National Institute of Biologicals  
Ministry of Health & Family Welfare, Govt. of India  
NATIONAL BLOOD DONOR VIGILANCE PROGRAMME  
(Haemovigilance Programme of India) 
Adverse Blood Donor Reaction Reporting Form

I) Donor Information

<table>
<thead>
<tr>
<th>Donor Id</th>
<th>Type of Donation: (a) Whole Blood, (b) Apheresis (1. RBC, 2. Platelets, 3. Plasma, 4. Plasma + Platelets)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sex</td>
</tr>
<tr>
<td></td>
<td>Donor Type: (a) Voluntary, (b) Replacement, (c) Family Donor (1. first-time, 2. repeat)</td>
</tr>
<tr>
<td></td>
<td>Weight of Donor (KG)</td>
</tr>
<tr>
<td></td>
<td>Age/Date of Birth</td>
</tr>
<tr>
<td></td>
<td>Venipuncture: (a) 1, (b) 2, (c) &gt;2</td>
</tr>
<tr>
<td></td>
<td>Data Captured: (a) Onsite, (b) Call back by donor, (c) Call back by Blood Centre</td>
</tr>
<tr>
<td></td>
<td>Site of Donation: (a) Camp (b) Blood Centre</td>
</tr>
</tbody>
</table>

II) Details of Blood Collected

<table>
<thead>
<tr>
<th>Lot No. of Blood Bag</th>
<th>Volume of Blood Collected (ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer of Blood Bag</td>
<td>Expiry date of Blood Bag</td>
</tr>
<tr>
<td>Date &amp; Time of Donation</td>
<td>Date &amp; Time of Reaction</td>
</tr>
</tbody>
</table>

III) Type of Complications (Refer Annexure I)

A1-Complications mainly characterized by the occurrence of blood outside the vessels
(a) Haematoma (bruise)
(b) Arterial puncture
(c) Delayed (bleeding/Re-bleeding)

A2-Complications mainly characterized by pain
(a) Nerve injury/irritation
(b) Other Painful arm

A3-Localised infection/inflammation along the course of a vein
(a) Thrombophlebitis
(b) Cellulitis

A4- Other major blood vessel injury -Serious conditions needing specialist medical diagnosis and attention
(a) Deep venous thrombosis (DVT)
(b) Arteriovenous fistula
(c) Compartment syndrome
(d) Brachial artery pseudoaneurysm

B-Complications mainly with generalized symptoms: Vasovagal reactions
(a) LOC (Loss of Consciousness) < 60 sec
(b) LOC (Loss of Consciousness) > 60 sec
(c) Without loss of consciousness (LOC)
(d) With injury
(e) Without injury
(f) Within Blood collection facility
(g) Outside blood collection facility

C-Complications related to apheresis
(a) Citrate reaction
(b) Haemolysis
(c) Air embolism
(d) Infiltration of IV fluids

D-Allergic reactions
(a) Allergy (local)
(b) Generalised allergic reaction (anaphylactic reaction)

E-Other serious complications related to blood donation
(a) Acute cardiac symptoms
(b) Myocardial infarction (MI)
(c) Cardiac arrest
(d) Transient Ischemic Attack (TIA)
(e) Cerebrovascular Accident
(f) Death

F-Other Reactions…………………………

IV) Outcomes

<table>
<thead>
<tr>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Resolved</td>
</tr>
<tr>
<td>□ On Follow Up</td>
</tr>
<tr>
<td>□ Recovered with Sequelae</td>
</tr>
<tr>
<td>□ Permanently Disabled</td>
</tr>
<tr>
<td>□ Death following the Adverse Reactions</td>
</tr>
<tr>
<td>□ Unknown</td>
</tr>
</tbody>
</table>

V) Imputability (Refer Annexure II)

<table>
<thead>
<tr>
<th>Imputability</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Definite (Certain)</td>
</tr>
<tr>
<td>□ Probable (Likely)</td>
</tr>
<tr>
<td>□ Possible</td>
</tr>
<tr>
<td>□ Unlikely (Doubtful)</td>
</tr>
<tr>
<td>□ Excluded</td>
</tr>
</tbody>
</table>

VI) Reporter ……………………..

Date of Report ………………………..
Annexure I

Donor Complication Form

Reference Document (Type of complication)

[] A 1. Complications mainly characterized by the occurrence of blood outside the vessels.
   [] a) Haematoma (bruise)
      [] Bruising/discolouration [] Redness/warmth [] Swelling [] Local pain/tenderness
      [] Nerve irritation/injury
   []b) Arterial puncture
      [] Bright Red blood [] Pulsating needle/tubing. [] Blood bag fills rapidly(< 4 min).
      [] Weak pain (elbow). [] Radial pulse weak/absent.
   [] c) Delayed bleeding/ Re-bleeding
      [] Inadequate Pressure at venipuncture site [] Inadequate duration of pressure (< 10 min)
      [] Heavy lifting or strain to the donor’s arm. [] Donor medications (anticoagulants/aspirin)

[] A2. Complications mainly characterized by pain
   [] a) Nerve injury/irritation
      [] Radiating, sharp pain moving away from the venepuncture site,
      [] Paraesthesias- tingling, burning sensations in the hand, wrist or shoulder area
      [] Onset of symptoms-on needle insertion or withdrawal
      [] Delayed pain when accompanied by haematoma.
      [] Worsening of symptoms in certain positions or with certain arm motions.
   [] b) Other Painful arm
      [] Arm pain described as ache or heaviness in the arm( Like vaccination)
      [] Absence of nerve irritation

[] A 3. Localised infection/inflammation along the course of a vein
   Symptoms localized to phlebotomy site
   [] Warmth [] tenderness [] Local pain [] Redness[] Swelling (at the site of phlebotomy)
   [] Fever Present/absent
   [] a) Thrombophlebitis: Symptoms along course of vein
   [] b) Cellulitis: The redness, swelling and tenderness affect the soft tissues

[] A4. Other major blood vessel injury -Serious conditions needing specialist medical diagnosis and attention
   [] a) Deep venous thromosis (DVT) [] Swelling and Pain in upper arm [] Signs of superficial inflammation/thrombosis( See A3) [] Additional risk factor of thrombosis(ExOC pills)
   [] b) Arteriovenous fistula [] Pulsating mass [] Palpable thrill/Associated bruit
      [] Affected area-warm [] Distal area –feels cool [] Distal veins-dilated& pulsatile
      [] Related to arterial puncture [] Related to venous laceration.
   [] c) Compartment syndrome [] Painful arm [] Swelling( Haematoma) [] Paresthesias
      [] Partial paralysis. [] Muscle and soft tissue necrosis.
   [] d) Brachial artery pseudoaneurysm
      [] Pulsating mass in the arm. [] Pain and paraesthesias[] Haematoma( large)
      [] May follow Arterial puncture (A1)
B. Complications mainly with generalized symptoms: Vasovagal reactions
- [ ] Generalized Weakness
- [ ] Anxiety
- [ ] Dizziness
- [ ] Nausea
- [ ] Vomiting
- [ ] Pallor (Skin and lips)
- [ ] Cold extremities
- [ ] Hyperventilation
- [ ] Hypotension
- [ ] Vomiting
- [ ] Rapid Pulse
- [ ] Low Vol Pulse
- [ ] Feeling of warmth
- [ ] Vomiting
- [ ] Convulsions
- [ ] Tetany
- [ ] Twitching
- [ ] Vomiting
  - a) [ ] LOC (Loss of Consciousness) < 60 sec
  - b) [ ] With injury
  - c) [ ] Within Blood collection facility
  - [ ] LOC (Loss of Consciousness) > 60 sec
  - [ ] without injury
  - [ ] Outside blood collection facility
- [ ] Without loss of consciousness (LOC)

C. Complications related to apheresis
- [ ] Citrate reaction
  - [ ] Numbness/tingling/vibrations-lips, fingers
  - [ ] Metallic taste
  - [ ] Vomiting
  - [ ] Chills/shivering
  - [ ] light-headedness
  - [ ] Muscle twitching
  - [ ] Carpopedal spasm
  - [ ] rapid or slow pulse
  - [ ] Irregular Pulse
  - [ ] shortness of breath.
  - [ ] Tetany (generalized muscle contractions)
  - [ ] Shock
  - [ ] Cardiac arrest

- [ ] Haemolysis
  - [ ] Pink or red plasma
  - [ ] Blood in lines
  - [ ] Pink or red urine

- [ ] Air embolism
  - [ ] Bubbling sound or feeling at venipuncture
  - [ ] Cough
  - [ ] Dyspnea
  - [ ] Apprehension
  - [ ] Sweating
  - [ ] Chest pain
  - [ ] Confusion
  - [ ] Tachycardia
  - [ ] Hypotension
  - [ ] Nausea
  - [ ] Vomiting.

- [ ] Optional category: Infiltration of IV fluids
- [ ] Swelling at venipuncture site

D. Allergic reactions
- [ ] Allergy (local)
  - [ ] Itching and redness at the venepuncture site
  - [ ] Bandage site
  - [ ] Skin disinfection area
  - [ ] Raised rash
  - [ ] hives that may expand to cover a larger area of the arm.
  - [ ] Occurrence
  - [ ] Soon after donation
  - [ ] Hours later
  - [ ] Days later.

- [ ] Generalised allergic reaction (anaphylactic reaction)
  - [ ] Occurs soon after reaction
  - [ ] Cardiac arrest
  - [ ] Apprehension/Anxiety
  - [ ] Flushing
  - [ ] swelling of eyes, lips or tongue
  - [ ] cyanosis
  - [ ] cough
  - [ ] wheezing
  - [ ] Dyspnea
  - [ ] Chest tightness
  - [ ] cramps, nausea, vomiting, diarrhoea,
  - [ ] tachycardia
  - [ ] Hypotension
  - [ ] altered mentation.

E. Other serious complications related to blood donation
- Major cardiovascular event (MCE) (Upto 24 hours after donation).
  - a) [ ] Acute cardiac symptoms (other than myocardial infarction or cardiac arrest).
  - b) [ ] Myocardial infarction (MI)
  - c) [ ] Cardiac arrest
  - d) [ ] Transient Ischemic Attack (TIA)
  - e) [ ] Death
IMPUTABILITY LEVELS (Grading of complication severity and Imputability strength of relation between donation and complication)

The Imputability levels are given below:

- **Definite (Certain):** when there is conclusive evidence beyond reasonable doubt for the relation.

- **Probable ( Likely):** when the evidence is clearly in favour of a relation.

- **Possible:** when the evidence is indeterminate for attributing the complication to the donation or an alternative cause.

- **Unlikely (Doubtful):** when the evidence is clearly in favour of attributing complication to other cause.

- **Excluded:** when there is conclusive evidence beyond reasonable doubt that the complication can be attributed to causes other than the donation.
<table>
<thead>
<tr>
<th>Denominator Data About All Donor</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Total donations in the month (of reporting)</td>
</tr>
<tr>
<td>Whole blood[ ] Apheresis[ ] If apheresis RBC[ ] Platelets[ ] Plasma [ ] Plasma + Platelets[ ]</td>
</tr>
<tr>
<td>2. Gender of Donor (Total)  Male [ ] Female [ ]</td>
</tr>
<tr>
<td>3. Donor Types (Total)  First-time donors [ ] Repeat donors [ ]</td>
</tr>
<tr>
<td>4. Volume of donation</td>
</tr>
<tr>
<td>No of 350 ml donations [ ] No of 450 ml donations[ ] others</td>
</tr>
</tbody>
</table>