last time you reported the data, check "Not Performed" to indicate the same. If no new tests have been performed since the last time the data was reported, click "Not Performed" at the category level to indicate that no new values are available for any of the fields in this category. *Refer to example in the "Most recent cardiopulmonary stress test" section.* 

**Assessment Date**: Enter the assessment date of the most recent sensitization data. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Check **Not performed** if no test was performed. This is a **required** field.

**CPRA**: Enter the current Calculated Panel Reactive Antibodies (CPRA) percentage into the space provided. The entry must fall between 0 and 100. Check **Not performed** if no test was performed. This is a **required** field. **Note:** Please enter the current CPRA value and not the peak CPRA value. If your lab did not provide you with a CPRA, but you have unacceptable antigens, use the <u>CPRA Calculator</u> to calculate the value.

**PRA typing method**: Select the Panel Reactive Antibodies (PRA) typing method from the list of options. Check **Not performed** if no test was performed. This is a **required** field.

Cytotoxicity testing – extended incubation

Cytotoxicity testing - wash

Cytotoxicity testing - wash and extended incubation

Cytotoxicity testing - AHG (antihuman immunoglobulin)

Flow cytometry with cell targets

Flow cytometry with bead targets

**ELISA** 

Micro array

Other, specify (if chosen, enter the method in Other specify text box)

**MFI threshold**: Enter the mean fluorescence intensity (MFI) threshold into the space provided. The entry must fall between 0 and 50000. If there are different cutoffs for different HLA loci, provide the lowest threshold used for that candidate. Check **Not performed** if no test was performed. This is a **required** field.

### **Most Recent Hemodynamic Data**

Enter the most recent hemodynamic data test date and the data obtained. If a certain test in this category has not been performed since the last time you reported the data, check "Not Performed" to indicate the same. If no new tests have been performed since the last time the data was reported, click "Not Performed" at the category level to indicate that no new values are available for any of the fields in this category. Refer to example in the "Most recent cardiopulmonary stress test" section.

Hemodynamic data obtained using: Select whether the data was obtained using Invasive pulmonary artery catheter, Implanted hemodynamic monitoring,

or **Other**. Select as many as necessary. Check **Not performed** at the category level if no hemodynamic measurements were obtained. This is a **required** field.

Were hemodynamic values obtained while the patient was on inotrope and or device support?: If hemodynamic values were obtained while the candidate was on inotrope and or device support, click the appropriate check boxes. If unknown, select **Not available** to indicate the same.

**Systolic blood pressure**: Enter the measure of systolic blood pressure in mmHg. The entry must fall between 50 and 200 mmHg. Check **Not performed** if no test was performed. This is a **required** field.

**Diastolic blood pressure**: Enter the measure of diastolic blood pressure in mmHg. The entry must fall between 20 and 150 mmHg. Check **Not performed** if no test was performed. This is a **required** field.

Resting heart rate (on same date as hemodynamic tests): Enter the resting heart rate in beats per minute (bpm). The entry must fall between 0 and 300. Check **Not** performed if no test was performed. This is a required field.

**Central venous pressure**: Enter the central venous pressure in mmHg. The entry must fall between 0 and 50 mmHg. Check **Not performed** if no test was performed. This is a **required** field.

**Pulmonary artery systolic pressure:** Enter the pulmonary artery systolic pressure in mmHg. The entry must fall between 0 and 200 mmHg. The pulmonary artery systolic pressure must be greater than mean pulmonary artery pressure. Check **Not performed** if no test was performed. This is a **required** field.

Pulmonary artery diastolic pressure: Enter the pulmonary artery diastolic pressure in mmHg. The entry must fall between 0 and 110 mmHg. Check **Not performed** if no test was performed. This is a **required** field.

**Mean pulmonary artery pressure:** Enter the mean pulmonary artery pressure in mmHg. The entry must fall between 0 and 150 mmHg. The mean pulmonary artery pressure must be greater than the pulmonary artery diastolic pressure. Check **Not performed** if no test was performed. This is a **required** field.

**Value obtained for PCWP or LVEDP?**: If a value was obtained for Pulmonary Capillary Wedge Pressure (PCWP) or Left Ventricular End-Diastolic Pressure (LVEDP), select **Yes**. If not, select **No**. If unknown, select, **Unknown**. If yes, select the appropriate option and enter the value in mmHg. The entry must fall between 0 and 100. This is a **required** field.

**Cardiac output**: Enter the cardiac output in L/min. The entry must fall between 0.2 and 15 L/min. Check **Not performed** if no test was performed. This is a **required** field.

**Cardiac index**: Enter the cardiac index in L/min/m2. The entry must fall between 0 and 50 L/min/m2. Check **Not performed** if no test was performed. This is a **required** field.

**Mixed venous oxygen saturation**: Enter the percentage of mixed venous oxygen saturation into the space provided. The entry must fall between 0 and 100. Check **Not performed** if no test was performed. This is a **required** field.

**Hemoglobin at time of SvO<sub>2</sub>**: Enter the measurement of oxygenation saturation from mixed venous blood (SvO<sub>2</sub>) in the pulmonary artery in g/dL. The entry must fall between 5 and 20 g/dL. Check **Not performed** if no test was performed. This is a **required** field.

# **Most Recent Data for VAD patients**

If the candidate is supported by a VAD, enter data in this section. If the candidate is not supported by a VAD, check "Not Performed" at the category level.

Enter the most recent data and the corresponding test date in the fields in this category. If a certain test in this category has not been performed since the last time you reported the data, check "Not Performed" to indicate the same. If no new tests have been performed since the last time the data was reported, click "Not Performed" at the category level to indicate that no new values are available for any of the fields in this category. Refer to example in the "Most recent cardiopulmonary stress test" section.

**Note:** Enter data in this section only if the candidate is currently on a ventricular assist device (VAD). If not, select not performed.

**LDH**: Enter the Lactic Acid Dehydrogenase (LDH) value in U/L. The entry must fall between 0 and 10000 U/L. Enter the test date. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Check **Not performed** if no test was performed. This is a **required** field.

**Plasma free hemoglobin**: Enter the plasma free hemoglobin value in mg/dL. The entry must fall between 0 and 200 mg/dL. Enter the test date. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Check **Not performed** if no test was performed. This is a **required** field.

Has the candidate experienced hemoglobinuria?: If the candidate has experienced hemoglobinuria at any point, select Yes. If not, select No. If unknown, select, Unknown. This is a required field. *Note:* If initially listing a candidate, indicate whether the candidate has experienced hemoglobinuria at any time prior to listing. If submitting a justification form, indicate whether the candidate has experienced hemoglobinuria since submission of the last justification form. If urinalysis was not repeated since the submission of the last justification form, select unknown.

# **Most Recent Heart Failure Severity Data**

Enter the most recent heart failure severity data and corresponding test date in the fields in this category. If a certain test in this category has not been performed since the last time you reported the data, check "Not Performed" to indicate the same. If no new tests have been performed since the last time the data was reported, click "Not Performed" at the category level to indicate that no new values are available for any of the fields in this category. Refer to example in the "Most recent cardiopulmonary stress test" section.

**Serum sodium**: Enter the serum sodium in mEq/L. The entry must fall between 100 and 200. Enter the test date. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Check **Not performed** if no test was performed. This is a **required** field. **Note:** Plasma sodium is also considered an acceptable value.

**Serum creatinine**: Enter the serum creatinine in mg/dL. The entry must fall between 0.01 and 40. Enter the test date. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Check **Not performed** if no test was performed. This is a **required** field. **Note:** Plasma creatinine is also considered an acceptable value.

**BUN**: Enter the Blood Urea Nitrogen (BUN) in mg/dL. The entry must fall between 0 and 300. Enter the test date. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Check **Not performed** if no test was performed. This is a **required** field.

**Serum albumin**: Enter the serum albumin in g/dL. The entry must fall between 0.5 and 9.9. Enter the test date. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Check **Not performed** if no test was performed. This is a **required** field.

**AST**: Enter the aspartate transaminase (AST) in U/L. The entry must fall between 0 and 40000. Check **Not performed** if no test was performed. This is a **required** field.

**Serum bilirubin**: Enter the serum bilirubin in mg/dL. The entry must fall between 0 and 50. Enter the test date. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Check **Not performed** if no test was performed. This is a **required** field.

**Arterial lactate**: Enter the arterial lactate in mmol/L. The entry must fall between 0 and 50. Enter the test date. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Check **Not performed** if no test was performed. This is a **required** field.

**INR**: Enter the International normalized ratio (INR) into the space provided. The entry must fall between 0 and 20. Enter the test date. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Check **Not performed** if no test was performed. This is a **required** field.

**Brain natriuretic peptide test performed?:** Select **Yes**, if a brain natriuretic peptide test was performed. If not, select **No**. If the unknown, select, **Unknown**. This is a **required** field.

If yes, select **BNP** or **NT Pro BNP** and enter the Brain natriuretic peptide in pg/mL into the space provided. The BNP entry must fall between 0 and 20000. The NT Pro BNP entry must fall between 0 and 40000. This is a **required** field.

### **Justification Form Information**

**Surgeon/Physician NPI:** Enter the NPI of the candidate's surgeon/physician. This is a **required** field.

<u>Surgeon/Physician name</u>: Enter the name of the candidate's surgeon/physician. This is a **required** field.

**Hospital telephone number:** Enter the transplant's hospital telephone number. This is a **required** field.

### **Justification Form Status 1**

To qualify for status 1, the patient must meet one of the following criteria.

# Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO)

Candidate is admitted to the transplant center that registered the candidate on the waitlist and is supported by VA ECMO for cardiogenic shock. Within 7 days prior to support.

### Select one of the following:

### Hemodynamic measurements were obtained and within 24-hour period

- Cardiac index was:
  - o Less than 1.8 L/min/m² if the candidate was not supported by an inotrope or
  - o Less than 2.0 L/min/m² if the candidate was supported by at least one inotrope
- Pulmonary capillary wedge pressure was greater than 15 mmHg and
- Systolic blood pressure was less than 90 mmHg

<u>Was the candidate on inotropes at the time cardiac index was obtained?</u>: If the candidate was on inotropes at the time cardiac index was obtained, select **Yes**. If not, select **No**. This is a **required** field.

<u>Cardiac index</u>: Enter the candidate's cardiac index in L/min/m<sup>2</sup>. The entry must fall between 0 and 1.79 if the candidate was not supported by inotropes and must be less than 2.0 L/min/m<sup>2</sup> if the candidate was supported by inotropes.

<u>Cardiac index - Test Date</u> Enter the Test Date of when the cardiac index value was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available.

<u>Cardiac index - Test Time</u> Enter the Test Time. The time must be in the following 24-hour format: HH:MM. Time must be in military format. This is a required field.

<u>Pulmonary capillary wedge pressure</u> Enter the candidate's pulmonary capillary wedge pressure in mmHg. The entry must fall between 16 and 100 mmHg.

<u>Pulmonary capillary wedge pressure - Test Date</u> Enter the <u>Test Date</u> of when the PCWP value was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the <u>Test Time</u>.

<u>Pulmonary capillary wedge pressure - Test Time</u> The time must be in the following 24-hour format: HH:MM. Time must be in military format. This is a **required** field.

**Systolic blood pressure** Enter the candidate's systolic blood pressure in mmHg. The entry must fall between 50 and 89 mmHg. Enter the **Test Time**.

<u>Systolic blood pressure - Test Date</u> Enter the **Test Date** of when the systolic blood pressure was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available.

**Systolic blood pressure - Test Time** The time must be in the following 24-hour format: HH:MM. Time must be in military format. This is a **required** field.

Hemodynamic measurements were not obtained. However, within 24 hours prior to ECMO support:

- CPR was performed on the candidate or
- systolic blood pressure was less than 70 mmHg or
- arterial lactate was greater than 4 mmol/L or
- aspartate transaminase was greater than 1,000 U/L or
- alanine transaminase was greater than 1,000 U/L.

### Enter a qualifying value for at least one of the following:

<u>Date of administration of CPR:</u> Enter the date of administration of CPR. The date must be in the following format: MM/DD/YYYY. A calendar link is available.

<u>Date of administration of CPR - Test Time</u>: Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time must be in military format.

**Systolic blood pressure**: Enter the candidate's systolic blood pressure in mmHg. The entry must fall between 50 and 69 mmHg.

<u>Systolic blood pressure - Test Date</u>: Enter the <u>Test Date</u> of when the systolic blood pressure was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available.

**Systolic blood pressure - Test Time**: Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time must be in military format.

<u>Arterial lactate</u>: Enter the candidate's arterial lactate in mmol/L. The entry must fall between greater than 4 and 50 mmol/L.

<u>Arterial lactate - Test Date</u>: Enter the <u>Test Date</u> of when the arterial lactate value was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. E

<u>Arterial lactate - Test Time</u>: Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time must be in military format.

<u>Aspartate transaminase</u>: Enter the candidate's aspartate transaminase in U/L. The entry must fall between 1001 and 40000 U/L.

<u>Aspartate transaminase - Test Date</u>: Enter the **Test Date** of when the aspartate transaminase value was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available.

<u>Aspartate transaminase - Test Time</u>: Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time must be in military format.

Alanine transaminase: Enter the candidate's alanine transaminase in U/L. The entry must fall between 1001 and 40000 U/L.

<u>Alanine transaminase - Test Date</u>: Enter the **Test Date** of when the alanine transaminase value was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available.

**Non-dischargeable, surgically implanted, non-endovascular biventricular support device**: Candidate is admitted to the transplant center that registered the candidate on the waitlist, is supported by a surgically implanted, non-endovascular biventricular support device, and must remain hospitalized because the device is not FDA-approved for out of hospital use.

<u>Mechanical circulatory support device (MCSD) with life threatening ventricular</u> <u>arrhythmia</u>: Candidate is admitted to the transplant center that registered the candidate on the waitlist, is supported by an MCSD, and is experiencing recurrent or sustained ventricular tachycardia or ventricular fibrillation. Select at least one of the following:

**Placement of a biventricular MCSD**: Placement of a biventricular mechanical circulatory support device for the treatment of sustained ventricular arrhythmias.

**Patient not considered for other treatments**: The patient was not considered a candidate for other treatment alternatives, such as ablation, by an electrophysiologist, and has experienced 3 or more episodes of ventricular fibrillation or ventricular tachycardia separated by at least an hour, over the previous 7 days that both:

- Occurred in the setting of normal serum magnesium and potassium levels
- Required electrical cardioversion despite receiving continuous intravenous antiarrhythmic therapies

**Exception for status 1**: Candidate does not meet any of the criteria above but is admitted to the transplant hospital that registered the candidate on the waiting list and has an urgency and potential for benefit comparable to that of other candidates at this status. A clinical narrative must be provided to support the candidate's eligibility at this status.

A transplant program may assign a candidate who does not meet any of the above status 1 criteria to status 1 by requesting an exception. The candidate must be admitted to the transplant hospital that registered the candidate on the waiting list, and the program must explain why it considers the candidate to have an urgency and potential for benefit comparable to other status 1 candidates using acceptable medical criteria. The review board will retrospectively review exception requests. If the review board denies an exception request, then within one day of receiving notification of the denial, the candidate's transplant program must either appeal to the review board or assign the candidate to the status for which the candidate qualifies.

# This exception request is specifically related to a device recall

<u>Clinical Narrative</u>: Enter a clinical narrative which supports the eligibility of the candidate for an exceptional case. *Note:* A maximum of 5000 characters is accepted.

### **Justification Form Status 2**

To qualify for status 2, the candidate must meet one of the following criteria.

# Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device (LVAD)

Candidate is admitted to the transplant center that registered the candidate on the waiting list, is supported by a surgically implanted, non-endovascular LVAD, and must remain hospitalized because the device is not FDA approved for out of hospital use.

# Total artificial heart (TAH), BiVAD, right ventricular assist device (RVAD), or ventricular assist device (VAD) for single ventricle patients

Candidate is supported by a TAH, BiVAD, RVAD, or VAD for single ventricle patients.

# Mechanical circulatory support device (MCSD) with malfunction

Candidate is admitted to the transplant center that registered the candidate on the Waitlist™ and is supported by an MCSD that is experiencing device malfunction as evidenced by all of the following.

- Malfunction of at least one of the components of the MCSD
- The malfunction cannot be fixed without an entire device replacement
- The malfunction is currently causing inadequate circulatory support or places the candidate in imminent risk of device stoppage

# Percutaneous endovascular mechanical circulatory support device

Candidate is admitted to the transplant center that registered the candidate on Waitlist™ and is supported by a percutaneous endovascular mechanical circulatory support device for cardiogenic shock. **Within 7** days prior to support:

# Select one of the following:

# Hemodynamic measurements were obtained and within 24 hour period

- Cardiac index was:
  - o Less than 1.8 L/min/m² if the candidate was not supported by an inotrope or
  - o Less than 2.0 L/min/m² if the candidate was supported by an inotrope
- pulmonary capillary wedge pressure was greater than 15 mmHg and
- systolic blood pressure was less than 90 mmHg

Was the candidate on inotropes at the time cardiac index was obtained?: If the candidate was on inotropes at the time cardiac index was obtained, select **Yes**. If not, select **No**. This is a **required** field.

Cardiac index: Enter the candidate's cardiac index in L/min/m². The entry must fall between 0 and 1.79 L/min/m² if the candidate was not supported by inotropes and must be less than 2.0 L/min/m² if the candidate was supported by inotropes. Enter the **Test Date** of when the cardiac index value were obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time must be in military format. This is a **required** field.

**Pulmonary capillary wedge pressure:** Enter the candidate's pulmonary capillary wedge pressure in mmHg. The entry must fall between 16 and 100 mmHg. Enter the **Test Date** of when the PCWP value was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time must be in military format. This is a **required** field.

**Systolic blood pressure**: Enter the candidate's systolic blood pressure in mmHg. The entry must fall between 50 and 89 mmHg. Enter the **Test Date** of when the systolic blood pressure was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time must be in military format. This is a **required** field.

Hemodynamic measurements were not obtained. However, within 24 hours prior to percutaneous endovascular mechanical support. Enter a qualifying value for at least one of the following:

**Date of administration of CPR:** Enter the date of administration of CPR. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. Enter the time that CPR was administered. The time must be in the following 24-hour format: HH:MM. Time must be in military format.

**Systolic blood pressure:** Enter the candidate's systolic blood pressure in mmHg. The entry must fall between 50 and 69 mmHg. Enter the **Test Date** of when the systolic blood pressure was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time must be in military format.

**Arterial lactate:** Enter the candidate's arterial lactate in mmol/L. The entry must fall between greater than 4 and 50 mmol/L. Enter the **Test Date** of when the arterial lactate value was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time should be in military format.

**Aspartate transaminase:** Enter the candidate's aspartate transaminase in U/L. The entry must fall between 1001 and 40000 U/L. Enter the **Test Date** of when the aspartate transaminase value was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time must be in military format.

**Alanine transaminase:** Enter the candidate's alanine transaminase in U/L. The entry must fall between 1001 and 40000 U/L. Enter the **Test Date** of when the alanine transaminase value was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time must be in military format.

# Intra-aortic balloon pump

Candidate is admitted to the transplant center that registered the candidate on Waitlist™ and is supported by IABP for cardiogenic shock. **Within 7 days prior to support:** 

# Select one of the following:

Hemodynamic measurements were obtained and within 24 hour period:

- Cardiac index was:
  - o Less than 1.8 L/min/m² if the candidate was not supported by an inotrope or

- Less than 2.0 L/min/m<sup>2</sup> if the candidate was supported by an inotrope
- Pulmonary capillary wedge pressure was greater than 15 mmHg and
- Systolic blood pressure was less than 90 mmHg

Was the candidate on inotropes at the time cardiac index was obtained?: If the candidate was on inotropes at the time cardiac index was obtained, select **Yes**. If not, select **No**. This is a **required** field.

Cardiac index: Enter the candidate's cardiac index in L/min/m². The entry must fall between 0 and 1.79 L/min/m² if the candidate was not supported by inotropes and must be less than 2.0 L/min/m² if the candidate was supported by inotropes. Enter the **Test Date** of when the cardiac index value was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time must be in military format. This is a **required** field.

**Pulmonary capillary wedge pressure:** Enter the candidate's pulmonary capillary wedge pressure in mmHg. The entry must fall between 16 and 100 mmHg. Enter the **Test Date** of when the PCWP value was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time must be in military format. This is a **required** field.

**Systolic blood pressure:** Enter the candidate's systolic blood pressure in mmHg. The entry must fall between 50 and 89 mmHg. Enter the **Test Date** of when the systolic blood pressure was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time must be in military format. This is a **required** field.

Hemodynamic measurements were not obtained. However, within 24 hours prior to IABP support. Enter a qualifying value for at least one of the following:

**Date of administration of CPR:** Enter the date of administration of CPR. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. Enter the time that CPR was administered. The time must be in the following 24-hour format: HH:MM. Time must be in military format.

**Systolic blood pressure:** Enter the candidate's systolic blood pressure in mmHg. The entry must fall between 50 and 69 mmHg. Enter the **Test Date** of when the systolic blood pressure was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in

the following 24-hour format: HH:MM. Time must be in military format.

**Arterial lactate:** Enter the candidate's arterial lactate in mmol/L. The entry must fall between greater than 4 and 50 mmol/L. Enter the **Test Date** of when the arterial lactate value was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time should be in military format.

**Aspartate transaminase:** Enter the candidate's aspartate transaminase in U/L. The entry must fall between 1001 and 40000 U/L. Enter the **Test Date** of when the aspartate transaminase value was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time must be in military format.

Alanine transaminase: Enter the candidate's alanine transaminase in U/L. The entry must fall between 1001 and 40000 U/L. Enter the **Test Date** of when the alanine transaminase value was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time must be in military format.

# Ventricular tachycardia (VT) or ventricular fibrillation (VF)

Candidate is admitted to the transplant center that registered the candidate on Waitlist™ and is not considered a candidate for other treatment alternatives, such as ablation, by an electrophysiologist, and is experiencing recurrent or sustained VT or VF with at least three episodes separated by at least one hour within a period of 14 days. The VT or VF must have occurred in the setting of normal serum magnesium and potassium levels and required electrical cardioversion despite receiving antiarrhythmic therapies. *Note:* Anti-tachycardia pacing (ATP) qualifies as electrical cardioversion, in a hospitalized candidate experiencing VT on anti-arrhythmic medication.

# **Exception for status 2**

Candidate does not meet any of the criteria above but is admitted to the transplant hospital that registered the candidate on the waiting list and has an urgency and potential for benefit comparable to that of other candidates at this status. A clinical narrative must be provided to support the candidate's eligibility at this status.

A transplant program may assign a candidate who does not meet any of the above status 2 criteria to status 2 by requesting an exception. The candidate must be admitted to the transplant hospital that registered the candidate on the waiting list, and the program must explain why it considers the candidate to have an urgency and potential for benefit comparable to other status 2 candidates using acceptable medical criteria. The review board will retrospectively review exception requests. If the review board denies an exception request, then within one day of receiving notification of the denial, the candidate's transplant program

must either appeal to the review board or assign the candidate to the status for which the candidate qualifies.

**Clinical Narrative:** Enter a clinical narrative which supports the eligibility of the candidate for an exceptional case. **Note:** A maximum of 5000 characters is accepted.

### **Justification Form Status 3**

To qualify for status 3, the candidate must meet one of the following criteria.

Dischargeable left ventricular assist device (LVAD) for discretionary 30 days. Candidate is supported by a dischargeable LVAD. The 30 days do not have to be consecutive. If the candidate undergoes a procedure to receive another replacement dischargeable LVAD, then the candidate qualifies for a new term of 30 days. When a candidate receives a replacement device, the 30 day period begins again, and the candidate cannot use any time remaining from the previous period.

<u>Multiple inotropes or a single high dose inotrope and hemodynamic monitoring</u>

Candidate is admitted to the transplant hospital that registered the candidate on the waiting list. Within 7 days prior to inotrope administration or while on inotropes, all of the following are true.

# Select one of the following:

Candidate has an invasive pulmonary artery catheter

Candidate has daily hemodynamic monitoring to measure cardiac output and left ventricular filling pressures

### **Candidate** is supported by either:

A continuous infusion of at least one high dose intravenous inotrope:

- Dobutamine greater than or equal to 7.5 mcg/kg/min
- Milrinone greater than or equal to 0.50 mcg/kg/min
- Epinephrine greater than or equal to 0.02 mcg/kg/min

A continuous infusion of at least two intravenous inotropes:

- Dobutamine greater than or equal to 3mcg/kg/min
- Milrinone greater than or equal to 0.25 mcg/kg/min
- Epinephrine greater than or equal to 0.01 mcg/kg/min
- Dopamine greater than or equal to 3 mcg/kg/min

# The candidate is in cardiogenic shock as evidenced by all the following values obtained within one 24 hour period

Cardiac index was:

- Less than 1.8 L/min/m<sup>2</sup> if the candidate was not on inotropic or mechanical support within 7 days prior to inotrope administration or
- Less than 2.2 L/min/m<sup>2</sup> if the candidate was on inotropic or mechanical support

Pulmonary capillary wedge pressure greater than 15 mmHg Systolic blood pressure less than 90 mmHg Was the candidate on inotropic or mechanical support at the time cardiac index was obtained?: If the candidate was on inotropic or mechanical support at the time of cardiac arrest, select **Yes**. If not, select **No**. This is a **required** field.

**Cardiac index:** Enter the candidate's cardiac index in L/min/m². The entry must fall between 0 and 1.79 L/min/m² if the candidate was not on inotropic or mechanical support and must be less than 2.2 L/min/m² if the candidate was on inotropic or mechanical support. Enter the **Test Date** of when the cardiac index value was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time must be in military format. This is a **required** field.

**Pulmonary capillary wedge pressure:** Enter the candidate's pulmonary capillary wedge pressure in mmHg. The entry must fall between 16 and 100 mmHg. Enter the **Test Date** of when the PCWP value was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time must be in military format. This is a **required** field.

**Systolic blood pressure:** Enter the candidate's systolic blood pressure in mmHg. The entry must fall between 50 and 89 mmHg. Enter the **Test Date** of when the systolic blood pressure was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time must be in military format. This is a **required** field.

### Mechanical circulatory support device (MCSD) with hemolysis

Candidate is supported by an MCSD that is not experiencing device malfunction, but is experiencing hemolysis, as evidenced by both of the following:

Two separate samples collected within 48 hours of each other confirming markers of active hemolysis as evidenced by at least two of the following:

- Blood lactate dehydrogenase (LDH) at least 2.5 times the upper limit of normal at the laboratory reference range
- Plasma free hemoglobin greater than 20 mg/dL
- Hemoglobinuria
- Documentation is available of at least one attempt to treat the condition using an intravenous anticoagulant, intravenous anti-platelet agent, or thrombolytic, with persistent or recurrent hemolysis.

# Mechanical circulatory support device (MCSD) with pump thrombosis

Candidate is admitted to the transplant hospital that registered the candidate on the waiting list, is supported by MCSD, and the transplant program has identified a suspected pump thrombosis in either an implanted LVAD or a dischargeable paracorporeal device and both of the following criteria are met:

The candidate has one of the following conditions:

Transient Ischemic Attack (TIA) lasting less than 24 hours or Reversible Ischemic Neurologic Deficit (RIND) lasting less than 72 hours (as observed by symptoms such as, but not limited to unilateral facial weakness, vision problems, and/or

slurred speech), Cerebrovascular Accident (CVA), or peripheral thromboembolic event in the absence of intracardiac thrombus or significant carotid artery disease

A condition that requires inotropic support and presence of leftsided heart failure not explained by structural heart disease such as Aortic Insufficiency (AI) as demonstrated by

- Pulmonary Capillary Wedge Pressure (PCWP) greater than 15, and
- Mean Arterial Pressure (MAP) less than 90

Abnormal pump parameters, such as significant and persistent increase in pump power and low flow despite good blood pressure control

Visually detected thrombus in a paracorporeal ventricular device (VAD)

**AND** The candidate is supported by one of the following treatments in the hospital:

- Intravenous anticoagulation (e.g., heparin)
- Intravenous thrombolytics (e.g., tPA)
- Intravenous antiplatelet therapy (e.g., eptifibatide or tirofiban)

# Mechanical circulatory support device (MCSD) with right heart failure

Candidate is supported by an MCSD and has at least moderate right ventricular malfunction in the absence of the left ventricular assist device (LVAD) malfunction and meets the following qualifying requirements:

Has been treated with at least one of the following therapies for at least 14 consecutive days and requires ongoing treatment with at least one of the following therapies:

**Dobutamine**: Enter the dosage of dobutamine in mcg/kg/min. The entry must fall between 5 and 999 mcg/kg/min. Enter the **Date of Initiation**. The date must be in the following format: MM/DD/YYYY. A calendar link is available.

**Dopamine**: Enter the dosage of dopamine in mcg/kg/min. The entry must fall between 4 and 999 mcg/kg/min. Enter the **Date of Initiation**. The date must be in the following format: MM/DD/YYYY. A calendar link is available.

**Epinephrine**: Enter the dosage of epinephrine in mcg/kg/min. The entry must fall between 0.05 and 999 mcg/kg/min. Enter the **Date of Initiation**. The date must be in the following format: MM/DD/YYYY. A calendar link is available.

**Milrinone**: Enter the dosage of milrinone in mcg/kg/min. The entry must fall between 0.35 and 999 mcg/kg/min. Enter the **Date of Initiation**. The date must be in the following format: MM/DD/YYYY. A calendar link is available.

**Inhaled nitric oxide**: Select checkbox, if applicable. Enter the **Date of Initiation**. The date must be in the following format: MM/DD/YYYY. A calendar link is available.

**Intravenous prostacyclin**: Select checkbox, if applicable. Enter the **Date of Initiation**. The date must be in the following format: MM/DD/YYYY. A calendar link is available.

Within 7 days prior to initiation of any of the therapies above, all of the following are true within one 24 hour period:

Pulmonary capillary wedge pressure less than 20 mmHg

### Central venous pressure greater than 18 mmHg

**Pulmonary capillary wedge pressure**: Enter the candidate's pulmonary capillary wedge pressure in mmHg. The entry must fall between 0 and 19 mmHg. Enter the **Test Date** of when the PCWP value was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time must be in military format.

Central venous pressure: Enter the candidate's central venous pressure in mmHg. The entry must fall between 19 and 50 mmHg. Enter the **Test Date** of when the CVP value was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time must be in military format.

# Mechanical circulatory support device (MCSD) with device infection

Candidate is supported by an MCSD, is experiencing a pump-related local or systemic infection and has one of the following symptoms or continues to require IV antibiotics:

- Erythema and pain along the driveline with either leukocytosis or a 50 percent increase in white blood cell count from the last recorded white blood cell count, and either:
  - Positive bacterial or fungal cultures from the driveline exit site within the last 14 days
  - A culture positive fluid collection between the exit site and the device
- Debridement of the driveline with positive cultures from sites between the exit site and the device requiring IV antibiotics
- Recurrent debridement
- Positive culture of material from the pump pocket of an implanted device
- Bacteremia treated with antibiotics
- Recurrent bacteremia that recurs from the same organism within four weeks following antibiotic treatment to which the bacteria is susceptible

# Mechanical circulatory support device (MCSD) with mucosal bleeding

Candidate is admitted to the transplant hospital that registered the candidate on the waiting list, and meets all of the following qualifying requirements:

- Is supported by an MCSD
- Has been hospitalized for mucosal bleeding at least two times within the past six months, excluding the candidate's hospitalization for implantation of the MCSD
- The candidate has received blood transfusions of at least two units of packed red blood cells per hospitalization during at least two hospitalizations for mucosal bleeding
- The candidate's international normalized ratio (INR) was less than 3.0 at the time of at least one of the bleeds

 The candidate's hematocrit upon admission is less than or equal to 0.20 or decreased by 20 percent or more relative to the last measured value at any time during the bleeding episode

Number of hospitalizations for mucosal bleeding within the past six months: Select 2 or 3 or more.

**Note:** Hospitalizations must exclude candidate's hospitalization for implantation of the MCSD.

# Mechanical circulatory support device (MCSD) with aortic insufficiency (AI)

Candidate is supported by an MCSD and is not exhibiting evidence of device malfunction, but is experiencing AI and meets all of the following requirements:

- At least moderate AI by any imaging modality in the setting of the mean arterial pressure (MAP) less than or equal to 80 mmHg
- Pulmonary capillary wedge pressure greater than 20 mmHg
- New York Heart Association (NYHA) Class III-IV symptoms

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# Veno-arterial extracorporeal membrane oxygenation (VA ECMO) after 7 days

Candidate is admitted to the transplant hospital that registered the candidate on the waiting list, is supported by VA ECMO, and the transplant hospital has already assigned the candidate to status 1 under the VA ECMO criteria for 7 days.

*Note:* The system will not allow this selection unless the prerequisites have been met.

# Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device (LVAD) after 14 days

Candidate is admitted to the transplant hospital that registered the candidate on the waiting list, is supported by a non-dischargeable, surgically implanted, non-endovascular left ventricular assist device (LVAD), and the transplant hospital has already assigned the candidate to status 2 under the non-dischargeable, surgically implanted, non-endovascular left ventricular assist device (LVAD)criteria for 14 days.

**Note:** The system will not allow this selection unless the prerequisites have been met.

### Percutaneous endovascular circulatory support device after 14 days

Candidate is admitted to the transplant hospital that registered the candidate on the waiting list, is supported by a percutaneous endovascular circulatory support device, and the transplant hospital has already assigned the candidate to status 2 under the percutaneous endovascular circulatory support device criteria for 14 days.

**Note:** The system will not allow this selection unless the prerequisites have been met.

### Intra-aortic balloon pump after 14 days

Candidate is admitted to the transplant hospital that registered the candidate on the waiting list, is supported by an intra-aortic balloon pump, and has already assigned the candidate to status 2 under the intra-aortic balloon pump criteria for 14 days.

*Note:* The system will not allow this selection unless the prerequisites have been met.

# Mechanical Circulatory Support Device (MCSD) with life threatening ventricular arrhythmia after 7 days

Candidate is admitted to the transplant hospital that registered the candidate on the waitlist, has already been assigned to status 1 under Mechanical Circulatory Support Device (MCSD) with Life Threatening Ventricular Arrhythmia for 7 days criteria for 7 days, and is supported by:

Select at least one of the following:

- Placement of a biventricular mechanical circulatory support device for the treatment of sustained ventricular arrhythmias.
- Receiving continuous intravenous antiarrhythmic therapy.

# **Exception for status 3**

Candidate does not meet any of the criteria above but is admitted to the transplant hospital that registered the candidate on the waiting list and has an urgency and potential for benefit comparable to that of other candidates at this status. A clinical narrative must be provided to support the candidate's eligibility at this status.

A transplant program may assign a candidate who does not meet any of the above status 3 criteria to status 3 by requesting an exception. The candidate must be admitted to the transplant hospital that registered the candidate on the waiting list, and the program must explain why it considers the candidate to have an urgency and potential for benefit comparable to other status 3 candidates using acceptable medical criteria. The review board will retrospectively review exception requests. If the review board denies an exception request, then within one day of receiving notification of the denial, the candidate's transplant program must either appeal to the review board or assign the candidate to the status for which the candidate qualifies.

**Clinical Narrative:** Enter a clinical narrative which supports the eligibility of the candidate for an exceptional case. *Note:* A maximum of 5000 characters is accepted.

### **Justification Form Status 4**

To qualify for status 4, the candidate must meet one of the following criteria.

# <u>Dischargeable left ventricular assist device (LVAD) without discretionary 30 days</u> Candidate is supported by a dischargeable LVAD.

### Inotropes without hemodynamic monitoring

Candidate is supported by a continuous infusion of a positive inotropic agent.

### Requires treatment with at least one of the following intravenous inotropes:

**Dobutamine**: Enter the dosage of dobutamine in mcg/kg/min. The entry must fall between 3 and 999 mcg/kg/min. Enter the **Date of Initiation**. The date must be in the following format: MM/DD/YYYY. A calendar link is available.

**Milrinone**: Enter the dosage of milrinone in mcg/kg/min. The entry must fall between 0.25 and 999 mcg/kg/min. Enter the **Date of Initiation**. The date must be in the following format: MM/DD/YYYY. A calendar link is available.

**Epinephrine**: Enter the dosage of epinephrine in mcg/kg/min. The entry must fall between 0.01 and 999 mcg/kg/min. Enter the **Date of Initiation**. The date must be in the following format: MM/DD/YYYY. A calendar link is available.

**Dopamine**: Enter the dosage of dopamine in mcg/kg/min. The entry must fall between 3 and 999 mcg/kg/min. Enter the **Date of Initiation**. The date must be in the following format: MM/DD/YYYY. A calendar link is available.

# Meets the following qualifying requirements:

**Cardiac index**: Enter the candidate's cardiac index in L/min/m². The entry must fall between 0 and 2.19 within 7 days prior to inotropic administration or while on inotrope infusion. Enter the **Test Date** of when the cardiac index value were obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. **Note:** The test date for cardiac index must be within 7 days prior to, or anytime after, the date of initiation of one of the inotropes.

**Pulmonary capillary wedge pressure:** Enter the candidate's pulmonary capillary wedge pressure in mmHg. The entry must fall between 16 and 100. Enter the **Test Date** of when the PCWP value was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available.

# **Congenital heart disease**

Candidate is diagnosed with a hemodynamically significant congenital heart disease. Check all that apply.

**Atrial Isomerism/Heterotaxy** 

**Atrioventricular Septal Defect** 

**Congenitally Corrected Transposition (L-TGA)** 

**Double Outlet Right Ventricle** 

**Ebstein's Anomaly** 

**Hypoplastic Left Heart Syndrome** 

Other left Heart Valvar/Structural Hypoplasia

**Pulmonary Atresia with Intact Ventricular Septum** 

Single Ventricle

**Tetralogy of Fallot** 

Transposition of the Great Arteries

**Truncus Arteriosus** 

**Ventricular Septal Defect(s)** 

Other

### Ischemic heart disease with intractable angina

Candidate is diagnosed with ischemic heart disease and has intractable angina with all of the following:

Coronary artery disease

Canadian cardiovascular society grade IV angina pectoris that cannot be treated by a combination of medical therapy, and percutaneous or surgical revascularization

Myocardial ischemia shown by imaging

# Amyloidosis, or hypertrophic or restrictive cardiomyopathy

Candidate is diagnosed with at least one of the following:

**Amyloidosis** 

Hypertrophic cardiomyopathy

Restrictive cardiomyopathy

Candidate meets at least one of the following requirements:

Canadian Cardiovascular Society Grade IV angina pectoris that cannot be controlled by medical therapy

New York Heart Association (NYHA) Class III-IV symptoms with either:

- Cardiac index less than 2.2 L/min/m<sup>2</sup>
- Left or right atrial pressure, left or right ventricular end-diastolic pressure, or pulmonary capillary wedge pressure greater than 20 mmHg

Ventricular tachycardia lasting at least 30 seconds

Ventricular fibrillation

Ventricular arrhythmia requiring electrical cardioversion

Sudden cardiac death

### **Retransplant**

Candidate has had a previous heart transplant and there is evidence of International Society of Heart and Lung Transplantation (ISHLT) coronary allograft vasculopathy (CAV) grade 2-3, or New York Heart Association (NYHA) Class III-IV heart failure symptoms. *Note:* Previous heart transplants include non-US transplants.

# **Exception for status 4**

Candidate does not meet any of the criteria above, but has an urgency and potential for benefit comparable to that of other candidates at this status. Provide a clinical narrative below to support the candidate's eligibility at this status.

A transplant program may assign a candidate who does not meet any of the above status 4 criteria to status 4 by requesting an exception. The program must explain why it considers the candidate to have an urgency and potential for benefit comparable to other status 4 candidates using acceptable medical criteria. The review board will retrospectively review exception requests. If the review board denies an exception request, then within one day of receiving notification of the denial, the candidate's transplant program must either appeal to the review board or assign the candidate to the status for which the candidate qualifies.

**Clinical Narrative:** Enter a clinical narrative which supports the eligibility of the candidate for an exceptional case. *Note:* A maximum of 5000 characters is accepted.

### Verify ABO

ABO: Verify the candidate's ABO.

Public Burden Statement: The private, non-profit Organ Procurement and Transplantation Network (OPTN) collects this information in order to perform the following OPTN functions: to assess whether applicants meet OPTN Bylaw requirements for membership in the OPTN; and to monitor compliance of member organizations with OPTN Obligations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0915-0157 and it is valid until XX/XX/202X. This information collection is required to obtain or retain a benefit per 42 CFR §121.11(b)(2). All data collected will be subject to Privacy Act protection (Privacy Act System of Records #09-15-0055). Data collected by the private non-profit OPTN also are well protected by a number of the Contractor's security features. The Contractor's security system meets or exceeds the requirements as prescribed by OMB Circular A-130, Appendix III, Security of Federal Automated Information Systems, and the Departments Automated Information Systems Security Program Handbook. The public reporting burden for this collection of information is estimated to average 0.27 hours per response, including the time for reviewing instructions, searching existing data sources, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HRSA Information Collection Clearance Officer, 5600 Fishers Lane, Room 14N39, Rockville, Maryland, 20857 or paperwork@hrsa.gov.