**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

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

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

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| --- |
| **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:  |   |

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

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| **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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| **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:  |   |

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| **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: |   |

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| **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: |   |