# Adult Heart and HeartLung Status 1-6 Justification Form 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 <a href="OPTN Policy">OPTN Policy</a>, 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.

<u>Any prior history of stroke?</u>: 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.

**Is the candidate on a diuretic?**: 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)).

**Bumetanide – Amount:** 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.

**<u>Bumetanide - IV/PO</u>**: 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.

**Is the candidate on pulmonary vasodilators?**: 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 SvO₂: Enter the measurement of oxygenation saturation from mixed venous blood (SvO₂) 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.

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.