Form 5: Rejection

Select the baseline immunosuppressive therapy at time of rejection
- Azathioprine
- Cyclosporine
- Everolimus
- Immune globulin
- Methotrexate
- Mycophenolate
- Plasmapheresis
- Prednisone
- Rituximab
- Sirolimus
- Tacrolimus
- Cytoxan (cyclophosphamide)
- Unknown
- Other, specify

Biopsy Prior to Rejection Event

3

Biopsy Performed Prior to Rejection Event
- No
- Yes

If performed prior to this rejection diagnosis, indicate the score of the most recent biopsy performed that did not lead to rejection treatment.

3

Biopsy Date Prior to Rejection

MM/DD/YYYY

Missing Reason:
- Unknown

3

ACR Score
2004 revised ISHLT scoring system for ACR:
(J Heart Lung Transplant. 2005 Nov;24(11):1710-20.)
ACR: acute cellular rejection (0, 1R, 2R, 3R)
- 0
- 1R
- 2R
- 3R
- Unknown

3

AMR Score
2013 revised ISHLT scoring system for pAMR:
(J Heart Lung Transplant 2013 Dec 32(12):1147-62.)
pAMR: pathologic antibody mediated rejection (0, 1h, 1i, 2, 3)
- Both histology and immunofluorescence/immunohistochemistry performed (ie. C4d or C3d)
- Did not assess biopsy for evidence of AMR
- Only assessed histology/ did not perform immunofluorescence/immunohistochemistry (ie. C4d or C3d)
- Unknown

3

AMR Findings
If only accessed histology/ did not perform immunofluorescence or immunohistochemistry (ie. C4d or C3d)
- No histologic features AMR
- Positive histologic features AMR (ie. Vasculitis/pericapillaritis)
- 0 (negative)
Rejection Events

Start with newly diagnosed rejection by biopsy (convert to ISHLT score) or other criteria leading to bolus immunotherapy. List all follow-up biopsies or changes in therapy. The last entry should be the first biopsy or echo not prompting additional therapy. Enter each subsequent rejection event until episode is resolved.

4 Was donor specific Ab testing performed at the time of the rejection event

- No, Did not send testing for any circulating antibodies
- Yes
- Unknown

4 Which antibodies were tested and what were the results

- HLA class I and/or class II DSA
- Isoagglutinin (A or B Ab) to ABO-i graft
- Non-HLA antibody (e.g. MICA, MICB, anti-endothelial, vimentin, anti-myosin, angiotensin receptor (AR1T), or other non-HLA
- Unknown

4 HLA Class I and/or II DSA Result

- Negative
- Positive
- Unknown

4 HLA class I and/or II DSA Result, Positive

- Complement fixing (C1q positive)
- Increased from last date tested
- New
- Present but stable (no new abs and not increased from baseline)
- Unknown

4 Non-HLA Ab Result

- Negative
- Positive
- Unknown

4 Non-HLA Ab Result, Positive

- Increased from last date tested
- New
- Present but stable (no new abs and not increased from baseline)
- Unknown

4 Isoagglutinin (A or B Ab) to ABO-i graft

- Negative
- Positive
- Unknown
**Date of rejection event**
Any episode leading to an increase in immunotherapy to treat a biopsy or clinically diagnosed episode of rejection
MM/DD/YYYY

### 5a Basis for Diagnosis of Current Rejection Event
- Biopsy
- Clinical
- ECHO
- New or increased Abs
- Unknown

### 5b Was biopsy performed?
- No
- Yes

#### 5b Indication for biopsy
Check all that apply.
- Objective Evidence of Graft Dysfunction
- Research
- Routine (scheduled as part of protocol surveillance)
- Symptoms

#### 5b ACR Grading
2004 revised ISHLT scoring system for ACR:
(J Heart Lung Transplant. 2005 Nov;24(11):1710-20.)
ACR: acute cellular rejection (0, 1R, 2R, 3R)
- 0
- 1R
- 2R
- 3R
- Unknown

#### 5b AMR Grading
2013 revised ISHLT scoring system for pAMR:
J Heart Lung Transplant 2013 Dec 32(12):1147-62.)
pAMR: pathologic antibody mediated rejection (0, 1h, 1i, 2, 3)
- Both histology and immunofluorescence/immunohistochemistry performed (ie. C4d or C3d)
- Did not assess biopsy for evidence of AMR
- Only assessed histology/ did not perform immunofluorescence/immunohistochemistry (ie. C4d or C3d)
- Unknown

#### 5b Histology results
- No histologic features AMR
- Positive histologic features AMR

#### 5b If both histology and immunofluorescence/ immunohistochemistry performed, indicate pAMR score
2013 revised ISHLT scoring system for pAMR:
J Heart Lung Transplant 2013 Dec 32(12):1147-62.)
pAMR: pathologic antibody mediated rejection (0, 1h, 1i, 2, 3)
- 0
- 1h
- 1i
- 2
- 3
- Positive with Unknown Score

### 5c Was there therapy used to treat this rejection episode?
If no rejection therapy was used, no more rejection episodes should be entered for this event.
- No
- Yes

#### 5c Select the therapy used
- ATG or ATGAM
- Bortezomib
<table>
<thead>
<tr>
<th>5d</th>
<th>Was episode of rejection associated with hemodynamic compromise?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>None - No significant change in cardiac function at the time of rejection</td>
</tr>
<tr>
<td></td>
<td>Mild - Worsening of cardiac function detected (decreased ejection fraction, hypotension, EKG changes) not requiring inotropes.</td>
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<tr>
<td></td>
<td>Severe Inotropic support added due to this rejection episode.</td>
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</tbody>
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<tr>
<th>6</th>
<th>Indicate date of the end of the rejection episode MM/DD/YYYY</th>
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<table>
<thead>
<tr>
<th>7</th>
<th>Was there baseline immunosuppressive therapy at time of resolution of rejection event</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
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<table>
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<tr>
<th>7</th>
<th>Baseline immunosuppressive therapy at time of resolution of rejection event</th>
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<tbody>
<tr>
<td></td>
<td>Azathioprine (Imuran)</td>
</tr>
<tr>
<td></td>
<td>Cyclosporine (Sandimmune, Neoral, Gengraf, CSA, CyA)</td>
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<tr>
<td></td>
<td>Everolimus</td>
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<tr>
<td></td>
<td>Immune globulin</td>
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<td></td>
<td>Methotrexate</td>
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<td></td>
<td>Mycophenolate (Cellcept, Myfortic)</td>
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<td></td>
<td>Prednisone</td>
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<td></td>
<td>Rituximab</td>
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<td></td>
<td>Sirolimus (Rapamycin, Rapamune)</td>
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<td></td>
<td>Tacrolimus (Prograf, FK506)</td>
</tr>
<tr>
<td></td>
<td>Cytoxan (Cyclophosphamide)</td>
</tr>
<tr>
<td></td>
<td>Unknown</td>
</tr>
<tr>
<td></td>
<td>Other, Specify</td>
</tr>
</tbody>
</table>

- Eculizumab
- Immune Adsorption
- Immunoglobulin
- Methotrexate
- Photopheresis
- Plasmapheresis
- Rituximab
- Steroid Taper
- Steroids, IV
- Steroids, Oral
- Tacrolimus
- Cytoxan (cyclophosphamide)
- Other, specify