Irish Blood Transfusion Service
Seirbhís Fuilaistriúcháin na hÉireann

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 Form use IBTS/QA/SOP/0080 Attachment 6.1 or MRTC/DIAG/SOP/0038-BT311

To: Quality Assurance Manager, IBTS, NBC, James's St., Dublin 8. **QC :** ______________
or Quality Assurance Manager, IBTS, MRTC, at St Finbarrs Hospital, Cork

Hospital: ______________________ Department: ______________________

Name of person reporting: ______________________

COMPLAINT/DEFECT/DETAILS:

- **Product:** ______________ Donation/Batch No.: ______________

  Date of Expiry: ______________ Date of observation/occurance: ______________

- **Service :** ______________________________

Nature of Complaint/Defect:..

....

....

....

Comments:...

....

Signature: .... Date: ....

FOR COMPLETION BY IBTS

Date Received: ______________ Signature: ....

Complaint/Defect Report No.: ______________ Recall No.______________

Referred on Yes / No Referred to :______________

Verify when in use. Status CURRENT Effective 07/01/2010 00:00.

INVESTIGATIONS AND CORRECTIVE ACTIONS

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Root Cause Analysis: ______________________

Signed: ______________________ Date: ______________________ Attach Documents

Consultant Comments/Instructions:

Donor:
Def Code ☐ __________
Obs Code ☐ __________
No Action ☐

Donation:
Suitable for Release ☐
Hold Pending Investigation ☐
Discard ☐
Recall ☐

Previous Donation/s:
No Action ☐
Quarantine ☐
Lookback ☐
Recall ☐

Signature: ______________________ Date: ______________________

Department Head of SectionComments ______________________

Signature: ______________________ Date: ____/____/________

Donor Record Updated by: ______________________ ***Date:*** ___/___/____

Recall completed by: ______________________ ***Date:*** ___/___/____

Reported to Director of Quality & NMD/RDCH YES NO ***Date:*** ___/___/____

Quality Assurance Department:
CAPA: ______________________

IMB informed by: ______________________ Date: __________ Attach Documents

HV informed by: ______________________ Date: __________

HV ID No: ______________________

Report/Letter Sent By: ______________________ On: __________

Signature: ______________________ Date: __________
Quality Assurance Manager

Category: __________

Closed ☐ Open ☐

Summary

Justified: YES/NO
SAR/SAE

Minor ☐ Major ☐ Critical ☐

IBTS Department responsible for close out: __________

Donor ☐ Hospital ☐
Patient ☐ Other ☐
Manufacturer ☐