## Transfusion Reaction Reporting to External Agencies Job Aid for Hospital TMS

### Table 1: Related to Blood Components (red blood cells, platelets, plasma)

<table>
<thead>
<tr>
<th>Type of Transfusion Related Adverse Reaction</th>
<th>Report to Health Canada*</th>
<th>Report to CBS*</th>
<th>Report to PBCO, within 30 days of conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>FNHTR, minor Allergic, TACO, TAD, Hypotensive reaction, Delayed hemolytic reaction, and all other reactions not related to the quality of the product</td>
<td>N/A</td>
<td>N/A</td>
<td>Final Report</td>
</tr>
<tr>
<td>• Positive culture of a component</td>
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<tr>
<td>• Severe allergic/anaphylactic/anaphylactoid</td>
<td>N/A</td>
<td>Final Report</td>
<td>Final Report</td>
</tr>
<tr>
<td>• Acute hemolytic reaction</td>
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<tr>
<td>• Significant hyperkalemia</td>
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<td>• Graft vs host disease</td>
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<tr>
<td>• Post transfusion purpura</td>
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<tr>
<td>• Post transfusion infections</td>
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<tr>
<td>• Unusual reactions e.g. red-eye syndrome</td>
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<td></td>
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<tr>
<td>Death linked to transfusion</td>
<td>• Within 24 hours of being notified</td>
<td>• As soon as suspected</td>
<td>Final Report</td>
</tr>
<tr>
<td>• TRALI (includes possible TRALI)</td>
<td>• Within 15 days of being notified</td>
<td>• As soon as suspected, include CBS TRALI Form for TRALI cases</td>
<td>Final Report</td>
</tr>
<tr>
<td>• Suspected bacterial contamination</td>
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<tr>
<td>• Product ABO/D incorrect</td>
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<td></td>
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<tr>
<td>• Product quality is doubtful</td>
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<tr>
<td>• A reaction with the case resulting in</td>
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<tr>
<td>• Their inpatient hospitalization or its prolongation</td>
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<tr>
<td>• Persistent or significant disability or incapacity</td>
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<tr>
<td>• Medical or surgical intervention to preclude a persistent or significant disability or incapacity</td>
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<td></td>
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<tr>
<td>• A life threatening condition</td>
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<tr>
<td>• Any other product attribute issue where the product would be quarantined so that another patient is not placed at risk</td>
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<tr>
<td>• Any other unexpected serious adverse event that may affect the safety of the blood supply</td>
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</tbody>
</table>

* When reporting to external agencies edit recipient identifier so that only the recipient’s date of birth, sex, hospital identification, and date of transfusion are required

**Note 1:** Cases concluded as, “No Transfusion Reaction” should not be reported to CBS, Health Canada or the PBCO

**Note 2:** Reports may be filed to CBS at the pathologist’s direction
Table 2: Related to Plasma Protein Products

<table>
<thead>
<tr>
<th>Type of Transfusion Related Adverse Reaction</th>
<th>Report to Manufacturer*</th>
<th>Report to PBCO, within 30 days of conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>• FNHTR, minor Allergic, TACO, TAD, Hypotensive reaction, IVIG Headache, Aseptic Meningitis and all other reactions not related to the quality of the product</td>
<td>N/A</td>
<td>Final Report</td>
</tr>
<tr>
<td>• Suspected bacterial contamination&lt;br&gt;• Incorrect ABO (eg SD Plasma)&lt;br&gt;• Any other product attribute issue where the product would be quarantined so that another patient is not placed at risk</td>
<td>• As soon as suspected&lt;br&gt;• Final Report</td>
<td>Final Report</td>
</tr>
<tr>
<td>Death linked to transfusion</td>
<td>• As soon as suspected&lt;br&gt;• Final Report</td>
<td>Final Report</td>
</tr>
<tr>
<td>Any other unexpected serious adverse event that resulting in:&lt;br&gt;• Their inpatient hospitalization or its prolongation&lt;br&gt;• Persistent or significant disability or incapacity&lt;br&gt;• Medical or surgical intervention to preclude a persistent or significant disability or incapacity&lt;br&gt;• A life threatening condition</td>
<td>• As soon as suspected&lt;br&gt;• Final Report</td>
<td>Final Report</td>
</tr>
</tbody>
</table>

* For reports to Manufacturer, edit recipient identifiers so that only the recipient initials, date of birth and date of reaction are sent. Include recipient gender, concomitant therapies/medications, contact or report's name and information, product storage details, product infusion details (rate, route) and recipient blood type.

Note 1: Cases concluded as, “No Transfusion Reaction” should not be reported to CBS, Health Canada or the PBCO.

Note 2: Reports may be filed to CBS and/or to Health Canada at the pathologist’s direction.