

|               |  |            |  |              |                           |           |                              |
|---------------|--|------------|--|--------------|---------------------------|-----------|------------------------------|
| Date Received |  | Risk Level |  | Imputability |                           | Signature |                              |
| HV No         |  |            |  |              | QC No:<br>(if applicable) |           | Recall No<br>(if applicable) |

## HV form 1: National Haemovigilance Office

### Initial Report Form

#### 1. Patient Details

|           |  |                        |  |                              |                                 |                                                  |        |  |
|-----------|--|------------------------|--|------------------------------|---------------------------------|--------------------------------------------------|--------|--|
| Hospital: |  | Unique Incident Number |  | Gender<br><i>Please</i><br>✓ | Male <input type="checkbox"/>   | Age<br><i>Please USE appropriate denominator</i> | Years  |  |
|           |  |                        |  |                              | Female <input type="checkbox"/> |                                                  | Months |  |
|           |  |                        |  |                              |                                 |                                                  | Days   |  |

#### 2. List unit numbers of components/products IMPLICATED

|                                              | Unit Numbers |
|----------------------------------------------|--------------|
| Red Cells                                    |              |
| Platelets Apheresis                          |              |
| Platelets Pooled                             |              |
| Solvent detergent (SD) Plasma                |              |
| FFP                                          |              |
| Cryoprecipitate                              |              |
| Medicinal Products ( <i>please specify</i> ) |              |

#### 3. Other Details

|                                            |                                                             |                          |               |                       |             |                       |               |
|--------------------------------------------|-------------------------------------------------------------|--------------------------|---------------|-----------------------|-------------|-----------------------|---------------|
| Date of transfusion                        | ___/___/___                                                 | Time Transfusion Started | ___:___ am/pm | Date reaction noticed | ___/___/___ | Time reaction noticed | ___:___ am/pm |
| Date error discovered                      | ___/___/___                                                 | Time error discovered    | ___:___ am/pm | Date error occurred   | ___/___/___ | Time error occurred   | ___:___ am/pm |
| Fluid balance recorded?<br><i>Please</i> ✓ | Yes <input type="checkbox"/><br>No <input type="checkbox"/> |                          |               | Volume transfused     | _____mls    |                       |               |

#### 4. Baseline observations prior to reaction

|       |  |        |  |     |  |
|-------|--|--------|--|-----|--|
| Temp: |  | Pulse: |  | BP: |  |
|-------|--|--------|--|-----|--|

|                                                                |                                   |                                               |
|----------------------------------------------------------------|-----------------------------------|-----------------------------------------------|
| 5. What is the patient's primary diagnosis?<br><i>Please</i> ✓ | Surgical <input type="checkbox"/> | Oncology/Haematology <input type="checkbox"/> |
|                                                                | Medical <input type="checkbox"/>  | Other <input type="checkbox"/>                |
| Obstetric <input type="checkbox"/>                             |                                   |                                               |
| Details:                                                       |                                   |                                               |

|                                                                |                                                                         |                                     |
|----------------------------------------------------------------|-------------------------------------------------------------------------|-------------------------------------|
| 6. What was the reason for the transfusion?<br><i>Please</i> ✓ | Low Platelet Count / Platelet Function Deficit <input type="checkbox"/> | Ante Natal <input type="checkbox"/> |
|                                                                | Haemorrhage <input type="checkbox"/>                                    | Post Natal <input type="checkbox"/> |
|                                                                | Anaemia <input type="checkbox"/>                                        | Other <input type="checkbox"/>      |
|                                                                | Plasma Coagulation Disorder <input type="checkbox"/>                    |                                     |
| Details:                                                       |                                                                         |                                     |

|               |  |            |  |              |                           |           |                              |
|---------------|--|------------|--|--------------|---------------------------|-----------|------------------------------|
| Date Received |  | Risk Level |  | Imputability |                           | Signature |                              |
| HV No         |  |            |  |              | QC No:<br>(if applicable) |           | Recall No<br>(if applicable) |

### 7. Previous medical or surgical history?

| History <i>Please ✓</i>                       | Details |
|-----------------------------------------------|---------|
| Surgical <input type="checkbox"/>             |         |
| Medical <input type="checkbox"/>              |         |
| Obstetric <input type="checkbox"/>            |         |
| Oncology/Haematology <input type="checkbox"/> |         |
| Other <input type="checkbox"/>                |         |

### 8. Transfusion History

| Year | Month | Outcome | Details |
|------|-------|---------|---------|
|      |       |         |         |
|      |       |         |         |
|      |       |         |         |
|      |       |         |         |

### 9. Pre-transfusion haematology values

|                                                              |  |                                             |                                                          |
|--------------------------------------------------------------|--|---------------------------------------------|----------------------------------------------------------|
| If red cells transfused state pre-transfusion Hb             |  | Pre-transfusion PT                          |                                                          |
| If platelets transfused state pre-transfusion platelet count |  | Pre-transfusion APTT                        |                                                          |
| If plasma transfused state pre-transfusion INR               |  | Was Vitamin K administered? <i>Please ✓</i> | Yes <input type="checkbox"/> No <input type="checkbox"/> |

### 10. Summary of Error/Omission

|                                                                                                                                                                                                 |                                                                          |         |  |  |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|---------|--|--|
|                                                                                                                                                                                                 |                                                                          |         |  |  |
| <b>11. Was the transfusion an emergency? <i>Please ✓</i></b><br>Yes <input type="checkbox"/><br>No <input type="checkbox"/><br>Unknown <input type="checkbox"/><br>N/A <input type="checkbox"/> | <b>12. Interval between commencing transfusion and onset of symptoms</b> | Minutes |  |  |
|                                                                                                                                                                                                 |                                                                          | Hours   |  |  |
|                                                                                                                                                                                                 |                                                                          | Days    |  |  |
|                                                                                                                                                                                                 |                                                                          | Weeks   |  |  |
|                                                                                                                                                                                                 |                                                                          | Months  |  |  |
| Further interval information if necessary:                                                                                                                                                      |                                                                          |         |  |  |

### 13. Symptoms present in the case of a reaction (tick and or record details in relevant boxes)

| Symptom          | ✓ | Details | Symptom                       | ✓ | Details |
|------------------|---|---------|-------------------------------|---|---------|
| Temperature Rise |   |         | Fever                         |   |         |
| Urticaria        |   |         | Chills/Rigors                 |   |         |
| Hypotension      |   |         | Back pain                     |   |         |
| Hypertension     |   |         | Sub-sternal discomfort        |   |         |
| Tachycardia      |   |         | GI symptoms, including cramps |   |         |

|               |  |            |  |              |                           |           |                              |
|---------------|--|------------|--|--------------|---------------------------|-----------|------------------------------|
| Date Received |  | Risk Level |  | Imputability |                           | Signature |                              |
| HV No         |  |            |  |              | QC No:<br>(if applicable) |           | Recall No<br>(if applicable) |

| Symptom               | ✓ | Details | Symptom                  | ✓ | Details |
|-----------------------|---|---------|--------------------------|---|---------|
| Bradycardia           |   |         | Falling haemoglobin      |   |         |
| Dyspnoea              |   |         | Falling urinary output   |   |         |
| Stridor / Wheeze      |   |         | Haemoglobinuria          |   |         |
| Cyanosis              |   |         | Pain along infusion site |   |         |
| Falling O2 saturation |   |         | Restlessness/anxiety     |   |         |
| Rising pCO2           |   |         | Other                    |   |         |
| Chest X ray changes   |   |         |                          |   |         |

|                                                                         |                              |                         |                |
|-------------------------------------------------------------------------|------------------------------|-------------------------|----------------|
| 14. Has your supplying IBTS Quality Assurance Department been informed? | Yes <input type="checkbox"/> | If Yes, person informed |                |
|                                                                         | No <input type="checkbox"/>  | If Yes, date Informed   | ____/____/____ |

|                                                                                                                                          |                              |                             |
|------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|-----------------------------|
| 15. Has this report has been submitted to the NHO from another reporting establishment e.g. Irish Blood Transfusion Service or hospital? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| If Yes, state name of reporting establishment                                                                                            |                              |                             |
| If Yes, what is unique incident number from that reporting establishment?                                                                |                              |                             |

### Nature of Incident

| Serious Adverse Event                                                              | ✓ | Details |
|------------------------------------------------------------------------------------|---|---------|
| Blood to wrong patient (if no reaction)                                            |   |         |
| Incorrect ABO and Rh D group transfused (if no reaction)                           |   |         |
| Incorrect ABO group transfused (if no reaction)                                    |   |         |
| Incorrect Rh D group transfused (if no reaction)                                   |   |         |
| Transfusion of other incorrect antigen / incompatible antigen RCC (if no reaction) |   |         |
| Incorrect component/product transfused                                             |   |         |
| Inappropriate transfusion                                                          |   |         |
| Failure to give an irradiated component                                            |   |         |
| Failure to give CMV negative component                                             |   |         |
| Transfusion of an incorrectly labelled component                                   |   |         |
| Transfusion of expired component                                                   |   |         |
| Transfusion of incorrectly stored component                                        |   |         |
| Transfusion of incorrectly distributed component                                   |   |         |
| Failure to administer product (Anti D)                                             |   |         |
| Delay in giving product (Anti D)                                                   |   |         |
| Other                                                                              |   |         |

|               |  |            |  |                           |  |                              |  |
|---------------|--|------------|--|---------------------------|--|------------------------------|--|
| Date Received |  | Risk Level |  | Imputability              |  | Signature                    |  |
| HV No         |  |            |  | QC No:<br>(if applicable) |  | Recall No<br>(if applicable) |  |

| Serious Adverse Reaction                                                | ✓                                                                                                                                                                | Details                                                                               |
|-------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|
| Immunological haemolysis due to ABO incompatibility                     |                                                                                                                                                                  |                                                                                       |
| Immunological haemolysis due to other allo-antibody (Acute < 24 hrs.)   |                                                                                                                                                                  |                                                                                       |
| Immunological haemolysis due to other allo-antibody (Delayed > 24 hrs.) |                                                                                                                                                                  |                                                                                       |
| Non-immunological haemolysis                                            |                                                                                                                                                                  |                                                                                       |
| Anaphylaxis/hypersensitivity                                            |                                                                                                                                                                  |                                                                                       |
| Febrile Non Haemolytic Transfusion Reaction                             |                                                                                                                                                                  |                                                                                       |
| Transfusion Associated Circulatory Overload                             |                                                                                                                                                                  |                                                                                       |
| Transfusion Associated Dyspnoea                                         |                                                                                                                                                                  |                                                                                       |
| Hypotensive Transfusion Reaction                                        |                                                                                                                                                                  |                                                                                       |
| Previously un-reported complication of transfusion (PUCT)               |                                                                                                                                                                  |                                                                                       |
| Other –Unclassified SAR                                                 |                                                                                                                                                                  |                                                                                       |
| Pre-deposit autologous donation                                         |                                                                                                                                                                  |                                                                                       |
| Post transfusion purpura                                                |                                                                                                                                                                  |                                                                                       |
| Graft versus host disease                                               |                                                                                                                                                                  |                                                                                       |
| Transfusion-transmitted bacterial infection*                            |                                                                                                                                                                  |                                                                                       |
| Transfusion related acute lung injury (TRALI) *                         |                                                                                                                                                                  |                                                                                       |
| Transfusion transmitted viral infection (HBV) *                         |                                                                                                                                                                  |                                                                                       |
| Transfusion transmitted viral infection (HCV) *                         |                                                                                                                                                                  |                                                                                       |
| Transfusion transmitted viral infection (HIV-1/2) *                     |                                                                                                                                                                  |                                                                                       |
| Transfusion transmitted viral infection – Other (please specify) *      |                                                                                                                                                                  |                                                                                       |
| Transfusion transmitted parasitica – Malaria *                          |                                                                                                                                                                  |                                                                                       |
| Transfusion transmitted parasitica – Other (please specify) *           |                                                                                                                                                                  |                                                                                       |
| Transfusion-transmitted prion infection*                                |                                                                                                                                                                  |                                                                                       |
| Imputability of serious adverse reaction                                | Excluded - 0 <input type="checkbox"/> Unlikely - 0 <input type="checkbox"/><br>Likely/Probable – 2 <input type="checkbox"/> Certain – 3 <input type="checkbox"/> | Possible - 1 <input type="checkbox"/><br>Not Assessable – NA <input type="checkbox"/> |

**\* NB**  
 If suspected please contact **Quality Control Laboratory** or Medical Scientist on duty at your blood supply centre:  
**Cork: 021 480 7400      Dublin: 01 432 2800**

For specific information on completing the form please consult The Haemovigilance Handbook: Requirements for Reporting Serious Adverse Reactions and Events to the National Haemovigilance Office (Current Version).

**Report made by:**

|                        |                      |
|------------------------|----------------------|
| Name: _____            | Title: _____         |
| Working Address: _____ |                      |
| Telephone: _____       | Date: ____/____/____ |

**Consultant Haematologist/Pathologist or patient's Primary Consultant must review each initial report prior to it being sent to:**

The National Haemovigilance Office  
 At The National Blood Centre, James's Street, Dublin 8

Tel: 01 432 2741/ 01 432 2825  
 Fax: 01 432 2933