**IRISH BLOOD TRANSFUSION SERVICE**

**COMPLAINT/DEFECT REPORT FORM**

For completion by reporting hospital in the event of a complaint/defect with Blood Product or Service. To report Adverse Transfusion Reactions where IBTS has performed compatibility testing use BT - 0311

To: National Quality Assurance Manager, IBTS, NBC, James’s St., Dublin 8 or scan and email to [qualityassurance@ibts.ie](mailto:qualityassurance@ibts.ie)

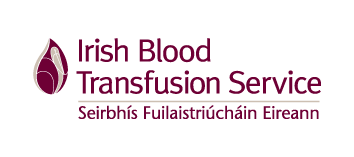
|  |  |  |  |
| --- | --- | --- | --- |
| Recall No: |  | QC No: |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Hospital: |  | | Department: |  |
| Name of person reporting: | |  | | |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **SECTION 1. COMPLAINT/DEFECT/DETAILS:** | | | | | | | |
| Product: |  | | Donation/Batch No. | | |  | |
| Date of Expiry: |  | | Date of observation/  occurrence: | | |  | |
| Service: |  | | Order Type: | | | Routine Emergency | |
| Nature of Complaint/Defect: | | | | | | | |
|  | | | | | | | |
| Did Complaint/Defect result in delay in transfusion? | | | | Yes  No | | | |
| Comments: | |  | | | | | |
| Signature: | |  | | | Date: | |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **SECTION 2. FOR COMPLETION BY IBTS** | | | | | |
| Received By: | Name: |  | | Date: |  |
| Department: |  | | | |
| Complaint Referred to Department for Investigation? | | | Yes  No | | |
| Referred to: | Name: |  | | Date: |  |
| Department: |  | | | |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **SECTION 3. FOR COMPLETION BY HEAD OF DEPARTMENT** | | | | | | | |
| Completion Due Date (*30 days from date registered*): | | | | |  | | |
| Complaint Category (*As per attachment 6.4*): | | | |  | | | |
| Initial Proposed Grade: | | Critical  / Major  / Moderate  / Minor  / Negligible | | | | | |
| Risk Assessment Required? | | | Yes  No | | | | |
| Completed by: |  | | | | | Date: |  |

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| QC No: |  |

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| **SECTION 4. QA/MEDICAL/HOD INSTRUCTION:** | | | | | | | | | |
| Donor | | | Donation/Product/Tissue/Equipment | | | | Previous Donation/s | | |
| Deferral Code | \_\_\_\_\_\_ | | Suitable for Release | |  | | No Action | |  |
| Obs Code |  | | Hold Pending Investigation | |  | | Quarantine | |  |
| No Action |  | | Discard | |  | | Lookback | |  |
|  |  | | Recall | |  | | Recall | |  |
| Other: |  | | | | | | | | |
| Recall No. |  | Authorised by: | |  | | Date: | |  | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **SECTION 5. HEAD OF DEPARTMENT INVESTIGATION/SUMMARY** | | | | |
|  | | | | |
| IR Required? | Yes  No | IR Ref No. |  | |
| Has there been a change to a procedure/process? | | Yes  No | Ref : |  |
| Has this complaint been closed out within 30 days of receipt? | | | Yes  No | |
| Have additional reports been attached? | | | Yes  No | |
| Comments: |  | | | |
| Signature: |  | Date: |  | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **SECTION 6. QA REVIEW/CLOSE OUT** | | | | | | |
| IR Required | Yes  No | | IR Ref No. |  | | |
| Trend/Index file | Yes  No | | Ref No. |  | | |
| Recall | Yes  No | | Recall No. |  | | |
| sSAE | Yes No | | sSAE No. |  | | |
| Final Classification | | Critical  / Major  / Moderate  / Minor  / Negligible | | | | |
| Comments: | |  | | | | |
| Signature: | |  | | | Date: |  |